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# Illinois Department of Financial and Professional Regulation Pharmacy Newsletter

*Published to promote compliance of pharmacy and drug law*

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## **A Message From Secretary Schneider**

Greetings,

Welcome to the August issue of the *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter*.

I am excited to announce that in addition to the pharmacy technician license, various other Illinois Department of Financial and Professional Regulation (IDFPR) professional license applications are now available online at <https://ilesonline.idfpr.illinois.gov/DFPR/Default.aspx>. Promoting efficiency while providing an overall better experience for licensed professionals has been the focus of IDFPR's endeavor to create a modernized licensure process.

As the IDFPR looks to further improve service to its professions already migrated online, **it is ending the practice of accepting paper applications for pharmacy technician licenses on September 1, 2017**. By doing this, the IDFPR completes its electronic transformation of pharmacy technician licenses to its online portal, granting its licensees the ability to apply for licensure or renewal anytime, anyplace through the convenience of their electronic device of choice. The IDFPR will continue to place additional professions' applications online in the coming months.

Very truly yours,

Bryan A. Schneider  
Secretary, IDFPR

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## **Pharmacy Legislation Update**

*By Garth K. Reynolds, BSP Pharm, RPh*

The following is a summary of new pharmacy legislation in Illinois. The bills below have passed both the House and Senate and are being reviewed by the Governor as of August 2, 2017.

### **House Bill (HB) 3462 – Pharmacy Practice Act: Effective Upon Becoming Law (Pending)**

Sponsor: Representative Michael Zalewski (D-Riverside, IL)

- ◆ Renews and extends the Pharmacy Practice Act until January 1, 2020.
- ◆ Makes various technical and terminology updates to the Pharmacy Practice Act.
- ◆ Updates the definitions of “Electronic Transmitted Prescription” and “Address of Record.”
- ◆ Adds the definition of “Email Address of Record.”
- ◆ Provides that applicants and licensees will keep the Department informed of a valid address and email address of record.

- ◆ Creates a Collaborative Pharmaceutical Task Force charged with discussing advancements of pharmacy practice and the needs of patients, pharmacies, pharmacists, and pharmacy technicians. This task force shall produce recommendations by September 1, 2019, and the Department will propose rules for adoption, based on the recommendations, by November 1, 2019.
- ◆ Removes a minimum number of pharmacy compliance investigators.
- ◆ Adds Confidentiality section protecting information gathered during an examination or investigation.
- ◆ Makes the pharmacy citation program for minor violations permanent.

### **Senate Bill (SB) 317 – Alpha-Hydroxyprogesterone Caproate: Effective January 1, 2018 (Pending)**

Sponsor: Senator John Mulroe (D-Chicago, IL)

- ◆ Amends the Pharmacy Practice Act, specifically the definition of the “Practice of Pharmacy,” and would allow pharmacists with appropriate training to administer alpha-hydroxyprogesterone caproate pursuant to a prescription order.

### **SB 636 – Dialysate: Effective Upon Becoming Law (Pending)**

Sponsor: Senator Terry Link (D-Gurnee, IL)

- ◆ Amends the Pharmacy Practice Act Exemptions section; provides that the Act shall not apply to, or in any manner interfere with, the sale or distribution of dialysate or devices necessary to perform home peritoneal renal dialysis for patients with end-stage renal disease so long as certain conditions are met.
  - ◇ The dialysate or devices may be held at a manufacturer or manufacturer's agent that is properly registered.
  - ◇ Dialysate or devices can only be delivered to the patient upon receipt of physician's prescription by a licensed pharmacy (and processed in accordance with the Act).
  - ◇ Does not include any other drugs for peritoneal dialysis, except dialysate.

### **SB 1790 – Emergency Refill: Effective Upon Becoming Law (Pending)**

Sponsor: Senator Steve Stadelman (D-Rockford, IL)

- ◆ Authorizes emergency refills if the following conditions are met:
  - ◇ Interruption of therapy might reasonably produce undesirable consequences or cause patient suffering.

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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]armacists 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/steady/training.html](http://www.cdc.gov/steady/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).

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- ◇ Pharmacy previously dispensed or refilled a prescription from the prescriber for the same patient and medication.
- ◇ Not for a controlled substance.
- ◇ The patient or the patient's agent is informed at the time of dispensing that prescriber authorization is required for future refills.
- ◇ Emergency dispensing is documented in the patient's prescription record and the pharmacist informs the prescriber of the emergency refill.
- ◇ Emergency supply must be limited to the amount needed for the emergency period.
- ◇ Total amount dispensed shall not exceed a 30-day supply.

### **SB 1944 – Hypodermic Syringes and Needles: Effective January 1, 2018 (Pending)**

Sponsor: Senator Chris Nybo (R-Lombard, IL)

- ◆ Increases the limit of hypodermic syringes or needles to a person without a prescription being required from 20 to 100.
- ◆ Reduces barriers for patients to access and obtain hypodermic syringes and needles, without the need for a prescription and increased health expenditures for a medical visit.
- ◆ Clarifies that electronic prescriptions may be used for hypodermic syringes and needles.
- ◆ Increases access to safe and clean needles to individuals who may utilize illicit substances.

### **HB 2957 – Medication Synchronization: Effective Upon Becoming Law (Pending)**

Sponsor: Representative Laura Fine (D-Glenview, IL)

- ◆ Allows for the coordination of two or more medications for one or more chronic conditions.
- ◆ Synchronization shall be allowed at least one occasion per insured per year.
- ◆ Medications must be covered and considered maintenance medications under the policy.
- ◆ Medications are not Schedule II, III, or IV.
- ◆ Medications can safely be utilized into a short-fill scenario to achieve synchronization.

- ◆ Medications do not have special handling or sourcing requirement under the policy.
- ◆ Policy shall allow a prorated daily cost-sharing rate to any medication dispensed.
- ◆ No dispensing fees shall be prorated, and dispensing fees shall be based on number of prescriptions filled or refilled.

*Garth K. Reynolds, RPh, is the executive director of the Illinois Pharmacists Association (IPhA) (www.ipha.org). The IPhA is dedicated to enhancing the professional competency of pharmacists, advancing the standards of pharmacy practice, improving pharmacists' effectiveness in assuring rational drug use in society, and leading in the resolution of public policy issues affecting pharmacists.*

### **Upcoming Pharmacy Board Meetings**

The IDFPR, Division of Professional Regulation – State Board of Pharmacy is scheduled to meet:

- ◆ September 12, 2017 – Chicago
- ◆ November 14, 2017 – Chicago
- ◆ January 9, 2018 – Chicago
- ◆ March 13, 2018 – Springfield, IL
- ◆ May 8, 2018 – Chicago

Chicago location: 100 W Randolph Street 9<sup>th</sup> Floor

Springfield location: 320 W Washington St

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