

February 2018



Illinois Department of Financial and Professional Regulation Pharmacy Newsletter

Published to promote compliance of pharmacy and drug law

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A Message From Secretary Schneider

Greetings,

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

I hope everyone's 2018 is off to a great start! As we head into the new year, there are many Illinois-specific pharmacy topics to provide updates on, including the new Collaborative Pharmaceutical Task Force. I am pleased to announce that the task force had its kickoff meeting in January and will continue to meet throughout the year. Please take time to read more about the task force and the other articles in this *Newsletter*.

Very truly yours,

Bryan A. Schneider

Secretary, IDFPR

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Renewal Reminder

The following licenses are currently in renewal and are scheduled to expire after March 31, 2018: pharmacist, pharmacy, pharmacy controlled substance, and pharmacy technician. For more information on licensure renewal, please visit the Illinois Department of Financial and Professional Regulation (IDFPR) – State Board of Pharmacy's [website](#).

Board Updates

The Board is a statutorily created advisory board of the IDFPR. It is made up of nine members, including seven pharmacists from various pharmacy practice settings and two public members.

At the November 2017 meeting, the Board voted to designate Yash Patel, RPh, as Chairperson. Long-standing Board Member Philip Burgess, MBA, DPh, RPh, recently concluded his service on the Board and has been appointed Chair of the Collaborative

Pharmaceutical Task Force, created pursuant to [Public Act 100-0497](#). Another longstanding Board member, Ned Milenkovich, PharmD, JD, RPh, has also concluded his service to the Board. The IDFPR thanks Mr Burgess and Mr Milenkovich for their many years of dedication to the public and welcomes its newest appointed Board members, Glen Pietrandoni, RPh, and Ryan McCann, PharmD, RPh.

The Board meets every other month to review and discuss matters germane to the pharmacy profession. Those interested in attending may find Board meeting notices and agendas on the Board's [website](#).

Illinois Pharmacy Investigator Earns Certification in Sterile Compounding

The IDFPR is proud to announce that Drug Compliance Unit Investigator Aarti Parikh has earned a Certification in Sterile Compounding for Inspectors as part of the Sterile Compounding Inspector Training Program. The National Association of Boards of Pharmacy® partnered with CriticalPoint, LLC, to launch this certificate program in 2016 to assist the state boards of pharmacy in credentialing individuals to promote public health and safety through compounded medicines. The IDFPR looks forward to registering additional investigators for this certification in the coming months.

Notice of Proposed Rulemaking

The IDFPR has proposed changes to the Rules for the Administration of the Pharmacy Practice Act, published in the December 26, 2017 issue of the *Illinois Register*, Volume 41, Issue 51 (also available through the Illinois Secretary of State). The publication of this notice began the 45-day public comment period, which will run through February 9, 2018. Persons who wish to comment on this proposed rulemaking may submit their written comments to:

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National Pharmacy Compliance News

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NABPF
National Association of Boards
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The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*, applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA’s website at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC’s *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with

prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report*, “Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015,” can be accessed on the CDC website at www.cdc.gov/mmwr/index.html in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient’s family member or close friend, which may be found in the August 2017 document, “AMA Opioid Task Force naloxone recommendations,” available on the AMA opioid microsite at <https://www.end-opioid-epidemic.org>.

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at www.fda.gov/Drugs/DrugSafety/ucm575307.htm.

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015*, found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. “Some counties have 13 pharmacies per capita, while others have none,” said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit <https://doi.org/10.1371/journal.pone.0183172>. The UIC news release is available at <https://today.uic.edu/access-to-pharmacies-limited-to-some-patients>.

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they

comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA’s website may be found at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch/report.

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Illinois Department of Financial and Professional
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For more information on the Illinois rulemaking
process, you may view this user-friendly [guide](#).

Collaborative Pharmaceutical Task Force

[Public Act 100-0497](#), the sunset reauthorization of the
Illinois Pharmacy Practice Act, created the Collaborative
Pharmaceutical Task Force to discuss and make recom-
mendations on how to further advance the practice of
pharmacy in a manner that recognizes the needs of the
health care system, patients, pharmacies, pharmacists,
and pharmacy technicians.

The task force is to include eight voting members,
including:

- ◆ One representative of a statewide organization
exclusively representing retailers, including phar-
macies;
- ◆ One retired licensed pharmacist who has previously
served on the Board and on the executive committee
of a national association representing pharmacists;
- ◆ One representative of a statewide organization
representing pharmacists;
- ◆ One representative of a statewide organization
representing unionized pharmacy employees;
- ◆ One representative of a statewide organization
representing physicians licensed to practice medi-
cine in all its branches in Illinois;
- ◆ One representative of a statewide professional
association representing pharmacists, pharmacy
technicians, pharmacy students, and others working

in or with an interest in hospital and health-system
pharmacy;

- ◆ One representative of a statewide organization
representing hospitals; and
- ◆ One representative of a statewide association
exclusively representing long-term care pharma-
cists.

Additionally, the task force is to include three
nonvoting members, including:

- ◆ One representative of the University of Illinois at
Chicago College of Pharmacy;
- ◆ One clinical pharmacist who has done ex-
tensive study in pharmacy e-prescribing and
e-discontinuation; and
- ◆ One representative of the IDFPR.

The task force will meet at least once per month
or more frequently if deemed necessary by the Task
Force Chair. The task force held its first meeting on
January 9, 2018. Future meetings are tentatively sched-
uled for the second Tuesday afternoon of each month.
If you are interested in following the work of the
Collaborative Pharmaceutical Task Force, future meet-
ing notices and agendas will be posted on the Board's
[website](#).

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