February 2017

Illinois Department of Financial and Professional Regulation Pharmacy Newsletter

Published to promote compliance of pharmacy and drug law

320 W Washington, 3rd Floor • Springfield, IL 62786 • Phone: 800/560-6420
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A Message From Secretary Schneider

Greetings,

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

I hope that everyone is staying warm and healthy this winter season. I am excited to report that the Illinois Department of Financial and Professional Regulation (IDFPR) is continuing to transfer initial license applications online. Applicants can now apply for certified pharmacy technician and student pharmacist licenses on IDFPR's new online portal.

Under the new portal, all application interactions are completed online from start to finish. All deficiency notices are now sent via the online portal. Applicants can also respond to and resolve deficiency notices online. Another user-friendly feature of the new portal is that applicants can check the status of their application online while waiting for their license to be issued.

Since the transition to the new portal, the license processing time for pharmacy technicians has decreased almost 70%. IDFPR continues to transfer additional professional licenses online and hopes that this enhancement will allow professionals to spend more time working and reduce the time it takes to obtain a license.

Very truly yours,

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

Illinois Board of Pharmacy Legal Counsel Update

Longtime IDFPR, Division of Professional Regulation – State Board of Pharmacy Legal Counsel Daniel Kelber recently transitioned into a new role as Deputy General Counsel within IDFPR's Division of Banking. IDFPR Division of Professional Regulation's Alex Cooper and Katy Straub have taken over Daniel's responsibilities and are excited to serve as Legal Counsel to the Board. Reflecting on his time with the Board, Daniel said, "It has been a great privilege for me to work all these years with the Board and the Department doing the important job of ensuring that the people of Illinois have access to safe and innovative pharmacy services. I am happy in the knowledge that the profession is being left in the very capable hands of Alex and Katy." IDFPR and the Board thank Daniel for his 14 years of outstanding service to the Board.

DEA Honors Two IDFPR Medical Prosecutors for 'Outstanding Contributions'

Prosecution Efforts Focused on Improper Controlled Substance Prescribing

IDFPR Chief Medical Prosecutor Laura Forester and Medical Prosecutor Vladimir Lozovskiy were recently honored by the United States Drug Enforcement Administration (DEA) with certificates of appreciation for their "outstanding contributions" in the field of drug enforcement. In the past two years alone, Medical Prosecutors Forester's and Lozovskiy's joint investigations with DEA have resulted in disciplinary action taken against more than 20 licensed health care professionals in Illinois over allegations of improper prescribing of controlled substances.

"Attorneys Vladimir Lozovskiy and Laura Forester are outstanding and tireless public servants who work daily to safeguard the citizens of Illinois from illegitimate medical practitioners," said DEA Special Agent in Charge Dennis A. Wichern. "We are fortunate to have such great partners as teammates for our investigations."

Wichern presented Forester and Lozovskiy with plaques in recognition of their service. Other officials from the DEA Chicago Field Division in attendance included Diversion Program Manager Daniel J. Gillen, Group Supervisor R. Timothy Lenzi, and Diversion Investigator Cori L. Rizman.

Noteworthy cases involving Forester and Lozovskiy include Joseph Giacchino, MD (aka "Dr Million Pills") and his alleged collaborators William J. McMahon, MD, and Paul Madison, MD.

"Laura and Vladimir work tirelessly to enforce our state's laws and safeguard the public from medical professionals that pose a threat to our health, safety and welfare," said Bryan A. Schneider, IDFPR Secretary. "By nature, their job can be grueling and thankless at times. This award is a testament to their continued hard work and dedication to public service."

To learn more about the regulation of Illinois' medical professionals, please visit *www.idfpr.com*. Stay current on statewide regulation of banks, financial institutions, and over 1 million licensed professionals by following IDFPR on Facebook, Twitter, and YouTube.

National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

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.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

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*.

Upcoming Pharmacy Board Meetings

The Board is scheduled to meet:

- March 14, 2017 – Springfield, IL
- May 9, 2017 – Chicago, IL

Springfield location: 320 W Washington Street

Chicago location: 100 W Randolph Street, 9th Floor

Pharmacy Community Mourns the Passing of Sister Margaret Wright

Content Provided by the National Association of Boards of Pharmacy® (NABP®)

IDFPR, Division of Professional Regulation – State Board of Pharmacy is sad to announce that former member Sister Margaret Wright, RSM, PhD, a Sister of Mercy for 63 years, passed away on Sunday, October 16, 2016. Her contributions to the state boards of pharmacy and the protection of public health were highlighted in the NABP November-December 2016 issue of *Innovations.*

Sister Margaret showed ongoing commitment to NABP by serving on numerous task forces and committees, including serving on the Foreign Pharmacy Graduate Equivalency Examination Review Committee for over 10 years. She also served on the Advisory Committee on Examinations and the Multistate Pharmacy Jurisprudence Examination Review Committee. Sister Margaret also consulted as a subject matter expert by reviewing the annual updates to the *Survey of Pharmacy Law* from 2010 to 2014.

In recognition of her dedication to the Association's mission and goals, NABP named Sister Margaret as its 1994-1995 honorary president. She was also awarded the Association's Lester E. Hosto Distinguished Service Award in 1987. In 1980, Sister Margaret was the first woman and first from a hospital setting to be named the Pharmacist of the Year by the Illinois Pharmacists Association (IPhA). The American Pharmacists Association awarded the Gloria Niemeyer Francke Leadership Mentor Award to Sister Margaret in 2004 for her contributions to the pharmacy profession, including mentoring new pharmacists.

Sister Margaret served as director of pharmacy services for Mercy Hospital and Medical Center from 1974 to 1990. She earned her bachelor of pharmacy degree from Creighton University in 1962, master of science degree in pharmacy administration from the University of Colorado in 1971, and PhD in pharmacy from the University of Illinois at Chicago in 1998.

Important Illinois Professionals Health Program Update

The Illinois Professionals Health Program (IPHP) is moving! IPHP will continue to provide the same services for pharmacists and pharmacy technicians. You can continue to reach IPHP at 1-800/215-HELP (4357). Additional contact information will be forthcoming.

Closing the Gaps in Medication Optimization Services in Illinois Survey

IPhA is conducting a survey of pharmacists to identify who is providing medication optimization (medication therapy management (MTM), comprehensive medication review, comprehensive medication management, etc) to Illinois patients in order to determine where there are gaps in services and where pharmacy has best practices. Please help us make a positive impact with our patients! Please help us identify pharmacists' MTM needs in Illinois as we prepare for our expanded roles!

The survey is research being conducted by Amber Simmons for the purpose of identifying gaps in medication management services in the State of Illinois. The title of this study is "Closing the Gap in Medication Optimization Services in Illinois." The Illinois Department of Public Health has partnered with IPhA to examine medication optimization services offered in Illinois. The results of this survey will be reported to the Centers for Disease Control and Prevention as a part of the national 1305 Coordinated Chronic Disease Grant, which aims to understand the landscape of medical therapy management services across the country. The results of this study may be published in scientific research journals or presented at professional conferences. However, your name and identity will not be revealed and your individual responses will remain confidential. Your participation will benefit Illinois' pharmacists and the development of future medication management services and programs. Your participation is strictly voluntary, and there will be no negative repercussions if you choose not to participate. Your completion of the survey will serve as your consent to participate. You may withdraw from participation at any time. No personal identifiers will be collected. The information you provide will be analyzed and reported in de-identified, aggregated manner only.

If you have questions about this research study, you can call Amber Simmons at 217/732-3056. If you have questions about your rights as a research participant, you can contact the Southern Illinois University Edwardsville Institutional Review Board at 618/650-2958 or via email at lskelto@siue.edu.

Please visit *https://www.surveymonkey.com/r/pharm17* to access the survey.

The *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter* is published by the Illinois Department of Financial and Professional Regulation (IDFPR) and the National Association of Boards of Pharmacy Foundation® (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the IDFPR unless expressly so stated.

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