A Message From Secretary Schneider

Greetings,

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

I hope that everyone’s fall season is off to a great start. I am pleased to announce that the Illinois Department of Financial and Professional Regulation (IDFPR) recently hired two new drug compliance investigators. They will be primarily serving northern Illinois by ensuring that pharmacy inspections are performed in a diligent and prompt manner. These new hires are a much welcomed addition to the IDFPR team.

On the topic of new hires, I am also excited to announce that Jessica Baer is the new Acting Director of IDFPR’s Division of Professional Regulation. Jessica previously served as the IDFPR’s General Counsel and also has experience practicing law in the private sector. I will let Jessica tell you more about herself in the article below.

Very truly yours,

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

A Message From Acting Director Baer

Welcome,

I am thrilled to be the Acting Director of IDFPR’s Division of Professional Regulation. As Secretary Schneider mentioned above, I had the pleasure of serving as General Counsel of IDFPR since March 2015 and am excited to continue my work at the IDFPR in this new capacity. Prior to my work with the State, I was in private practice with a focus on commercial litigation and antitrust law.

I look forward to working with you all and helping to ensure the safety and success of the pharmacy profession in Illinois.

Kind regards,

Jessica Baer
Acting Director, Division of Professional Regulation
jessica.baer@illinois.gov, 312/814-4477

Pharmacy Personnel Termination Reporting

On August 19, 2016, Governor Bruce Rauner signed into law Public Act 099-0863, which amended the Illinois Pharmacy Practice Act (Act) to require that a pharmacy or pharmacist-in-charge file a report with the chief pharmacy coordinator of the IDFPR any time a pharmacist, a registered certified pharmacy technician, or a registered pharmacy technician licensed by the IDFPR is terminated for actions that may have threatened patient safety. The law provides protection from criminal prosecution or civil damages when such report is made in good faith.

This report must be filed in writing with the IDFPR within 60 days after a pharmacy’s determination that a report is required under the Act. The IDFPR has created a designated form for this required reporting, which can be found on its Pharmacy web page, located under the “Resources & Publications” tab. For the convenience of the individual or organization making the report, completed reports may be emailed to the Division at fpr.pharmacyadverse@illinois.gov.

Upcoming Pharmacy Board Meetings

The IDFPR – State Board of Pharmacy is scheduled to meet:

♦ November 15, 2016 – Chicago, IL
♦ 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

Pharmacy Citation Program Update

By Alexander Hemsley, Policy Director, IDFPR Division of Professional Regulation

In February 2016, the IDFPR announced a pilot pharmacy citation program. This program was designed to reduce the amount of resources spent by both the IDFPR and the licensed pharmacists when dealing with minor infractions. During just over six months of this program, more than 80 tickets were issued.

Each pharmacy that was issued a ticket had the option of choosing not to pay the nominal fine amount of no more than $500. If the pharmacy did this, the infraction would continued on page 4
National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at https://vaers.hhs.gov/professionals/index.

Improper and Unsafe Vaccine Storage

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.

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications or in a refrigerator or freezer that is not temperature-monitored can also lead to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP’s March 26, 2015 newsletter1 contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.2

References

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System’s 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:
1. Read and follow the label.
2. Know which medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.

(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, www.knowyourdose.org.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA’s Division of Drug Information in the Center for Drug Evaluation and Research presents a series of 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 expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch. Additional details are available on FDA’s website at www.fda.gov/Safety/Recalls/ucm497812.htm.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with Burkholderia cepacia, a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of B. cepacia infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch. More information may be found in the safety alert on FDA’s website at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

♦ District 1: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.

♦ District 5: Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.


In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online interest form available in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.
be litigated through the system normally. Out of the tickets issued, no pharmacies chose to fight their fine.

The IDFPR views this as a great success. Over 80 different pharmacies agree.

Moving forward, the IDFPR has decided to make the citation program a permanent program. The IDFPR will continue with the same fine structure ($100 for one offense, $250 for two offenses, and $500 for three) that will only be applied to minor violations. This program is one of the many steps that the IDFPR is taking to reduce regulatory burdens without compromising patient care.

Updates to the NAPLEX and the MPJE

By Maria Incrocci, PhD, RPh, Competency Assessment Senior Manager, NABP

The National Association of Boards of Pharmacy® (NABP®) has provided ongoing notification to prospective candidates for licensure and the boards of pharmacy regarding several recent changes to the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®) programs. The examination development cycle includes systematic evaluations of the content and topics covered on the examinations as well as validation studies conducted via national surveys of pharmacist practitioners, regulators, and academicians. The NAPLEX and MPJE are developed to assist the boards of pharmacy with decisions regarding pharmacist licensure.

NAPLEX Program Updates

♦ Following the 2014 National Pharmacy Practice Survey, the NAPLEX underwent changes to the content domains to better reflect the expanded role pharmacists play in patient evaluation, medication management, preparation, and delivery. Subject matter experts analyzed results of the survey, which were also reviewed by the NAPLEX Review Committee, the Advisory Committee on Examinations (ACE), and the NABP Executive Committee. The new NAPLEX competency statements and test plan were implemented in November 2015. The new test plan included an increase in the number of clinically based, patient-centered test items.

♦ The passing standard for the NAPLEX was evaluated in March 2015 by pharmacists representing the NABP Executive Committee, ACE, the NAPLEX Review Committee, and pharmacist practitioners and academicians from across the United States. The new passing standard was implemented in November 2015, along with the new competency statements and test plan.

♦ In November 2016, the NAPLEX will increase in length from the current 185 questions to 250 questions. Candidates will have six hours (current time is 4.25 hours) to complete the examination. In addition, the examination assembly format will change from a computer-adaptive exam (assembled as the candidate is testing) to a linear exam format (pre-assembled to meet specific measurement targets). The change to the assembly format will be transparent and is not expected to affect the test-taking experience. The fee for the new NAPLEX will be $575.

♦ The waiting period for the NAPLEX will also change from the current 91-day waiting period to 45 days. A waiting period is the time between a failed attempt on the NAPLEX and the next scheduled appointment to test. The NABP Executive Committee and ACE have revised the policy to reduce the waiting period, which also includes a provision that there shall be no more than three attempts to pass the NAPLEX in a 12-month period.

MPJE Program Updates

♦ Like the NAPLEX, the MPJE underwent a content review and national survey of pharmacy regulators in 2014-2015.

♦ The passing standard for the MPJE was evaluated in November 2015 by pharmacists representing ACE, the MPJE Review Committee, pharmacist practitioners, regulators, and academicians.

♦ The MPJE increased in length from 90 questions to 120, and the time allotted to complete the examination was increased from two hours to 2.5 hours. Both the new passing standard and the longer examination were implemented in April 2016. The fee for the MPJE is $250.

♦ The MPJE continues to be administered as a computer-adaptive examination.

♦ The waiting period for the MPJE remains at 30 days between attempts.

Detailed information regarding the NAPLEX and MPJE programs is included in the NAPLEX/MPJE Candidate Registration Bulletin on the NABP website at www.nabp.org.pharmacy.

Assistance for Illinois Pharmacy Professionals

Illinois Professionals Health Program

The Illinois Professionals Health Program (IPHP) is a statewide program providing support and earned advocacy for health care professionals throughout Illinois. The IPHP is recognized by the Federation of State Physician Health Programs as the approved physician health program for Illinois, and by the National Organization of Alternative Programs as the alternative to discipline program for Illinois. The IPHP assists health care professionals who have difficulties with stress management, substance abuse, medical or psychiatric illness, or other issues that may affect professionals’ health, well-being, or ability to practice.

Pharmacists and pharmacy technicians in Illinois currently have a portion of their licensing fees dedicated to certain services provided through the IPHP. This allows these professionals to have the initial screening, enrollment, and monthly case management fees covered by the IDFPR.

The IPHP strives to facilitate and promote the health and well-being of Illinois health care professionals of all disciplines by effectively addressing any and all physical, mental, emotional, and/or behavioral problems that may adversely affect their private or professional lives. This is accomplished in several ways:

♦ Screening and referral to resources who have expertise in the area being addressed and who are familiar with the specialized needs of licensed health care professionals are provided.

♦ Consultation and guidance are offered to people concerned about the health and functioning of a health care professional residing or practicing in Illinois.

♦ Support and monitoring of professionals are offered so that they may be able to sustain meaningful life

continued on page 5
changes for the sake of their health and to maintain
the trust and confidence of those whom they serve.
♦ **Accountability** is implemented through documentation
of compliance with recommended treatment and/or
behavioral plans for professionals who need advocacy
with various regulatory or administrative agencies.

The IPHP offers an effective way to ensure that im-
paired pharmacy professionals receive the help they need
as quickly as possible. This includes a confidential initial
screening, referral to an appropriate network of treat-
ment providers and support systems, education regarding
licensure concerns, and help to ensure quality of care,
monitoring, and advocacy.

The IPHP’s ultimate goal is to help impaired pharmacy
professionals return to safe practice by giving them the
best opportunities for career success through an accepted
 treatment protocol and appropriate aftercare designed for
health care professionals.

**Confidentiality**

The IPHP complies with federal law Title 42 Code of
Federal Regulations Part 2, 42 USC §290dd-2, which pro-
tects confidentiality. Participation in the IPHP is voluntary
and confidential. **Communication with the IPHP is kept
strictly confidential.** Information may only be released
with the written consent of the participant. The IPHP has no
disciplinary authority. **The IPHP’s activities are strictly
limited to providing assistance and advocacy.**

**Access:** A 24-hour help line is available to address
urgent concerns from anyone regarding a health care pro-
essional, including hospital administrators, employers,
colleagues, family, or friends.

| 24-Hour Help Line: 1-800/215-HELP (4357) |

For more information about the IPHP, please contact:
Terry Lavery
701 Lee Street, Suite 100
Des Plaines, IL 60016-4545
847/795-2810 or 800/215-4357

More information is also available at [www.advocatehealth.com/IPHP](http://www.advocatehealth.com/IPHP) and [www.fsphp.org](http://www.fsphp.org).