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Nevada State Board of Pharmacy News

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Board Members

Counseling Revisited

Omnibus Budget Reconciliation Act (OBRA) of 1990. Since 1990, counseling regulations have been in effect, and lawmakers have been aware of the importance of counseling in the prescription filling process. In fact, counseling is considered so important in Nevada that it is **mandatory** on all new prescriptions, as you all should be aware. A pharmacist **must** counsel, and if the patient refuses to listen, that refusal must be made **to the pharmacist.** A technician cannot ask whether a patient wants counseling and take that refusal.

Quality of Counseling. Consider the following actual case: A prescription is written for clomi**phene** (a fertility drug), then entered incorrectly into the computer system by a technician as clomi**pramine** (an antidepressant). A pharmacist verifies the prescription as correct and it is filled by the technician. A second pharmacist then verifies that what is on the label is what is in the bottle, which it was, but **it is the wrong drug!** The second pharmacist argues at his hearing that this is okay because his job in this process is to compare the drug to the label, regardless of whether the drug in the bottle is the correct one. It makes no sense that verifying a wrong drug is acceptable; maybe that system needs to be reexamined to have a meaningful check at this point as well. Regardless, we still have the counseling piece, which is the pharmacist's last chance at getting it right. The counseling pharmacist then proceeds to counsel based on what is on the label and what is actually in the bottle (the clomi**pramine**), which is totally wrong. One can only wonder what he discussed with that patient. She is to take a fertility drug and supposedly is counseled by the pharmacist on an antidepressant – what did they talk about? Did he inform her that this was an antidepressant and inquire about her depression? It makes no sense! The patient took the clomi**pramine** thinking it would help her get pregnant; she got sick instead.

One of the most basic of all counseling goals is to ensure that the patient receiving a medication knows what the drug is and what it is to treat. The most complete counseling on the wrong drug is not only useless but dangerous. Some tips:

1) Compare the drug to the hard copy (or image) at all points of the filling process. It is senseless to verify a wrong drug simply because it is wrongly printed on a label.
2) **Open the bottle!** "Show and tell" is considered by the Nevada State Board of Pharmacy to be an integral part of counseling and it does prevent injury.
3) Ask the patient to describe the intended use of the medication.
4) Ask the patient to read back to you the name of the drug and directions for use.

In a recent court case *(Oleckna v. Daytona Discount Pharmacy)*, the opinion released stated: "A pharmacy owes a customer a duty of reasonable care. Pharmacists are required to exercise that degree of care that an ordinarily prudent pharmacist would under the same or similar circumstances." In other words, as opined by David Brushwood from the University of Wyoming, "Duty is not determined by a list of tasks that must be completed. It is determined by the nature of the relationship and expectations (individual and social) that are created by that relationship."

Proper counseling (including a final check that the correct drug is in the bottle) ensures that everyone in that often fragmented filling process got it right. Take it seriously; you owe it to your patients!

FDA Issues Warning About Name Confusion for Brintellix and Brilinta

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm.*

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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.*

This is part two of a three-part series on seven persistent safety gaffes of 2014.

3) Vaccine Errors: Repetitive Errors Reported in the Last Decade

How often do DTaP (diphtheria and tetanus toxoids, and acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

5) Disrespectful Behavior: A History of Tolerance in Health Care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later demonstrates little progress. Disrespect diminishes a person's ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

FDA Advises Caution Against Codeine for Treating Colds in Young Patients

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at *www.fda.govSafety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.*

Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns

In June 2015, FDA warned health care providers and consumers that Daytrana®, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.*

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm* provides more details.

Baxter International, Inc, Recalls Three Lots of IV Solutions Due to Particulate Matter

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm.*

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that "injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs." More information about this recall is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm.*

FDA Warns Against Unapproved Prescription Ear Drops

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- benzocaine;
- benzocaine and antipyrine;
- benzocaine, antipyrine, and zinc acetate;
- benzocaine, chloroxylenol, and hydrocortisone;
- chloroxylenol and pramoxine; and
- chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm.*

Acino Products in New Jersey Ordered to Stop Selling Rectacort-HC and GRx HiCort 25

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm.*

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President Basch!

Congratulations to Leo Basch on being elected president of the Board. Leo is serving his second stint on the Board, so he brings a wealth of knowledge and experience in all Board matters, and has demonstrated a work ethic and devotion to the public health unmatched in the world of pharmacy. Board staff welcomes Leo and looks forward to an assuredly long and fruitful tenure.

Update From Medicaid

Pharmacy Dispensing Fee Increase and Pricing Methodology Using NADAC Files

Effective November 1, 2015 (pending Centers for Medicare & Medicaid Services approval), Nevada Medicaid will be increasing the professional dispensing fee and implementing a new drug pricing methodology using National Average Drug Acquisition Cost (NADAC) files. This is a two-part change to be in compliance with the Patient Protection and Affordable Care Act of 2010.

1. The professional dispensing fee for outpatient and retail pharmaceuticals will be increased.
   a. The state's dispensing fee for all outpatient retail pharmacies is increasing from $4.76 to $10.17 per prescription.
   b. Intravenous therapy and long-term care will receive the same dispensing fee as the retail pharmacies; per policy, their rate will be daily.
   c. The dispensing fee for supplies, including diabetic supplies, will remain unchanged.
2. The Actual Acquisition Cost will be modified to utilize the NADAC fee schedule in the pharmacy pricing algorithm.
   a. NADAC pricing will be added to the pharmacy pricing algorithm for retail and Nevada physician-administered drug claims. Wholesale Acquisition Cost (WAC) is being changed from WAC +2% to WAC +0%, which will be offered for those drugs not available on NADAC.
   b. The Incentive Fee Program will remain unchanged.

The above changes will have no impact on the OBRA of 1987 and supplemental rebate programs.

Reminder – October 2015 Is Renewal Time for Pharmacists

Please ensure all staff are properly licensed by using the Board's License Verification tab on the website, *http://bop.nv.gov.* It is a public search, so anyone can check. Printing the verification is also an acceptable form for posting should the renewed certificate not arrive fast enough.

If you require your pharmacists to work on November 1 and/or shortly thereafter, either encourage them to renew online using the codes printed on their renewal form, or mail in the renewal form by October 11 to allow sufficient time for processing.

Should a pharmacist tell you a renewal form was not received, suggest that he or she email the Board office to request another form. Sadly, not all pharmacists notify the Board of a change of address.

One aspect of renewing is the completion of one hour of Nevada-approved law continuing education (CE). The Board performs an audit every renewal cycle, so please safeguard your license by taking the appropriate law CE. Links are available on the Board's Continuing Education web page, found at *http://bop.nv.gov/services/CE.*

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