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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 May issue of the *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter.*

I was thrilled to learn that the Illinois Department of Financial and Professional Regulation's (IDFPR's) pharmacy citation program was recently featured in *Innovations,* the National Association of Boards of Pharmacy® (NABP®) newsletter. The article is also included below in this *Newsletter.* The pharmacy citation program is just one example of IDFPR's commitment to innovation and effective enforcement. As we head into the second half of 2017, the IDFPR will continue its dedication to streamlining processes and making improvements for all stakeholders.

Very truly yours,

Bryan A. Schneider
Secretary, IDFPR
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Multiple State Boards of Pharmacy Now Use Citation and Fine Programs for Minor Violations

The following article has been reprinted from the April 2017 issue of Innovations *with permission by NABP.*

Some state boards of pharmacy have explored new options for effectively enforcing their state's regulations, while also streamlining processes and making the most efficient use of board resources. For example, three boards – Illinois, California, and Virginia – have citation or fine programs in place that can be used to help pharmacies address easily correctable violations. Such programs can be targeted to certain types of infractions as an alternative to lengthy disciplinary actions.

Illinois Pilot Program Becomes Permanent

In October 2016, [the IDFPR], which includes the state board of pharmacy, made permanent a pilot ticket and fine program. Since it was established in early 2016, the voluntary program replaces formal disciplinary actions taken in response to minor violations of the state's pharmacy act and rules with monetary penalties. For example, if a pharmacy's fridge were used to improperly store both food and medicine, the pharmacy would have the option to settle the matter by paying a fine.

In this way, the pilot program aimed to improve the state board of pharmacy's internal productivity by allowing the IDFPR to focus resources on more severe infractions. In addition, the program was intended to ease regulatory burdens faced by pharmacies, providing them with streamlined options for resolving easily correctable issues. This streamlining of the formal disciplinary process has allowed the IDFPR to improve its turnaround time when processing these low-level infractions.

At the same time, licensees are motivated to correct infractions, thus protecting the public health. Examples of minor infractions that may be subject to a monetary penalty include failure to display a current license in a conspicuous location, having a can of soda in the work area, or having one or two unlabeled or expired medications with active stock.

The traditional system required the investigator to inform the pharmacist-in-charge (PIC) to be prepared to receive a complaint from the IDFPR about the violations. Under the new ticketing system, the investigator may now provide the PIC with a ticket, making the PIC aware of the charges against the pharmacy and the proposed fine. The PIC will be asked to sign the ticket to acknowledge that the violation and charges were explained by the investigator. This signature is not considered an admission of guilt.

From here, the pharmacy has two options:

- First, it may pay the fine, at which point the ticket and violations will be put into its IDFPR record as a nondisciplinary infraction and the matter will be considered settled.
- Second, the pharmacy may decline to pay the fine, which will revert the process back to the original system, starting with a formal complaint filed by the IDFPR against the pharmacy, followed by settlement negotiations and possibly a full, formal hearing.

The second option is likely to be more expensive than the first, especially when considering legal resources and staff time. In addition, the formal disciplinary actions will be disclosed on the IDFPR's monthly disciplinary report and attached to the pharmacy's license profile on the IDFPR website.

Although the program was not intended to be a significant source of revenue for the IDFPR, as of October 2016 the pharmacy citation program had issued 86 tickets and brought in $23,000 in fines, as stated in a news article published in

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DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at *www.deadiversion.usdoj.gov/drugreg/index.html.*

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

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.*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit *https://www.ismp.org/Survey/NewMssacap/Index.asp.*

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists,* CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at *www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdf.*

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at *https://jcpp.net.*

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf.*

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register,* which can be found at *www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.*

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at *www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.*

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at *www.ptcb.org* in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit *www.BuySafeRx.pharmacy.*

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at *http://lawatlas.org/datasets/pharmacist-vaccination,* explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

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The Washington Times. The program is also credited with reducing the burden of legal fees for pharmacies. Officials at the IDFPR believe that making the program permanent will allow inspectors to focus on matters that are more serious threats to public health and safety.

Before the ticketing program was implemented, the IDFPR described the existing process for resolving minor infractions in its February 2016 newsletter as "exceedingly long, often lasting months, with voluminous correspondence between the pharmacy, its attorneys, and the IDFPR, often concluding with public discipline and a small fine paid to the State." Writing reports on such infractions also consumed large amounts of staff members' time, which the IDFPR argued could be better spent in the field.

Monetary Penalties in California and Virginia

Similar citation programs are active in at least two other states, California and Virginia. Specifically, the California State Board of Pharmacy has the authority to issue citations containing fines and orders of abatement for certain violations. In this case, a citation does not necessarily preclude the California Department of Consumer Affairs from filing a disciplinary action to revoke or suspend a permit; however, as with the Illinois program, citations are typically issued for minor violations of a provision or regulation that can be easily resolved.

California's citations are served personally or by certified mail, after which the cited pharmacy typically has 30 days to pay the fine, though longer periods of time may be approved. Failure to pay the fine within the time limit is considered grounds for formal disciplinary action. While not actively publicized, information about citations and other disciplinary actions taken against a licensee may be disclosed to members of the public upon request.

In Virginia, a prescriptive list of deficiencies that are discovered during a pharmacy inspection may incur monetary penalties. For larger infractions, these penalties are levied at specific amounts based on the type of violation. For example, if pharmacy technicians are observed performing duties on an expired license or registration, the pharmacy may be fined $100 per individual. Examples of larger penalties include $1,000 for a nonoperational alarm, and $5,000 for pharmacists not documenting final verification of sterile compounding. In addition to these penalties, a list of minor violations, such as lacking a sink with hot and cold running water in the prescription department or exceeding the allowed pharmacy technician to pharmacist ratio, may also incur penalties if five or more such deficiencies are observed.

Boards of pharmacy that wish to utilize such programs may want to consider the following questions: How effective are citations and fines in enforcing the regulations? Are citation, fine, or ticket programs a good means for partnering with licensees to educate them on compliance with their state's regulations? To what extent can such programs streamline administrative processes and lead to speedier resolutions? How might such programs motivate licensees to avoid violations and minor infractions while preventing a culture that considers fines part of the cost of doing business?

NABP gave executive officers an opportunity to explore this topic at the October 2016 Interactive Executive Officer Forum during the session "Citations Are Just 'Fine' or Are They?" The Association will continue to review information about such programs and share updates in future meetings and communications as appropriate. Additional information on the IDFPR pilot program is available in the February 2016 issue of the *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter.*

Important Adverse Reporting Requirements Reminder

When filling prescriptions, patients trust their pharmacists to dispense medications that are safe and effective. However, medication errors occasionally occur and can have serious consequences for patients. In an effort to minimize errors, the Illinois General Assembly passed legislation that Governor Bruce Rauner signed into law effective August 19, 2016. Public Act 099-0863 amended the Illinois Pharmacy Practice Act (Act) to require that a pharmacy or PIC 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 Board of Pharmacy web page under the "Resources & Publications" tab. For the convenience of the individual or organization making the report, completed reports may be emailed to the IDFPR, Division of Professional Regulation – State Board of Pharmacy at fpr.pharmacyadverse@illinois.gov.

Below is the direct statutory language taken from the Act (225 ILCS 85/30.1).

> Sec. 30.1 Reporting.
>
> (a) When a pharmacist, registered certified pharmacy technician, or a registered pharmacy technician licensed by the Department is terminated for actions which may have threatened patient safety, the pharmacy or pharmacist-in-charge, pursuant to the policies and procedures of the pharmacy at which he or she is employed, shall report the termination to the chief pharmacy coordinator. Such reports shall be strictly confidential and may be reviewed and considered only by the members of the Board or by authorized Department staff. Such reports, and any records associated with such reports, are exempt from public disclosure and the Freedom of Information Act. Although the reports are exempt from disclosure, any formal complaint filed against a licensee or registrant by the Department or any order issued by the Department against a licensee, registrant, or applicant shall be a public record, except as otherwise prohibited by law.
>
> (b) The report shall be submitted to the chief pharmacy coordinator in a timely fashion. Unless otherwise provided in this Section, the reports shall be filed in writing, on forms provided by the Department, within 60 days after a pharmacy's determination that a report is required under this Act. All reports shall contain only the following information:
>
> (1) The name, address, and telephone number of the person making the report.

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(2) The name, license number, and last known address and telephone number of the person who is the subject of the report.

(3) A brief description of the facts which gave rise to the issuance of the report, including dates of occurrence.

(c) The contents of any report and any records associated with such report shall be strictly confidential and may only be reviewed by:

(1) members of the Board of Pharmacy;

(2) the Board of Pharmacy's designated attorney;

(3) administrative personnel assigned to open mail containing reports, to process and distribute reports to authorized persons, and to communicate with senders of reports;

(4) Department investigators and Department prosecutors; or

(5) attorneys from the Office of the Illinois Attorney General representing the Department in litigation in response to specific disciplinary action the Department has taken or initiated against a specific individual pursuant to this Section.

(d) Whenever a pharmacy or pharmacist-in-charge makes a report and provides any records associated with that report to the Department, acts in good faith, and not in a willful and wanton manner, the person or entity making the report and the pharmacy or health care institution employing him or her shall not, as a result of such actions, be subject to criminal prosecution or civil damages.

(Source: P.A. 99-863, eff. 8-19-16.)

PTCB Suspends Implementation of Accredited Education Requirement Originally Planned for 2020

The following content has been reprinted from the Pharmacy Technician Certification Board January 23 news release and has been lightly edited for style.

By Laura Humphrey, Jan 23, 2017

WASHINGTON, DC – The Pharmacy Technician Certification Board (PTCB) has decided to suspend the implementation of the planned 2020 accredited education requirement for pharmacy technicians who seek PTCB Certification.

PTCB originally announced in 2013 that the requirement would take effect in 2020 as part of a road map of program changes designed to keep pace with the evolution of technician roles in the pharmacy. "We have determined that additional deliberation and research are needed to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors and [chief executive officer (CEO)] of the Michigan Pharmacists Association.

"The pharmacy community is prepared to engage in a thoughtful discussion regarding the potential for an education requirement for pharmacy technician certification," said PTCB Executive Director and CEO Everett B. McAllister, MPA, RPh. "PTCB is part of the broad pharmacy community and we listen to those invested in, and affected by, our policies. Ultimately, this deliberative approach serves patients and advances our common missions to improve medication safety and advance patient care."

As the role of the pharmacy technician evolves to meet current health care needs, PTCB continues to take steps to support the pharmacy community. PTCB recently completed a Job Analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam, and is in the process of developing advanced certification programs. PTCB [hosted] an invitational conference [. . .] in February. Pharmacy leaders and stakeholders [examined] entry-level standards and [provided] information to help determine future plans for implementation of PTCB program changes.

"PTCB is studying the many roles and responsibilities of today's pharmacy technicians at different levels and in varying settings," said Mr McAllister. "This information needs to be taken into consideration as we determine the appropriate requirements for initial certification applicants."

"PTCB is committed to advancing medication safety and establishing standards for pharmacy technician certification to protect the public and advance patient care in every state and territory in the [United States]," said Mr Wagenknecht. "Advancing medication safety requires the pharmacy community to reach a level of consensus together."

"PTCB is a nonprofit organization. We are continually collecting feedback from the pharmacy community and seeking consensus to guide our program," said Mr McAllister. "This process can make our decision-making more complicated, but it is more supportive of the pharmacy profession and critical to fulfilling our mission as a nonprofit organization."

Upcoming Board Meetings

The Board is scheduled to meet:

- May 9, 2017 – Chicago, IL

Chicago location: 100 W Randolph St, 9th Floor

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.