June 2019

# Iowa Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

400 SW 8th St, Suite E • Des Moines, IA 50309-4688 • Tel: 515/281-5944
Fax: 515/281-4609 • Website: *https://pharmacy.iowa.gov*

## License Verifications

The Iowa Board of Pharmacy licenses over 6,000 pharmacists, and just under 50% of those licensees are actively practicing in the state of Iowa. A pharmacist's formal education consists of a minimum of two years of undergraduate study, which is followed by three years or an equivalent of didactic study in pharmacy, and is finished off with one year of clinical rotations. Many students go on to complete a pharmacy residency.

Recently, allegations surfaced in another state that an unlicensed and untrained individual was able to fraudulently practice pharmacy by assuming the license identity of another individual who was licensed to practice pharmacy in that state.

The potential impact on public safety of an unlicensed individual practicing pharmacy cannot be overstated. The Board would like to remind its licensees that employ pharmacists, technicians, and interns to diligently verify licensure and registration with the Board prior to, and periodically throughout, employment. This can be done through the Board's website at *https://iowa.igovsolution.com/iboponline/Lookups/Lookup_Individual.aspx.* Additional steps should be taken to verify that the license or registration provided by the employee is indeed issued to that individual.

## Electronic Prescribing Mandate – January 1, 2020

In 2018, the Iowa Legislature passed legislation that will require all prescriptions, including controlled substances (CS), to be electronically prescribed by prescribers and electronically received by pharmacies, beginning on January 1, 2020.

According to Surescripts data from March 2019, Iowa's prescribers' e-prescribing activity is still well below the national averages. Of Iowa's prescribers, 66.7% (versus 73.9% nationally) are submitting electronic prescriptions to pharmacies. A total of 63.1% of Iowa's prescribers have certified and audit-approved software that is capable of transmitting electronic prescriptions for controlled substances (EPCS). Yet, only 31.6% of Iowa's prescribers have enabled this feature within their e-prescribing software (versus 34.4% nationally).

Conversely, Iowa's pharmacies are on par with the national average for the ability to receive electronic prescriptions (both are 98.4%), while the rate of EPCS-enabled pharmacies in Iowa hedges out the national averages by just over 2% (97.9% versus 95.3%, respectively).

The legislation requiring e-prescribing permitted several exceptions to the e-prescribing mandate. Prescriptions that are excluded from the mandate include:

1. A prescription for a patient residing in a nursing home, long-term care facility, correctional facility, or jail.
2. A prescription authorized by a licensed veterinarian.
3. A prescription dispensed by a United States Department of Veterans Affairs pharmacy.
4. A prescription requiring information that makes electronic submission impractical, such as complicated or lengthy directions for use or attachments.
5. A prescription for a compounded preparation containing two or more components.
6. A prescription issued in response to a public health emergency in a situation where a non-patient-specific prescription would be permitted.
7. A prescription issued pursuant to an established and valid collaborative practice agreement, standing order, or drug research protocol.
8. A prescription issued during a temporary technical or electronic failure at the practitioner's or pharmacy's location, provided that a prescription issued pursuant to this exception shall indicate on the prescription that the practitioner or pharmacy is experiencing a temporary technical or electronic failure.
9. A prescription issued in an emergency situation pursuant to federal law and regulation rules of the Board.

Additionally, a practitioner, medical group, or pharmacy that is unable to timely comply with the electronic

*continued on page 4*

# National Pharmacy Compliance News

**June 2019**

NABPF
National Association of Boards of Pharmacy Foundation

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 Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

## FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

## Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP $AWAR_XE$® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the $AWAR_XE$ program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

## New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

## FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

## FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

*continued from page 1*

prescribing requirements may petition the Board for an exemption based on economic hardship; technical limitations that the practitioner, medical group, or pharmacy cannot control; or other exceptional circumstances. The Board may grant exception requests for a period of time that may not exceed one year, which may be renewable with Board approval. Exemption petition forms and additional information regarding the e-prescribing mandate can be found on the Board's website.

After the mandate becomes effective on January 1, 2020, a pharmacist who receives a written, oral, or faxed prescription that is otherwise legitimate will not be required to verify that the prescription is subject to an exception previously listed and may dispense the prescription. However, a pharmacist must exercise professional judgment in identifying and reporting suspected violations of the e-prescribing mandate to either the Board or the appropriate professional licensing board of the practitioner.

A prescriber who violates this mandate is subject to an administrative penalty of $250 per violation, up to a maximum of $5,000 per calendar year. The administrative penalty assessed by the prescriber's primary licensing board will not be considered a disciplinary action or reported as discipline. A practitioner may appeal the assessment of the administrative penalty, which will initiate a contested case proceeding. The administrative penalties collected will be deposited into the drug information program fund to further support and enhance Iowa's prescription monitoring program (PMP).

## Updates to Rules Governing the PMP

Iowa Administrative Code 657-37, which governs the PMP, has been updated to implement various requirements identified by Iowa's "Opioid Bill" from the 2018 legislative session. The following changes became effective on May 15, 2019.

- Pharmacists who are involved in direct patient care are required to be registered with the PMP.
- The specific number of delegates allowed is removed. (It was previously capped at six.)
- Reporting any dispensing from a hospital setting is required (eg, discharge-home medications, medication dispensed from an emergency room).
- Reporting the administration or dispensing of an opioid antagonist to an emergency department patient is required.
- The administration of a CS to an emergency department patient at the discretion of the treating practitioner is required.
- Reporting the dispensing of a CS or an opioid antagonist to a patient upon discharge from a hospital or care facility is required.
- The form of transmission of a prescription origin is added as a required reporting element.
- Reporting opioid antagonist administrations by first responders is required.
- Reporting prescriber-dispensed prescriptions is required.

Exemptions include:

- medication dispensed by a licensed hospital pharmacy for the purposes of inpatient hospital care;
- medication dispensed by a licensed pharmacy for a patient residing in a long-term care or inpatient hospice facility;
- the administration by a prescriber of a CS for the purposes of outpatient procedures;
- reporting by a licensed veterinarian who administers or dispenses a CS in the normal course of the veterinarian's professional practice; and
- reporting by a Drug Enforcement Administration-registered narcotic treatment program that is subject to the record-keeping provisions of 21 Code of Federal Regulations Section 1304.24.

Mandated use of the PMP is governed by the individual practitioners' professional licensing boards. At the present time, pharmacists are encouraged but not required to utilize the PMP.

## Statewide Protocols

The Board's statewide protocols for naloxone, nicotine replacement products, and immunizations went into effect on April 5, 2019. Pharmacists acting under the statewide protocol may need to obtain a national provider identification (NPI) number in order to properly bill the prescriptions to third-party payers.

Additionally, the Iowa Legislature postponed the sunsetting of the physician-approved immunization protocols from July 1, 2019, to July 1, 2020. The legislature recognized that additional time may be necessary to ensure that Iowa Medicaid recognizes the pharmacists' NPI number on the claims being submitted for immunizations under the statewide protocol.



The *Iowa Board of Pharmacy News* is published by the Iowa Board of Pharmacy 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 Board unless expressly so stated.

Andrew Funk, PharmD - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Suhajda - Communications Manager