



Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Welcome From Executive Director Alex Adams

It is an honor to work with all of you as the new executive director of the Idaho State Board of Pharmacy.

Put simply, my top priority is promoting, preserving, and protecting the health and safety of the public through the effective control and regulation of the practice of pharmacy. I often quip that this passion preceded my birth, as my father, grandfather, and great-grandfather were all independent pharmacy owners. I am honored to carry on the rich pharmacy tradition, and I have focused my career on the intersection of public health and pharmacy practice.

Idaho has been a leading state in pharmacy practice and is noted for its progressiveness in practice. I look forward to continuing this rich tradition. My goals for this role include providing outstanding customer service, increasing transparency and accountability, facilitating inclusion and collaboration, and demonstrating strong fiscal responsibility.

I will be visiting many pharmacies across the state in the coming months to hear your ideas and concerns. Please do not hesitate to reach out at any time if you have questions or would like assistance at alex.adams@bop.idaho.gov or 208/334-2356.

Best regards,

Alex J. Adams, PharmD, MPH

2016 Board Meeting Schedule Is Set

Board meetings play an important role in the regulation of pharmacy practice in Idaho. The Board extends an open invitation to all pharmacists, technicians, and interested parties to attend and actively participate in these meetings. Your feedback and engagement can help ensure that public health and safety are optimized in Idaho.

- ◆ January 18-19 – Boise, ID
- ◆ April 7-8 – Pocatello, ID
- ◆ June 2 – Coeur d'Alene, ID
- ◆ July 11 – Conference call
- ◆ August 3-4 – Boise
- ◆ October 26-27 – Boise

Please visit the Board's website for more information, including meeting agendas, minutes, and public meeting materials.

Pharmacist Prescriptive Authority for Opioid Antagonists

Prescription drug abuse is the fastest growing drug problem in the United States. Idaho currently ranks as the fourth highest state in the country with respect to the non-medical use of prescription medications.

Opioid antagonists, such as naloxone, are an increasingly important tool in combating drug overdoses. When administered during an overdose, naloxone blocks the effects of opioids on the brain and restores breathing. It can be given as an injection into a muscle (via syringe or auto-injector) or as a nasal spray. According to the Centers for Disease Control and Prevention, the use of naloxone administered by laypersons has resulted in over 26,000 drug overdose reversals between 1996 and 2014.

In an effort to facilitate greater access to opioid antagonists, Governor Butch Otter signed House Bill 108 into law in 2015, which allows Idaho pharmacists to prescribe an opioid antagonist to the following individuals:

- ◆ A person at risk of experiencing an opiate-related overdose;
- ◆ A person in a position to assist a person at risk of experiencing an opiate-related overdose;
- ◆ A person who, in the course of his or her official duties or business, may encounter a person experiencing an opiate-related overdose; or
- ◆ A person who in the opinion of the prescriber or pharmacist has valid reason to be in the possession of an opioid antagonist.

Further, a pharmacist acting in good faith and exercising reasonable care may administer an opioid antagonist directly to another person who appears to be experiencing an opiate-related overdose. Under Idaho law, pharmacists who prescribe or administer opioid antagonists shall not be liable in a civil or an administration action or subject to criminal prosecution. For more information, see Idaho Code 54-1733B.

The Board encourages pharmacists to consider offering this important public health service in their communities. To assist pharmacists, a toolkit made available by the College of Psychiatric and Neurologic Pharmacists may be found at <https://cpnp.org/docs/guideline/naloxone/naloxone-access.pdf>. In addition, the Idaho Office of Drug Policy provides videos on appropriate naloxone administration on its website, www.odp.idaho.gov.

Idaho Medicaid has released guidance for pharmacy billing. Medicaid will pay for naloxone prescribed by the pharmacist, but only for actual Medicaid patients. It can then be dispensed to the caretaker, family member, loved one, etc, to have on hand for the actual Medicaid patient whose name is on the prescription. The pharmacist needs to use his or her individual National Provider Identifier number on the point-of-sale submission and not that of the pharmacy.

Use of Discount Cards for CS Prescriptions

Many patients attempt to use a discount card when paying for a controlled substance (CS) prescription. Pharmacists are encouraged to keep the following points in mind:

- ◆ Paying cash for a prescription is considered a "red flag," especially when it has been documented that the patient has insurance that would traditionally cover the prescription.
- ◆ A potential recipient of a CS prescription must first be positively identified. A discount card is **not** a form of insurance and thus cannot be used as a presumptive means of verifying a patient's identity.
- ◆ The source of payment for a CS prescription is one element that must be reported to the Idaho Prescription Monitoring Program. For patients using a discount card, the pharmacy should report the source of payment as cash.

Review of Prescription Refill Authority

The Board continues to receive reports of pharmacies refilling prescriptions beyond the expiration date indicated by the prescriber on a prescription drug order. A prescription drug order may be refilled only when permitted by state and federal laws, and only as specifically authorized by the prescriber.

The **maximum** number of refills that may be authorized by a prescriber are as follows:

continued on page 4



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.gov/Safety/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.

continued from page 1

- ◆ Schedule II: No refills.
- ◆ Schedules III-V: No refills more than six months after the date of issue, or, in the case of Schedule III or IV, no more than five total refills.
- ◆ Non-controlled drug: Refills up to 15 months after the date of issue.

If the prescriber indicates fewer refills on the prescription drug order than the maximum allowed under law, a pharmacist may **not** exceed the prescriber's authorized refills without prior consultation with, and agreement by, the prescriber. A pharmacist may only exceed this authority without consultation in an emergency situation in which the prescriber is not available, and the health or safety of a patient is in jeopardy if the prescription is not refilled. In such a scenario, a pharmacist may only dispense a sufficient quantity until a prescriber may be contacted for further renewal instructions.

CPE Requirements and New Home Study Law CPE

Board staff recently completed its audit of continuing pharmacy education (CPE), and more than 30% of all audited Idaho pharmacists did not complete the minimum legal requirements. As a reminder, each pharmacist applicant for license renewal must **annually** complete **15** CPE hours. At a minimum, 12 of the CPE hours obtained must be accredited by the Accreditation Council for Pharmacy Education (ACPE) or the Accreditation Council for Continuing Medical Education (ACCME). Thus, a maximum of three of the CPE hours obtained may be Board-approved programs not accredited through ACPE or ACCME. At least one of the CPE hours obtained must address federal, state, or local laws pertaining to the practice of pharmacy. Additional requirements are in place for pharmacists who administer immunizations or engage in the practice of sterile compounding.

The advent of the National Association of Boards of Pharmacy® (NABP®) CPE Monitor® increases the efficiency with which Board staff can audit CPE completion. It is the responsibility of the pharmacist to ensure that his or her CPE credits are documented appropriately in CPE Monitor.

To provide additional law CPE opportunities for Idaho pharmacists, the Board will periodically post a free program for home study credit on its website, http://bop.idaho.gov/continuing_education/index.html. The first free home study program is available for download, and covers the changes that pharmacists may make to Schedule II prescription drug orders. This program is approved for 0.5 hours of law CPE.

Congratulations, Former Board Chair Marilyn Silcock!

After 40 years of service to the profession of pharmacy, Marilyn Silcock, PharmD, will be retiring from Portneuf Medical Center. Dr Silcock leaves an impressive legacy and has made invaluable contributions to the practice of pharmacy in Idaho.

Dr Silcock grew up in the Blackfoot, ID area, and completed pharmacy school at Idaho State University. She was first employed as a pharmacist in 1975 for Bannock Regional Medical Center, which later became Portneuf Medical Center. Dr Silcock became director of pharmacy in 1995, serving until her retirement in October 2015.

She holds the distinction of being the first woman to serve on the Board, with a term from 1995 to 2005, and was chairperson of the Board

on two separate occasions. Further, Dr Silcock served twice on the NABP Committee for Law Enforcement/Legislation. She received Idaho State University's Professional Achievement Award in 2008.

Marilyn and her husband, Rod, have two children and seven grandchildren. Her plans for the future include spending more time with her family and enjoying traveling. The Board congratulates Dr Silcock for her exemplary service to the profession of pharmacy in Idaho and wishes her well in her retirement!

Help Is Available for Impaired Pharmacists Through Idaho PRN

The Board subsidizes the state's Pharmacist Recovery Network (PRN). The primary function of this program is to assist the impaired pharmacist in every aspect of recovery from chemical dependence, including intervention, consultation, monitoring, advocacy, education, and support. If you need confidential help or know an associate who does, please contact the program's vendor, Southworth Associates, by phone at 866/460-9014.

Recent Board Discipline

S.H., MD: CS registration conditioned as per State of Idaho Board of Medicine order.

S.M., Technician-in-Training: Ordered to undergo an evaluation and enter into a two-year contract with PRN for falsifying an application.

K.F., PharmD: Ordered to complete the 18-credit hour CPE course, Patient Safety and Medication Error Prevention for Pharmacy, for failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents, or labeling.

T.H., PharmD: Ordered to complete the 18-credit hour CPE course, Patient Safety and Medication Error Prevention for Pharmacy, for failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents, or labeling.

W.C., DDS: CS registration conditioned for personal use of CS without a prescription.

G.M., RPh: Fine of \$2,000 and up to six hours of continuing education for unprofessional conduct associated with early refills of CS.

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them filed in your pharmacy, preferably in your *Idaho Pharmacy Law Book*, for future reference.

Page 4 – December 2015

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