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Nevada State Board of Pharmacy News

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Board Members

Refrigerator and Freezer Temperature Regulation

Effective December 16, 2010, Chapter 639 of NAC was amended to include a section on the regulation of refrigerator and freezer temperatures in pharmacies. This becomes exceedingly important given the fact that many pharmacies in Nevada now offer vaccinations of various types, many of which must be carefully stored under refrigeration or frozen.

The new regulation requires each refrigerator and freezer that stores medicines to have a monitor with an alarm that records or displays an alert when the temperature rises or falls outside of the acceptable temperature range. The range, as defined by United States Pharmacopeia, for a refrigerator is between 36°F and 46°F. A freezer or freezer section of a refrigerator must be maintained below 32°F.

Further, the regulation requires that if the temperature falls outside of the acceptable temperature range, the pharmacist must document that alert; take steps to correct the issues; document those steps; and finally assess and ensure that the medicines within are either safe to dispense or be destroyed.

Please note that some vaccines need to be stored at very specific temperatures. An example noted by one of the Nevada State Board of Pharmacy inspectors involved a freezer that was set at a temperature of 29°F containing a vaccine that must be stored at 5°F or colder.

So what to do in the event of a power outage? Refrigerated vaccines usually are OK in an unopened unit for several hours, but frozen vaccines are much more sensitive. If your facility is backed up by a generator, make certain that the vaccine storage unit is plugged into an outlet serviced by that generator. Tape the doors shut so that the storage unit is not inadvertently opened allowing cold air to escape, and watch and record the temperature if possible.

Please work with your supervisor to implement compliance with these very important requirements as soon as possible.

Signature Requirements

Reminder: **All** written prescriptions, faxed, or otherwise require a manual (or "wet") signature. Examples:

1. A printed prescription that is paper faxed to the pharmacy must be wet signed on the original prior to faxing to the pharmacy (this is a "faxed" prescription).
2. A prescription faxed from an e-prescribing system to the pharmacy (computer to fax) is **not** an e-prescription, but also is a "faxed" prescription, and must be wet signed on the original.
3. A prescription handed to the patient to be taken to the pharmacy that was generated by an e-prescribing system must be wet signed.

Speaking of e-prescribing, another reminder is that the e-prescribing of controlled substances is yet to be implemented, although legal as of June 1, 2010. The certification process required by Drug Enforcement Administration is still in the developmental stages, so as of the date of this writing, e-prescriptions for controlled substances of any class are not valid.

Tendered CII Prescription

Some of the more often asked questions received by Board staff involve the tendering of a Schedule II prescription, so as a review:

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Obtain Your NABP e-Profile ID Online Now, ID Required for ACPE-Accredited CPE

The new National Association of Boards of Pharmacy® (NABP®) CPE Monitor service, a collaborative effort between NABP, the Accreditation Council for Pharmacy Education (ACPE), and their providers, will allow pharmacists and technicians to easily track their ACPE-accredited continuing pharmacy education (CPE) credits beginning in the latter part of 2011. In addition, the service will provide a streamlined reporting and compliance verification process for participating state boards of pharmacy. When pharmacists and technicians complete an ACPE-accredited CPE program, their participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching NABP e-Profile. Then, if the board of pharmacy participates in CPE Monitor, the pharmacists' or technicians' CPE credits will be automatically transmitted to the board, saving pharmacists and technicians the trouble and expense of documenting and submitting compliance with state-mandated CPE requirements for license renewal. This eliminates paper forms and the overall need to submit paper copies of CPE statements of credit to the board of pharmacy for CPE activities from ACPE-accredited providers.

For convenience, the NABP e-Profile will be available 24/7 for viewing a comprehensive list of the CPE activities completed. All information will be maintained in a highly secure environment. NABP does not distribute any personal information for commercial purposes without consent.

To prepare for the new process, pharmacists and technicians are encouraged to obtain their NABP e-Profile identification to ensure their e-Profile is properly set up. Beginning in the latter part of 2011, all pharmacists and technicians will be able to provide their NABP e-Profile ID, plus their birthdate (mmdd) to receive credit for any accredited CPE activities from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering or when submitting participation data to the provider. Please note that CPE Monitor will not initially track CPE from non-ACPE-accredited providers. This feature will be added in Phase 2 of the CPE Monitor service, and, until then, pharmacists and technicians will need to submit non-ACPE-accredited CPE directly to their board of pharmacy when required to do so.

NABP and ACPE will work with CPE providers to ensure an adequate amount of time is allotted to implement this new service.

Pharmacists can obtain their ID by creating an NABP e-Profile using the portal in the Pharmacists section of the NABP Web site at *www.nabp.net/pharmacists*. Technicians can obtain their ID by creating an NABP e-Profile using the portal in the Technicians section of the NABP Web site at *www.nabp.net/technicians*. Visit *www.MyCPEmonitor.net* for more information.

FDA Asks Manufacturers to Limit Acetaminophen Strength

In the interest of patient safety, Food and Drug Administration (FDA) asked drug manufacturers to limit the strength of acetaminophen in prescription drug products – which are predominantly combinations of acetaminophen and opioids – to 325 mg per tablet, capsule, or other dosage unit. In addition, FDA reports that the labels of all prescription drug products that contain acetaminophen will now include a boxed warning that highlights the potential for severe liver injury and a warning that highlights the potential for allergic reactions. FDA has taken these actions to reduce the risk of severe liver injury and allergic reactions associated with acetaminophen. FDA notes that over-the-counter products containing acetaminophen are not affected by this action.

While the maximum amount of acetaminophen in a prescription tablet, capsule, or other dosage unit will be limited to 325 mg, the total number of tablets or capsules that may be prescribed and the time intervals at which they may be prescribed will not change as a result of the lower amount of acetaminophen. Additional information for health care providers and patients is included in an FDA Drug Safety Communication available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/ucm239821.htm.*

Looking for Risk

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 a 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.*

Health care organizations focused on improving patient safety must first identify, ascertain the causes of, and employ strategies to reduce risk. Everyone on staff in an organization has responsibility for risk assessment and, therefore, risk management.

This includes involving patients in their care and seeking their help to identify risk in the system. Assessing risk in an organization is important to understanding and prioritizing areas of highest risk and for discovering which improvements will have the greatest overall impact on patient safety.

FMEA

The Failure Mode and Effects Analysis (FMEA) process is a "systematic method of identifying and preventing product and process problems before they occur." FMEA is the tool that has the potential to be an integral part of any risk assessment and, therefore, the risk management process.

FMEAs focus on identifying and removing defects, enhancing safety, and increasing customer satisfaction.

AROC

Assessing Risk and Opportunities for Change (AROC) is designed to help community pharmacy personnel identify potential medication safety risks and prevent errors. Pharmacists can use these materials and tools to pinpoint specific areas of weakness in their medication delivery systems and to provide a starting point for successful organizational improvements.

Pharmacists' Role

Pharmacists are often assumed to be the "guardians" in ensuring that medication errors do not occur. This expectation is unrealistic, because avoiding error is a health care team effort. It has, however been suggested that pharmacists should assume a leadership role in implementing safe medication use efforts in their organization.

Objectives for the pharmacist and other pharmacy staff who participate in the assessment process:

- Explain the important processes and sub-processes of medication use from prescription through administration.
- Participate in identifying failure modes and risk throughout the entire medication process, especially in information that should be available to the prescriber and nurse, as well as describing the steps in the process that occur after the medication order is transferred to the pharmacy.
- Offer possible causes for medication errors because of breakdowns in the prescription to administration process.
- Identify effects, as well as their severity and probability, when a system failure occurs.
- Offer suggestions, along with all team members, for actions that should be taken to prevent medication errors.

Pharmacists are an integral part of any medication safety assessment process. They not only offer information – as do the other disciplines in the organization – they can also expand their knowledge through participating in these risk assessments. Pharmacy participation should include frontline staff, pharmacists, pharmacy technicians, and pharmacy support staff. It is important to have multilevel involvement so that all system enhancements are discussed and identified.

To learn more about assessing risk in acute care pharmacy visit *www.ismp.org/Tools/pathways.asp.*

To learn more about assessing risk in community pharmacy visit *www.ismp.org/communityRx/aroc/*.

NABP Launches New and Improved NAPLEX/ MPJE Application in March

In March 2011, NABP launched a new and improved application process for the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®). The online application was upgraded to be more user friendly, allowing candidates to perform more registration tasks and providing status information to examination candidates.

In addition to providing the basic features of registering for the NAPLEX, NAPLEX score transfer, and MPJE, the new application also allows candidates to make changes to, add to, or withdraw an application, eliminating the need for candidates to call NABP for this service. Changes that can be made to an application include registering for the MPJE in additional jurisdictions and adding NAPLEX score transfer requests until the time of the examination. Technological enhancements to the application allow for the elimination of the previous requirement that candidates submit score transfer requests five business days prior to sitting for the NAPLEX.

The new application also gives candidates who miss sitting for an examination or who do not cancel within two business days of their appointment the ability to submit resitting fees online rather than having to send a payment to NABP via mail. This expedites the receipt of the candidate's new Authorization to Test so that he or she may schedule another examination appointment more quickly.

An additional benefit to candidates is the ability to monitor the status of their profile. After submitting an application, candidates can log in to their profile and see if the application has been received; if eligibility has been requested, granted, denied, or expired; if Authorization to Test has been generated; if the application has been withdrawn or expired; and history of examinations taken.

The profiles of candidates who registered for the NAPLEX or MPJE before the new application was launched will need to create a user name and password through the new application so that they can view the historical data of their NAPLEX and MPJE registrations. Upon creating a new user account, the system will match the newly created account with applications previously submitted or currently in progress so that all the information will be viewable by the candidate.

The new application also allows users to update their profiles as needed and review past orders.

In addition, the score results for the NAPLEX and MPJE are also accessible when candidates log in to the application, provided that the board for which the candidate tested participates in the online score interface. Currently, 21 boards utilize this service.

Overall, candidates can expect a clearer and smoother registration process because both front and back-end functionality of the application has been streamlined and tightly integrated.

New FDA Drug Info Rounds Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss the role of FDA in responding to and mitigating drug shortages. Drug Info Rounds is developed with contributions from pharmacists in the FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information. FDA Drug Info Rounds training videos may be accessed on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

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1. A Schedule II prescription must be tendered (taken to a pharmacy) within 14 days of the date written.
2. The pharmacist may fill it on that day, or file it for filling on a future date at the request of the patient or as specified on the prescription by the practitioner (ie, "do not fill until").
3. The prescription "dies" if not filled within six months of the date it was written (may not be filled).
4. A properly tendered prescription at one pharmacy may be picked up by the patient and taken to another pharmacy for filling; however, the new pharmacy must verify the proper tendering with the original pharmacy, and document that activity on the prescription.

Better Communication With Your Patients

As you all are aware, in Nevada patient counseling by a pharmacist is **mandatory** for all new prescriptions, and that counseling must be documented by the counseling pharmacist. Refusal of counseling by the patient must be made to a pharmacist, and that refusal must be documented by that pharmacist as well. Studies have shown that over half of your patients read and comprehend at about the fifth grade level, making effective counseling challenging at times. Some tips on helping your patients understand not only what you say, but what you hand them:

1. Get their attention (ask them to get off their iPhone . . .), focus on them, and by all means be ready to listen.
2. Involve the patient in the conversation by asking open-ended questions and encouraging feedback. Again, be ready to listen.
3. Do not use "medical-ease"; use language they can understand like "heart" rather than "cardiac" and "liver" rather than "hepatic."

Counseling is probably the most important part of the filling process and is the last shot you have to make certain that what you are about to send your patient home with is correct. A recent case involved a prescription for estrogen filled with a blood pressure pill and marked "counseled." One wonders what that conversation entailed.

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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