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Iowa Board of Pharmacy News

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Rules Update

The Iowa Board of Pharmacy has recently revised many of its administrative rules. A summary is provided below. Please review the rules online at *www.legis.iowa.gov/IowaLaw/AdminCode/chapterDocs.aspx?agency=657* for additional information.

1. 657 IAC: Chapters 2, 3, 5, 8, 10, 12, 17, 24, and 30 – Reduction of Licensing and Registration Fees

Rules 2.3(1), 2.6, 2.9(4), 2.11, 2.11(1), 3.10(1), 5.9(1), 5.9(2), 5.11(1), 8.35(4), 10.3, 10.3(2), 12.7(2), 17.3(2), 24.7(4), and 30.8

Initial, renewal, and penalty fees are reduced by at least 10%.

In addition, the Iowa Pharmacy Recovery Network surcharge will not be applied to pharmacists, technicians, or interns during 2013.

License Type	Previous Fee/ Revised Fee	Reduction
Pharmacy License	$150/$135	10%
Wholesaler License	$300/$270	10%
Pharmacist License	$220/$180	18%
Intern Registration	$33/$30	9%
Tech Registration	$55/$40	27%
Pharmacy Support Persons Registration	$30/$25	16%
Controlled Substance Application Registration	$100/$90	10%

Effective January 16, 2013.

2. 657 IAC: Chapter 2 – Pharmacist Licenses

Rule 2.12 Continuing education requirements

Pharmacists shall be required to register with the National Association of Boards of Pharmacy® CPE Monitor® service for the purpose of recording and maintaining evidence of continuing education (CE) activities.

Rule 2.17 Continuing professional development portfolio

Pharmacists may fulfill CE requirements for license renewal or reactivation by submission of a continuing professional development portfolio that utilizes documented learning outcomes.

The Board is offering a pilot program for 2013 renewals for those pharmacists who notify the Board by April 1, 2013. This will be available for up to 50 pharmacists.

Effective March 13, 2013.

3. 657 IAC: Chapter 6 – General Pharmacy Practice

Rule 6.2(14) Pharmacist in charge – Policies & Procedures

The duties of the pharmacist-in-charge (PIC) regarding written policies and procedures (P&P) are clarified. PIC shall ensure that all pharmacy personnel are familiar with P&Ps.

Effective January 16, 2013.

Rule 6.9(3) Transfer of prescription – Communication

Prescriptions may be transferred from one pharmacy to another via facsimile (pharmacist or intern must initiate the transfer).

The prescription transfer record shall contain certain required information.

Effective November 7, 2012.

4. 657 IAC: Chapter 7 – Hospital Pharmacy Practice

Rules 7.7 and 7.7(1) Verification by remote pharmacist

Remote pharmacist services may be provided when the pharmacy department is open to supplement on-site hospital pharmacy services. Such activities are intended to increase the availability of the hospital pharmacist for involvement in cognitive and patient care activities. Appropriate records shall be maintained.

Effective January 16, 2013.

Rule 7.11(2)"c" Outpatient services, drug administration in the outpatient setting

An outpatient medication order for administration of a Schedule II controlled substance (CS) may authorize the administration of an appropriate amount of the prescribed substance for a period not to exceed 90 days from the date ordered.

Effective September 12, 2012.

5. 657 IAC: Chapter 8 – Universal Practice Standards

Rule 8.5(4) Environment and Equipment Requirements – Remodel or Relocation – Inspection

Requirements for the remodeling or relocation of a pharmacy department are clarified, including Board notice (30 days prior) and inspection.

Effective January 16, 2013.

Rule 8.40 Pharmacy pilot or demonstration research projects

Procedures and application requirements are established. Projects shall not exceed 18 months in duration. Only projects that expand pharmaceutical care services and contribute to positive patient outcomes will be considered.

Effective November 21, 2012.

Continued on page 4

NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, *www.livertox.nih.gov*, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to 'Double Check, Don't Double Up' on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition's "Double Check, Don't Double Up" message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the *KnowYourDose.org* Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state's regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an "unexpected occurrence involving death or serious physical or psychological injury or risk thereof," and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves "Why did this happen?" until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask "Why do our systems allow these types of mistakes to happen so easily?" or "What factors set this person up to make this error?"

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer "What normally happens?"(Question 2, in the above table). The difference between "What normally happens?" and "What do the policies and procedures require?" (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. "Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a 'patient-centered' manner that best reflects how most patients seek out and understand medication instructions," as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients

misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- Emphasizing instructions and other information important to patients
- Improving readability
- Giving explicit instructions
- Including purpose for use
- Addressing limited English proficiency
- Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at *http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010*.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law "prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or $1 million." According to the Coalition for Patient Safety and Medicine Integrity, "current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips." By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at *www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf*.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards' collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP's member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies' e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.

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Continued from page 1

6. 657 IAC: Chapter 11 – Drugs in Emergency Medical Services Programs

Rules 11.4(2), 11.11(1), and 11.20(1)

The definition of "drug" is clarified to **not** include non-medicated intravenous solutions such as saline.

Required records shall be maintained for inspection. The requirements for monthly inspections of drug supplies maintained at the primary emergency medical services program site are clarified. The requirements for record keeping following the administration of a CS are clarified.

Effective November 7, 2012.

7. 657 IAC: Chapter 24 – Pharmacy Internet Sites

Rule 24.3(3) Iowa PMP

Out-of-state and Internet pharmacies that provide CS to patients in Iowa shall report such information to the Iowa Prescription Monitoring Program (PMP).

Effective January 1, 2013.

8. 657 IAC: Chapter 37 – Iowa Prescription Monitoring Program

Rules 37.2 and 37.4(1)

"Health care professional" and "practitioner's agent" are defined.

A practitioner may authorize up to three health care professionals to act as the practitioner's agent for the purpose of requesting PMP information. Agents shall register with the PMP program and may not delegate program access to other individuals.

Effective July 1, 2012.

Rules 37.2 and 37.3(3)

The definition of "dispenser" is expanded to include pharmacies located outside of Iowa that hold an Iowa nonresident pharmacy license and that dispense CS to patients in Iowa.

Reporting frequency for pharmacies is increased from twice a month to at least weekly.

Effective January 1, 2013.

9. 657 IAC: Chapter 100 – Iowa Real-Time Electronic Pseudoephedrine Tracking System

Rule 100.3(4)

Sales transactions shall be maintained when the electronic system is unavailable. Such transactions shall be entered within 72 hours of when the electronic system is again available. The definition of "law enforcement officer" is expanded to include probation and parole officers.

Effective July 18, 2012.

A Reminder Regarding Online Medical and Prescription Services

The Board has become aware that new online medical services are being offered to patients by various health care providers. Iowa pharmacists should review the following rule, which applies to these types of practices:

> **657 IAC 8.19(5)** *Legitimate purpose.* The pharmacist shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner acting in the usual course of the practitioner's professional practice. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued solely on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation and without a valid preexisting patient-practitioner relationship.

Compounding Hydroxyprogesterone Caproate

On June 15, 2012, Food and Drug Administration (FDA) issued a statement indicating it will apply its normal enforcement policies for pharmacies compounding hydroxyprogesterone caproate. In line with FDA's statement, licensees are reminded that 20 CSR 2220-2.200(9) provides:

> Compounding of drug products that are commercially available in the marketplace or that are essentially copies of commercially available Federal [Food and] Drug Administration (FDA) approved drug products is prohibited. There shall be sufficient documentation within the prescription record of the pharmacy of the specific medical need for a particular variation of a commercially available compound. Accordingly, licensees must have sufficient documentation of a specific medical need prior to compounding hydroxyprogesterone caproate in the future.

The *Iowa Board of Pharmacy News* is published by the Iowa Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, 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 the Foundation or the Board unless expressly so stated.

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TOGETHER EVERYONE ACHIEVES MORE NO SEIZURES

Working Together Patients, Providers and Pharmacists

Did You Know?

When treating seizures it is vital that the patient receives the same medication from the same manufacturer monthly in order to maintain the expected level of seizure control and side effects.*

PROVIDERS

- Indicate on prescription with “for seizures” or “for epilepsy”
- Write or indicate Dispense As Written or “DAW”
- Talk to your Patients about the importance of their medication and how all pills may not be the same

PHARMACISTS

- Note Patient’s medical condition in the pharmacy profile
- Maintain the Patient on the same manufacturer when possible
- Notify the Patient and Provider when a manufacturer change may need to be made

PATIENTS

- Notify your Provider of unusual seizure activity or breakthrough seizures
- Know the manufacturers of your medications. If your medications look different, talk to your Pharmacist before taking it
- Don’t wait until you are out of your medication to pick up or request a refill, this allows the necessary time for your Pharmacist to ensure your medications are in stock

Brought to you by the **Iowa Epilepsy Treatment & Education Task Force** working together Patients, Providers and Pharmacists towards the goal of no more seizures.

* Information came from http://www.NoMoreSeizures.org
For task force information or to print more flyers please go to http://www.idph.state.ia.us/CDPM/ETFI.aspx
For questions or additional information please email efiowa@efncil.org