



# Idaho State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Proposed Rulemaking Session Scheduled: October 25**

The Idaho State Board of Pharmacy wishes to thank the many pharmacists and public stakeholders who have provided input to date on the Board's proposed rules through listening sessions and other public meetings. Your feedback has certainly strengthened the Board's proposed updates!

The Board will host its official proposed rulemaking session on **October 25, 2017**, at 9 AM MST at the Idaho State Capitol, Room WW53, 700 W Jefferson Street, Boise, ID.

The current drafts of all proposed rules are available on the Board's website at [https://bop.idaho.gov/code\\_rules](https://bop.idaho.gov/code_rules). A description of the Board's approach to rulemaking and the organization of the rules into different chapters is available in the [June edition](#) (pages 54-56) of the Idaho Administrative Bulletin.

As a reminder, the Board has proposed to divide its existing rulebook into different chapters organized by topic:

- (1) General Provisions
- (2) Rules Governing Licensure and Registration
- (3) Rules Governing Pharmacy Practice
- (4) Rules Governing Pharmacist Prescriptive Authority
- (5) Rules Governing Drug Compounding
- (6) Rules Governing DME, Manufacturing, and Distribution

No substantive edits have been proposed regarding drug compounding, durable medical equipment (DME), manufacturing, and distribution. The Board is merely organizing these topics into new chapters.

All interested parties are encouraged to review the proposed rules and provide feedback to the Board. The Board invites any additional written comments to be submitted in advance of the meeting, and the Board will also accept verbal comments at the meeting. Comments may be submitted in writing to Board Executive Director Alex J. Adams at [alex.adams@bop.idaho.gov](mailto:alex.adams@bop.idaho.gov) or by fax to 208/334-3536.

## **Pharmacy-Based Drug Take-Back Programs: Grant Money Available**

Idaho law allows pharmacies to serve as collectors for disposal of unused and unwanted medications that are in patients' possession. Pharmacies wishing to do so must first modify their Drug Enforcement Administration registration to become an authorized collector of controlled substances (CS). Federal law also has requirements related to collection receptacle placement, use of inner liners, and reverse distribution, among others. The Board has summarized the federal requirements in a free home-study continuing pharmacy education program, titled "[How to Start a Drug Take-Back Program in Your Pharmacy.](#)"

The Idaho Office of Drug Policy and the Board received a grant from the state's Millennium Fund to help defray the start-up costs of pharmacy-based drug take-back programs. The funds cover the initial costs as well as one year of reverse distribution costs and marketing. While the grant funds have secured 22 pharmacy-based take-back programs to date, a limited amount of grant funds remain on a first come, first served basis. Any interested pharmacies are encouraged to contact Alex Adams ([alex.adams@bop.idaho.gov](mailto:alex.adams@bop.idaho.gov); 208/334-2356) as soon as possible for more information on grant availability.

## **Can I Convert a Chronic Medication From a 30-Day to a 90-Day Supply?**

Board Rule 116, "Prescription Drug Order: Refills," notes that a pharmacist using his or her best professional judgment may "dispense a prescription drug that is not a controlled substance up to the total amount authorized by the prescriber including refills."

Thus, a pharmacist may convert a prescription for a **non-controlled** drug from a 30-day supply to a larger quantity as long as the fill does not exceed the total amount authorized by the prescriber on the initial prescription. Therefore, if a patient with 12 refills wanted all dispensed at once because of an extended international trip, the pharmacist could use his or her professional judgment to do so, as long as the drug is not a CS.

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## **WHO Launches Global Patient Safety Challenge on Medication Safety**

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at <http://who.int/mediacentre/news/releases/2017/medication-related-errors/en>.

## **Continuous Quality Improvement and Patient Safety Organizations**

 *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](http://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](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing

well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*.

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda*, which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit <https://www.pso.ahrq.gov/faq>.

## **NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster**

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at [www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation\\_v1\\_4.pdf](http://www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf). Additional information for pharmacists about emergency preparedness is available on the NCPDP website at [www.ncdp.org/Resources/Emergency-Preparedness](http://www.ncdp.org/Resources/Emergency-Preparedness).

## **FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil**

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

News to a particular state or jurisdiction can only be ascertained  
such state or jurisdiction.

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at [www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm](http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm).

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at [www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm](http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm).

### **FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding**

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a “bulk drug substance” and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at [www.fda.gov/Drugs/DrugSafety/ucm502075.htm](http://www.fda.gov/Drugs/DrugSafety/ucm502075.htm), FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA’s website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf) and [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf).

### **APhA Resource Guide Applies JCPP Pharmacists’ Patient Care Process to Immunization Services**

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists’ Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists’ Patient Care Process to Immunization Services*. “[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation,” indicates the APhA guide. For more information, visit the APhA Immunization Center at [www.pharmacist.com/immunization-center](http://www.pharmacist.com/immunization-center).

### **CPE Training on Older Adult Fall Prevention Available Online**

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, “STEADI: The Pharmacist’s Role in Older Adult Fall Prevention,” visit the CDC website at [www.cdc.gov/steadi/training.html](http://www.cdc.gov/steadi/training.html) for more information.

### **New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act**

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, “Combat Methamphetamine Epidemic Act,” pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was 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](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

### **FDA Presents Series of CE Webinars for Students and Clinicians**

FDA’s Division of Drug Information in the CDER 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 FDA’s role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA’s website at [www.fda.gov/DDIWebinars](http://www.fda.gov/DDIWebinars).



Rule 116 also allows limited instances in which a pharmacist may dispense a total quantity that **exceeds** what was initially authorized on the initial prescription. 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 also did not limit extension to a one-time deal, as some patients may need to be resynchronized over time. Importantly, the ability to extend may **not** be exercised in the case of CS, compounded drugs, or biological products. The authority to exceed the initial quantity written may only be exercised in the context of a medication synchronization program, which Board rules define as "An opt-in program provided by a pharmacy for aligning the refill dates of a patient's prescription drugs so that drugs that are refilled at the same frequency may be refilled concurrently."

### **Prescription Monitoring Program: Ways to Increase Utilization**

As of July 1, 2017, all Idaho pharmacists who hold an active state CS registration have successfully enrolled for access to the state's prescription monitoring program (PMP).

As a reminder, the PMP is a useful tool to identify and resolve common "red flags" that the pharmacist may encounter in the dispensing process. Common red flags include, but are not limited to:

- ◆ The patient requests to pay with cash or a discount card, especially if insurance is on the patient's record;
- ◆ The patient travels a long distance to the prescriber or pharmacy;
- ◆ There is evidence of "doctor shopping" or "pharmacy shopping";
- ◆ The patient engages in a pattern of early refills or makes statements suggesting abuse;
- ◆ Patients travel in groups with others filling similar prescriptions;
- ◆ The prescriptions appear altered or are missing key requirements of a valid prescription; or
- ◆ The prescriptions are for highly abused "cocktails" (eg, a combination of opiate, benzodiazepine, and muscle relaxant).

Optimal PMP use has been linked to reduced prescription drug abuse and diversion. But use of the PMP may not always fit into the fast-paced workflow of a community pharmacy. To assist with this, the Board has recently launched two tools to help pharmacists better leverage PMP data in their daily practices.

First, the Board has enabled delegate access to the PMP. Each pharmacist may designate up to four technicians or student pharmacists to check the PMP on their behalf.

A technician or student pharmacist 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. A proposed delegate must submit a registration for access to the Board by visiting <https://idaho.pmpaware.net/identities/new>.

Second, the Board officially launched PMP Gateway, which enables the integration of PMP data directly into electronic medical records and pharmacy dispensing systems. This integration allows instant access to PMP data for prescribers and pharmacists without having to separately log on to the Board's PMP web portal. PMP Gateway is operated by Appriss, Inc, the Board's PMP vendor. Initial integration and ongoing maintenance fees are managed by Appriss and do not pass through the Board. Use of PMP Gateway is subject to Appriss' terms and conditions, and users must take care to ensure their use is consistent with the limits placed on prescribers and pharmacists in the Idaho Code. Several Idaho pharmacies are currently using PMP Gateway, and their use of the PMP exceeds all other pharmacies in the state, which speaks to the benefit of making it easier to access PMP data in the workflow.

To learn more about designating a delegate to access the PMP on your behalf, or to begin the process of integrating your pharmacy dispensing system with PMP Gateway, please contact Teresa Anderson at [teresa.anderson@bop.idaho.gov](mailto:teresa.anderson@bop.idaho.gov).

### **Free Home-Study Continuing Education Programs Available**

The Board has made the following free home-study programs available, accredited for Board-approved law credits in Idaho:

- ◆ Pharmacist-in-Charge (PIC) Ethical and Legal Responsibilities (2 hours)
- ◆ How to Start a Drug Take-Back Program at Your Pharmacy (0.5 hours)
- ◆ How to Obtain a CLIA Waiver & Begin Testing (0.5 hours)
- ◆ Pharmacists' Prescriptive Authority for Epinephrine Auto-Injectors (0.5 hours)

### **The Idaho Licensing Freedom Act**

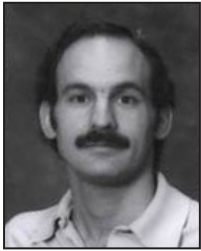
On May 19, 2017, Idaho Lieutenant Governor Brad Little issued [Executive Order 2017-06](#) ("Order"), the Licensing Freedom Act, which aims to assess whether licensure requirements are necessary and in the public interest. In addition, the Order aims to identify recommendations for improvement, modification, or elimination of licensing requirements or other regulatory burdens.

The Board is committed to occupational licensing reform and has worked closely with community stakeholders to comprehensively identify categories of licensure to eliminate, as well as to identify and remove outdated regulations that are stifling the emergence of

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new technology or business models. While rulemaking to this effect is ongoing as part of the proposed rule-making process, the Board invites feedback from any interested person on or before May 1, 2018, to help the Board further the goal articulated in the Order. Any and all feedback may be submitted directly to the Board by emailing [info@bop.idaho.gov](mailto:info@bop.idaho.gov), or to Lieutenant Governor Little through the following website: <https://lgo.idaho.gov/freedomact>.

## **Congratulations, Francois (Frank) Casabonne!**



After nearly 40 years of service to the profession of pharmacy, Frank Casabonne has retired as pharmacy manager at Albertsons Companies. Frank leaves an impressive legacy of service to both the profession of pharmacy and the patients he has served.

A 1978 graduate of the Idaho State University College of Pharmacy, Frank forged a career as a leader in community pharmacy practice. He served as president of the Idaho State Pharmacists Association from 1991-1992. He later served on the Idaho State Board of Pharmacy from July 1996 through August 2006, a time in which pharmacy practice was greatly expanded in the state of Idaho. Frank also served nationally when he was appointed to the Task Force on the Regulation of Pharmacy Benefit Managers by the National Association of Boards of Pharmacy® from 1999-2000. The Board congratulates Frank for his outstanding pharmacy career!

## **Help Is Available for Impaired Pharmacists Through the 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.



**Know a Pharmacist in trouble with drugs/alcohol or mental health problems?**  
Please contact the Pharmacist Recovery Network for help.  
[www.SouthworthAssociates.net](http://www.SouthworthAssociates.net) 800.386.1695  
**24 HOUR** CONFIDENTIAL Toll free Crisis Line  
**866.460.9014**

## **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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