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Idaho State Board of Pharmacy News

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2017 Rule Changes Set to Take Effect

This issue of the *Idaho State Board of Pharmacy Newsletter* will detail the rule changes that are anticipated to become effective upon *sine die* of the 2017 Idaho legislature, which is expected to be on or around March 24. While this *Newsletter* provides a descriptive summary of pending rule changes, all licensees are encouraged to read the actual pending rule change language, which may be found on the Board's website at *https://bop.idaho.gov/code_rules*. The Board will update its application and inspection forms in accordance with these rule changes.

Expanded Certified Pharmacy Technician Roles

As the role of the clinical pharmacist continues to develop and advance, it is critical to ensure that pharmacists can operate in a practice environment and workflow that supports the full deployment of their clinical skills. When pharmacy technician roles are optimized, patient safety can be enhanced and pharmacists may dedicate more time to advanced clinical services.

The Board spent a substantial amount of time in 2016 reviewing the published literature on expanded pharmacy technician roles. The Board also learned from the experiences of other states that already allowed expanded technician roles, in some instances for up to 40 years. The track record was compelling, and the Board's pending rules thus remove some of the current restrictions on technician practice.

There are two main points to emphasize before getting to the new authorities:

1. For a technician to perform any task or function, it must be legally permissible **and** delegated to him or her by a supervising pharmacist. Thus, the locus of control remains with the pharmacist, and a pharmacist may use his or her discretion to **not** delegate any of these tasks to a technician if the pharmacist feels uncomfortable doing so.
2. The expanded technician duties are reserved to **certified** technicians – thus, they may **not** be delegated to a grandfathered technician or a technician-in-training. Certified technicians must be registered with the Board and maintain their national certification. Idaho accepts certifications through the Pharmacy Technician Certification Board and the National Healthcareer Association.

Under the new rules, pharmacists may delegate the following tasks to certified technicians:

- **Accept a Verbal Prescription.** A certified technician may receive a new verbal prescription drug order from a prescriber or other person authorized by law and either manually or electronically reduce the order to writing. The Board encourages pharmacies to consider adopting policies in alignment with Institute for Safe Medication Practices guidelines, such as the read-back, spell-back technique to ensure certified technicians are appropriately hearing and documenting core prescription elements.
- **Consult With Prescriber.** If directed by the supervising pharmacist, a certified technician may consult with the prescriber prior to filling if clarification of information is needed regarding a patient or the prescription drug order.
- **Communicate a Transfer.** A certified technician may transfer prescription drug order information for the purpose of filling or refilling, either verbally, electronically, or via fax. The requirement that a pharmacist be one party of a transfer was struck.
- **Administer a Vaccine.** A certified technician may administer a vaccine if he or she has completed an Accreditation Council for Pharmacy Education-accredited course on appropriate immunization administration techniques and holds a current certification in basic life support from the American Heart Association or a comparable provider. The pharmacist must be available on site when the technician administers the immunization, but the rule does not require direct supervision by the pharmacist.
- **Perform Accuracy Checking.** A certified technician may perform final verification on prescription drug orders that have previously undergone prospective drug review by a pharmacist. This practice, sometimes referred to as tech-check-tech, has been proven safe and effective over decades. Previously, accuracy checking was allowed only in acute care hospitals. The pending rule allows this practice in any pharmacy setting. The rule requires site-specific training for participating certified technicians and specifies quality assurance requirements, such as random audits. In addition, community pharmacies deploying this model must meet certain technology requirements as specified in rule.

In addition, the rules allow technicians to perform data entry from remote settings, such as a home. Such an arrangement may assist with workload balancing across pharmacies. Pharmacies considering this model should consult pending Rule 321.

To be clear, the tasks enumerated in the new rules for technicians are not designed to be exhaustive. The Board's focus was on loosening restrictions currently listed in rule that are supported by evidence and/or practice experience in other states. It is known that technicians can and do perform more extensive tasks, particularly with regard to clinical service support (eg, medication reconciliation, basic physical assessment, point-of-care testing). There were no restrictions on these activities in existing Idaho law, and thus the Board determined that no additional changes were necessary for a pharmacist to delegate these tasks to technicians in practice.

Streamlining Medication Synchronization

Medication synchronization programs have grown rapidly in the United States. The goal of medication synchronization is to align the refill dates of a patient's prescription medications, which creates substantial convenience benefits for patients and has been shown to improve medication adherence rates.

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
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FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

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.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

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DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf*.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf*.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm*.

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (CE) 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. Previous webinar topics have included an overview of drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars*.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm*.

Latest FDA Drug Info Rounds Training Videos Available

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's 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*.

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Updates to Rule 116 sought to remove the administrative burden placed on pharmacists and prescribers when synchronizing a patient's medications. Specifically, if a patient opts in to a medication synchronization program, a pharmacist could use his or her judgment to extend a maintenance drug beyond the quantity initially authorized by the prescriber for the purpose of coordinating a patient's refills. Thus, a pharmacist would not have to call a prescriber for a short fill or burn one of the patient's refills by partial filling. Instead, the pharmacist may extend the prescription by the "limited quantity necessary" to coordinate a patient's refills. The rules did not limit extension to a one-time deal either, as some patients may need to be resynchronized over time. Importantly, the ability to extend may **not** be exercised in the case of controlled substances (CS), compounded drugs, or biological products.

Expanding Telepharmacy Access in Idaho

The Board made significant updates to rules related to telepharmacy practice and remote dispensing site registration (Rules 71, 710, 711, and 712). While individuals considering operating a telepharmacy or remote dispensing site should read all of the applicable updates, the following are among the more significant changes.

- The Board removed the requirement that a proposed remote dispensing site must seek specific permission from the Board and present information justifying the need. A remote dispensing site may now register similar to any other pharmacy in Idaho and may operate after passing an initial inspection.
- The Board removed the requirement that a remote dispensing site must be located in a medical care facility.

Miscellaneous Rule Updates

- **Prescription Drug Labeling.** Rule 140 was updated to allow prescriptions to be labeled in the name of a facility or entity. For example, an epinephrine auto-injector can be dispensed in the name of a day care facility, or an opioid antagonist could be dispensed in the name of a police department. The update also creates additional flexibility for expiration dating. For example, if a product is dispensed in the original, unopened manufacturer packaging, the pharmacist may label the expiration date in accordance with the manufacturer's original expiration date.
- **Partial Filling of Schedule II Prescriptions.** Rule 114 was updated to allow a Schedule II CS prescription drug to be partially filled and dispensed for non-hospice and non-long-term care patients, in accordance with a new federal law change. Specifically, the remaining portion of a partial fill shall not be filled later than 30 days after the date on which the prescription is written.
- **Pharmacy Take-Back Programs.** Rule 262 was updated to clarify that a pharmacist registered with Drug Enforcement Administration (DEA) as a collector may collect controlled and non-controlled drugs for destruction, in accordance with federal law.
- **Pharmacist-in-Charge (PIC) Qualifications.** Rule 300 was updated to clarify that a pharmacist may neither be designated nor function as the PIC of more than two pharmacies.
- **Prescription Monitoring Program (PMP) Delegates.** Rule 204 was updated to reflect that pharmacy technicians and other delegates may register for PMP access and use it in accordance with their supervisor's scope of professional practice.
- **Delivery of CS.** Rule 503 was updated to allow delivery of a CS to a licensed or registered health care provider if the drug is intended for direct administration (eg, intrathecal administration).
- **Infusion Clinic Emergency Kits.** Rule 635 was updated to reflect that pharmacies may supply emergency kits to an infusion clinic.
- **Emergency Room Dispensing.** Rule 637 was updated to allow emergency rooms to dispense even when a pharmacist is on duty in the community.
- **Pharmacist Licensure Examinations.** Rule 32 was updated to cap North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® attempts at five. In addition, a candidate who fails the NAPLEX three times must complete at least 30 hours of continuing education prior to each subsequent exam attempt.
- **Pharmacy References.** Rule 603 was updated to add the DEA *Pharmacist's Manual* as a required reference while removing the specifically named private references from the existing rule.
- **Pharmacy Security.** Rule 605 was updated to remove specifically delineated requirements related to doors, hinges, locks, and walls. It is the Board's expectation that a pharmacy must take action to prevent unauthorized access, acquisition, or use of a pharmacy, and failure to do so may constitute grounds for discipline to the PIC and the facility.

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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