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Illinois Department of Financial and Professional Regulation Pharmacy Newsletter

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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 pleased to announce that the Illinois Department of Financial and Professional Regulation (IDFPR) is continuing to enhance its social media presence. The IDFPR frequently issues press releases on its website at www.idfpr.com and also distributes information regularly via social media.

Below are the links to the IDFPR's social media pages:

- ◆ <https://www.facebook.com/ILDFPR>
- ◆ <https://twitter.com/idfpr>
- ◆ <https://www.linkedin.com/company/illinois-department-of-financial-and-professional-regulation>
- ◆ <https://www.youtube.com/user/IDFPRmedia>

I encourage you to follow the IDFPR on the social media platforms above and stay connected!

Very truly yours,

Bryan A. Schneider
Secretary, IDFPR
bryan.schneider@illinois.gov, 312/793-3676

Pharmacy Best Practice and Regulation Review: 2016-2017 Influenza Season and Opioid Antagonist Training for Pharmacists

By Garth K. Reynolds, RPh, IPhA Executive Director

Major Change in Influenza Vaccine Recommendations for 2016-2017

The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recently voted to recommend against the use of live attenuated influenza vaccine (LAIV). LAIV is commonly available in a nasal spray formulation and marketed in the United States as FluMist[®] (manufactured by MedImmune, a division of AstraZeneca). During the 2015-2016 influenza season, LAIV was recommended for healthy individuals ages two to 49 years old. The recent ACIP decision was not reached lightly and was based on recent study data from multiple sources that exhibited unsatisfactory effectiveness from 2013 through 2016.

This decision by the ACIP results in no nasal spray formulation being available for the 2016-2017 influenza season.

The ACIP continues to recommend that all individuals age six months and older receive an annual influenza vaccine. Pharmacists are reminded that in Illinois, you are able to administer influenza vaccine to patients 10 years and older by either a patient-specific prescription or a standing order. Make sure to contact your wholesaler if you had reserved LAIV formulations for the 2016-2017 influenza season and to adjust your incoming stock with inactivated influenza vaccine and/or recombinant influenza vaccine formulations.

For more information, please refer to the complete CDC announcement, available at www.cdc.gov/media/releases/2016/s0622-laiv-flu.html.

This is also a reminder that in accordance with *Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, it is recommended that you receive your annual influenza vaccine, as well.

Illinois State Opioid Antagonist Training Program Provided by IPhA

The Illinois State Opioid Antagonist Training Program, provided by the Illinois Pharmacists Association (IPhA), is an on-demand, web-based training and is now available for pharmacists throughout Illinois seeking to dispense naloxone, a drug widely utilized to counter the effects of overdose from narcotics such as morphine and heroin. By completing the Illinois State Opioid Antagonist Training Program, pharmacists will gain the ability to dispense naloxone without a prescription to those who might benefit most, including trained first responders, school nurses, or any individuals at risk of overdose. The program is the result of a new law passed in September 2015 (Public Act (PA) 99-0480), which expanded access to the opioid antagonist drug, naloxone.

The Illinois State Opioid Antagonist Training Program has been approved by the Illinois Department of Human Services to meet the requirements set forth in PA 99-0480.

Please visit www.ipha.org for more information about the training program and to register.

As a reminder, once you have completed the Illinois State Opioid Antagonist Training Program, you need to contact the Illinois Prescription Monitoring Program (www.ilpmp.org) to obtain access to the Naloxone Standardized Procedures of the Opioid Antagonist Initiative. Also, the [Illinois Department of Healthcare and Family Services](#) is requiring pharmacists to maintain a copy of the continuing pharmacy education (CPE)

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FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- ◆ Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- ◆ Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- ◆ Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- ◆ Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- ◆ Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- ◆ Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- ◆ Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- ◆ Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.

More 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.

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as $154 \text{ mEq}/0.9\% = x/3\%$ and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag ($77 \text{ mEq}/0.9\% = x/3\%$).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,¹⁻⁵ and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.⁶ The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that



most of these errors happened within the first 14 days after discharge.⁵ The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).⁴

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

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USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings*, has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at www.usp.org in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium*.

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

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 February 2016 Drug Info Rounds video, “Emergency Preparedness – Keeping Medications Safe,”

pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, 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.

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency’s effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency’s approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA’s Drug Safety Communication announcement, available at www.fda.gov/Drugs/DrugSafety/ucm489676.htm.

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus’ facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.

statement of credit verifying completion of the Illinois State Opioid Antagonist Training Program. To obtain a transcript of your CPE activity or a CPE Monitor® Statement for an individual CPE activity, log in to your NABP e-Profile account by visiting the National Association of Boards of Pharmacy® (NABP®) website at www.nabp.net.

Garth K. Reynolds, RPh, is the executive director of the 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.

Illinois State Board of Pharmacy Member Elected to APhA

IDFPR, Division of Professional Regulation – Illinois State Board of Pharmacy Member Philip P. Burgess, MBA, DPh, RPh, was elected as the 2017-2018 honorary president of the American Pharmacists Association (APhA). All officers will be installed at the 164th APhA Annual Meeting & Exposition in San Francisco, CA, held March 24-27, 2017.

The official announcement may be found at <http://www.pharmacist.com/apha-announces-results-2016-board-elections>.

The Board sends its congratulations to Phil on this impressive accomplishment.

Board Members Attend the NABP Annual Meeting

By Lemrey "Al" Carter, Illinois State Board of Pharmacy Member

On May 14-17, 2016, many Board members attended the NABP 112th Annual Meeting in San Diego, CA, where the theme for the weekend was "All Hands on Deck – Forging Ahead to a New Regulatory World." This meeting is a gathering of all 50 state boards of pharmacy and US provinces and several of NABP's international members, including Canada, the Bahamas, New Zealand, and Australia. During this four-day meeting, there were many presentations that focused on some of the most pressing issues affecting pharmacy today such as prescription drug abuse, diversion, and doctor shopping; pharmacist prescriptive authority and the regulatory landscape overseeing this authority; federal and

state drug supply chain regulations and the impact on patient safety; and educational programs/certifications, licensing requirements, and the increasing responsibilities placed on pharmacy technicians.

Daniel Kelber, IDFPR associate general counsel and legal counsel to the Board of Pharmacy and the Illinois State Board of Medicine, participated in a panel discussion with the executive director of the Texas State Board of Pharmacy and the chief advocacy officer of the Federation of State Medical Boards to discuss telepractice. This panel discussed the current state of telepractice and the use of technology by physicians and pharmacists to provide medical and pharmaceutical care to patients without being in the same physical location as the patient.

In addition to the presentations, this meeting provided Board members the opportunity to network with fellow board members from other states and provinces. The 2017 NABP Annual Meeting will be held in Orlando, FL.

Upcoming Pharmacy Board Meetings

The Board is scheduled to meet:

- ◆ September 13, 2016 – Chicago, IL
- ◆ November 15, 2016 – Chicago
- ◆ January 10, 2017 – Chicago
- ◆ March 14, 2017 – Springfield, IL
- ◆ May 9, 2017 – Chicago

Chicago location: 100 W Randolph Street, 9th Floor

Springfield location: 320 W Washington Street