March 2015

Iowa Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Iowa PMP Update

As of December 31, 2014, 5,147 prescribers have registered to use the Iowa Prescription Monitoring Program (PMP) (an increase of 14.5% from one year ago) and 2,390 pharmacists have registered to use the program (an increase of 15% from one year ago). Between January 1, 2014 and December 31, 2014, a total of 239,852 requests for data were submitted to the program (an increase of 35% from one year ago). The program has registered 721 practitioner agents (an increase of 70% from one year ago). The program is continuing to reduce the incidence of patients who utilize multiple pharmacies and multiple prescribers to obtain controlled substances (CS) in Iowa. The number of patients filling prescriptions for Schedule II, III, and IV CS and utilizing five or more prescribers or pharmacists has fallen from 3,293 in 2009 to 527 in 2014 (a decrease of 84%). In the past six years, the number of doses of CS dispensed to patients in Iowa has grown by 18%, from 228,149,732 doses in 2009 to 269,466,402 doses in 2014.

An Iowa PMP Conference was held in Johnston, IA, on February 10, 2015, co-sponsored by the Iowa Board of Pharmacy and the Governor's Office of Drug Control Policy. The conference included a review and discussion of other state PMPs; a comparison of Iowa's PMP to other state PMPs; Iowa PMP success stories; the impact of the Iowa PMP on prescribing practitioners, pharmacists, and patients; and needs for the future. Recommendations as a result of the conference will be forthcoming.

Pharmacy Support Persons in Iowa

As of January 2015, there are 1,792 pharmacy support persons (PSPs) registered in Iowa. Since 2010, the number of PSPs in Iowa has grown by **140%** from 746. Each Iowa pharmacy has approximately two PSPs per pharmacy location. Board administrative rules relating to PSPs are contained in 657 Iowa Administrative Code (IAC) Chapter 5. It is important to be aware of the functions that PSPs may and may not perform in Iowa pharmacies.

Subrule 657 IAC **§5.18** provides the following tasks that PSPs **may** perform.

1. The duties of a pharmacy clerk (eg, placing prescription container into bag)
2. Processing of drug orders from wholesaler/supplier
3. Routine clerical duties (eg, filing paperwork)
4. Updating or changing patient demographic information in the pharmacy computer, excluding allergies and disease state information
5. Receiving a prescription refill request from a patient
6. Drug inventory duties, including checking for outdated drugs
7. Delivering drugs to patient care areas
8. Any routine pharmacy support function not prohibited in Subrule 657 IAC §5.17
9. Nonjudgmental tasks in a nuclear pharmacy if under the direct supervision of a nuclear pharmacist

Subrule 657 IAC **§5.17** provides the following tasks that PSPs **shall not** perform.

1. Providing the final verification for a filled prescription or medication order
2. Conducting prospective drug use review or evaluating a patient's medical record
3. Providing patient counseling or patient-specific drug information
4. Making decisions that require a pharmacist's professional judgment
5. Receiving new or refill prescription orders from prescribers or their agents
6. Providing a prescription or drug to a patient without a pharmacist's verification and in the absence of a pharmacist
7. Packaging, pouring, or placing drugs into containers for subsequent dispensing to patients, including reconstitution of oral antibiotic liquids
8. Affixing prescription labels to prescription containers for dispensing to patients
9. Processing or entering patient or prescription information into the pharmacy computer system, except as provided in Subrule §5.18(4)
10. Prepackaging or labeling multi-dose and single-dose packages of drugs, including dose picks for unit-dose cart fills in hospitals and long-term care facilities
11. Checking or inspecting drug supplies located outside of the pharmacy department
12. Reconstituting prefabricated noninjectable medications, preparing parenteral products, or compounding sterile or nonsterile drug products

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DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.*

System-Based Causes of Vaccine Errors

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.*

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter *(www.ismp.org/sc?id=307),* ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
5) Preparing and administering the vaccine immediately after verification, and
6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous

review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm*.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at *www.ptcb.org*.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at *http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full.*

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at *www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf*. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access. Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at *www.njconsumeraffairs.gov/press/05012013.pdf.*

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, *www.rxpatrol.com*, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.*

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc, of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm412431.htm*.

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13. Transferring prescriptions between pharmacies
14. Assisting with or witnessing the destruction or wastage of CS
15. Performing any of the technical duties of a pharmacy technician who is registered pursuant to 657 IAC Chapter 3

The Board's application form for registration as a pharmacy support person is available for download on the Board's website at *www.state.ia.us/ibpe/pdf/58.pdf.*

50-Year Pharmacists

The Board congratulates the following 26 Iowa pharmacists who were originally licensed in 1965, have continuously maintained their Iowa pharmacist license, and have devoted a half-century of service to the public and the profession:

- Edward P. Bean, Wayland, IA
- Maurice D. Bell, Afton, IA
- Terry M. Carley, Avoca, IA
- Larry P. Costello, Clear Lake, IA
- Gary A. Daws, Dixon, IL
- John L. Drzycimski, Cedar Rapids, IA
- Marvin T. Feidler, Phoenix, AZ
- Gerald H. Getter, Corning, IA
- Duane J. Haberichter, Oskaloosa, IA
- Charles S. Haigh, West Des Moines, IA
- Stephen G. Haigh, Des Moines, IA
- John R. Hofmann, Green Bay, WI
- Lois A. Hurst, Runnells, IA
- Corliss H. Klaassen, Chariton, IA
- David E. Johnson, Burlington, IA
- Robert S. McCaffrey, Boone, IA
- Roger D. Nichols, Prairie City, IA
- Martin N. Ogden, Olathe, KS
- Stephen E. Peterson, Bettendorf, IA
- John M. Phillips, Newton, IA
- Carl E. Rouse, Centerville, IA
- Wayne K. Ruhl, Melrose, IA
- Darrell J. Shirk, Gravois Mills, MO
- Robert P. Shores, New London, IA
- William F. Sievers, Jr, Sioux City, IA
- Roger W. Snook, Council Bluffs, IA

Board Meeting Calendar – 2015

The Board plans to hold regular meetings on the following dates at the Board office in Des Moines:

- March 9-11,
- April 28-29,
- June 23-24,
- September 1-2, and
- November 3-4, 2015.

Please contact the Board office at 515/281-5944 to confirm times and location.

Board Website

Please visit the Board's website at *www.state.ia.us/ibpe* for more information.

Board Mission

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices. Iowa Code §155A.2(1).

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