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Idaho State Board of Pharmacy News

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2016 Changes to Idaho Code

The following pharmacy-related bills were passed by the Idaho legislature and signed into law by Governor Butch Otter with an effective date of July 1, 2016. Full details of the bills may be found on the state legislature's website at *https://www.legislature.idaho.gov/legislation/2016/minidata.htm*.

House Bill (HB) 335: Removes [^{123}I]ioflupane, a radiopharmaceutical used in the diagnosis of Parkinson's disease, from the list of Schedule II controlled substances (CS).

HB 336: Modernizes the governance of the Idaho State Board of Pharmacy by removing the one-year term limit placed on Board **officers** (ie, chairperson and vice chairperson). It also modernizes the honorarium provided to Board members.

HB 337: Updates the list of authorized individuals who can receive Idaho Prescription Monitoring Program (PMP) data by allowing access to coroners and medical examiners for the purposes of determining a cause of death.

HB 338: Updates the list of who may possess legend drugs in their usual course of practice to include 1) midwives pursuant to their limited formulary and 2) home health and hospice agencies possessing emergency kits.

HB 339: Clarifies that CS must be stored in accordance with federal law and Board rule. Specifically, pharmacies must store CS in a locked cabinet or safe or disperse them (in whole or part) throughout a stock of non-CS. A prescriber drug outlet, by contrast, must store CS in a locked cabinet or safe.

HB 340: Repeals the archaic laws governing the regulation of non-prescription contraceptives and prophylactics.

HB 373: Expands the Legend Drug Donation Act to allow Regional Behavioral Health Clinics to both donate and receive products under certain circumstances.

HB 481: Allows patients with a terminal diagnosis the right to try any investigational drug if it is in at least Phase II of Food and Drug Administration clinical trials and is provided under the supervision of a prescriber.

HB 483: Requires pharmacists to notify a prescriber if an interchangeable biological product is substituted. Such notification must occur within five business days of dispensing. Importantly, notification can occur through a variety of means, and adjudication of a claim to a pharmacy benefits manager qualifies as a means of notification.

Three additional relevant bills were signed into law this session and will be covered in greater detail in the subsequent articles.

Delegating PMP Access to a Pharmacy Technician

As of April 2016, 75% of Idaho pharmacists are registered with the PMP. Registration is free and easy. Pharmacists who fail to register are putting themselves at risk of missing red flags in the dispensing process, which can result in Board discipline.

HB 374 takes effect on July 1, 2016, and will provide pharmacists with a new tool to streamline access to the PMP. Specifically, pharmacists who are already registered with the PMP will be able to designate up to four registered pharmacy technicians who are under their supervision to access the PMP on their behalf. A technician may access information to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing any CS, or for the purposes of a pharmacist providing pharmaceutical care as defined in law.

To register a pharmacy technician as a PMP delegate, the following must occur:

(1) A proposed delegate must submit a registration for access to the Board by visiting *https://idaho.pmpaware.net/identities/new* and verifying his or her email address using the link sent to him or her by the system.

(2) As part of the registration process, a proposed delegate must enter his or her supervising pharmacist's email address.

(3) The supervising pharmacist must log in to his or her PMP account and authorize the proposed delegate. Delegates associated with a pharmacist's account are displayed in a table found at User Profile → Delegate Management. From this location, a supervising pharmacist is able to approve or reject new delegates or deactivate existing delegates from his or her account. To approve, the user selects the delegate and clicks the approve button. To reject or deactivate, the user selects the delegate and clicks the reject button. This removes the delegate from the supervisor's list.

(4) Board staff confirms that all requirements have been met for the delegate's user account and approves the account. The delegate will receive an email stating that his or her account has been approved and is now active.

The Board encourages you to take advantage of this important new opportunity! Please contact Teresa Anderson with any questions at teresa.anderson@bop.idaho.gov or call 208/334-2356.

Pharmacist Prescriptive Authority for Epinephrine Auto-Injectors

Senate Bill (SB) 1322 takes effect on July 1, 2016, and provides new authorities to help speed time to treatment of allergic reactions. Specifically, it grants pharmacists the ability to prescribe epinephrine auto-injectors to a person at risk of experiencing anaphylaxis, or to a person or an authorized entity that may be in a position to help a patient at risk. Such authorized entities may include, but are not limited to, schools, day care centers, restaurants, Girl Scout or Boy Scout troops, and gyms, among others. The law provides liability protections to pharmacists who prescribe or dispense epinephrine to an authorized entity.

If prescribing to an authorized entity, proof must be presented that at least one individual at the entity has completed a training program that covers certain statutorily required elements. At the pharmacy level, this may be accomplished by having the entity sign a form of attestation. A sample form has been made available as part of a Board-approved home study continuing education (CE) program available on the Board's website.

FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm.*

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.*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing "whack-a-mole," addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News.*

Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.[1]

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.[1,2] Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.[3] In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.[4]

Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: "Insulin glargine (Lantus) 100 units/mL," followed on the next line with "6 units subcutaneous daily every evening."

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk

of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

References

1. Adelman JS, Kalkut GE, Schechter CB, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. *J Am Med Inform Assoc*. 2013; 20(2):305-310.
2. Green RA, Hripcsak G, Salmasian H, et al. Intercepting wrong-patient orders in computerized provider order entry system. *Ann Emerg Med*. 2015; 65(6):679-686.
3. Galanter W, Falck S, Burns M, Laragh M, Lambert BL. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc*. 2013; 20(3):477-481.
4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health*. 2014; 73(10):322-328.

FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy

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 January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research (CDER), 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.*

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

(1) Always read and follow the medicine label.
(2) Know if their medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at *www.knowyourdose.org.*

Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, *www.perrigo.com,* under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information, CDER, presents a series of continuing education webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

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Expanded Pharmacist Immunization Authority

SB 1294 was signed into law with an effective date of July 1, 2016. This bill expands the prescriptive authority of pharmacists for immunizations to include patients six years of age or older. Previously, pharmacists could only prescribe immunizations for patients 12 years of age and older. Pharmacists can still administer vaccines to younger children pursuant to a prescription drug order or under a properly authorized collaborative practice agreement with a prescriber.

Several themes were raised during the legislative discussion on this bill that may serve as useful reminders for immunizing pharmacists:

- Under Idaho Code 39-4804, immunizations are not mandatory and may be refused by patients on religious or other grounds.
- Parental consent is required for immunizations. The Board encourages you to ensure that your informed consent form has an explicit line to document parental consent.
- Under Board rules, a pharmacist should report administration of an immunization to Idaho's Immunization Reminder Information System (IRIS) as required. Today, only 65% of pharmacies are reporting to IRIS. Registries are important public health tools that exist to improve information sharing across health professionals and to ensure duplicate vaccines are not provided. For more information on how to access and report to IRIS, visit *https://iris.dhw.idaho.gov/IRIS/portalHeader.do.*
- Adverse events that stem from an immunization must be reported to the health care provider identified by the patient, if any, and also to the Vaccine Adverse Event Reporting System.

Does That DEA Number Really Match?

When filling a CS prescription, selecting the correct prescriber is just as important as entering all other requirements of a prescription. When wrong prescribers are entered into the PMP, it can lead to prescribers misinterpreting the PMP data and wrongfully accusing a patient of doctor shopping. Licensing boards may also wrongfully send an unsolicited report or take disciplinary action on a prescriber for allegedly overprescribing.

The PMP is a powerful tool, but it is only as good as the information that pharmacists provide to it. The dispensing pharmacist is ultimately accountable for the information in the pharmacy record. The Board recently fined a pharmacist $250 for submitting incorrect information to the PMP that led to a domino effect of misinformation. Please take care to ensure you select the correct prescriber when dispensing a medication.

New Inspection Forms Available Online

The Board has comprehensively updated its inspection forms, which are available for download on the Board's website at *http://bop.idaho.gov/licensing/facilities.html.*

The Board encourages pharmacists to consider completing a self-inspection of their facility as these are the same forms that will be used by compliance officers as they conduct their routine inspections.

Separate inspection forms are used and available for:

- Community pharmacy
- Nonsterile compounding
- Sterile compounding
- Telepharmacy
- New or remodeled pharmacy
- Durable medical equipment
- Institutional pharmacy
- Non-pharmacy drug outlet
- Prescriber drug outlet
- Veterinary drug outlet
- Wholesale distributor and manufacturer

Recent Board Discipline

For a more detailed report on cases, you may view the draft minutes of the April 7-8 Board meeting at *http://bop.idaho.gov/board_meeting.*

H.A., PharmD: $3,500 plus investigation costs for unprofessional conduct (dispensing seven CS prescriptions without a valid prescription).

P.A., RPh: $2,000 fine and ordered to complete 18 hours of CE for a medication dispensing error (wrong dose of clonazepam; the pharmacist's second discipline for a medication error in the past two years).

J.F., RPh: Ordered to complete 18 hours of CE for a medication dispensing error (wrong dose of Wellbutrin®).

J.V., RPh: $2,000 fine and ordered to complete 18 hours of CE for a medication dispensing error (dispensed Percocet® despite warning of a potential severe reaction due to an acetaminophen allergy); $500 fine for failure to counsel.

S.T., PharmD: $250 fine for reporting incorrect information to the Idaho PMP (selected wrong prescriber when filling prescription).

M.F., RPh: Ordered to complete 18 hours of CE for medication dispensing errors (wrong dose of Wellbutrin; dispensing Zolpidem® instead of Zoloft®).

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 it carefully.

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