



Oregon State Board of Pharmacy

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No. 514: Report Address Change or Change of Employment

The renewal cycle for pharmacists is just around the corner. Your electronic renewal application must be completed by May 31, 2013. If your renewal is submitted after May 31, you will be assessed a \$50 delinquent fee.

Please be sure that your current correct home address and workplace are on file with the Oregon State Board of Pharmacy before completing your renewal. If you have changed your address or workplace in the past year since your last renewal, please make sure you have updated your records for the Board's file. According to OAR 855-019-0205(7), a pharmacist must notify the Board in writing within 15 days of any change in employment location or residence address.

Similarly, if you have changed your name, please make sure that you have provided the legal documents with a name change request to the Board in plenty of time to get the name changed on the new license.

No. 515: Board Amends Rules

The Board held a public rules hearing on November 29, 2012, to provide an opportunity for public comment on several rule amendments under OAR Chapter 855 that had been proposed for adoption. During the hearing, no public testimony was presented. Throughout the public comment period, no written comments were received from the public. During its regularly scheduled meeting on December 12, 2012, the Board voted to adopt the rules as they were presented at the hearing. These rules took effect upon filing in December 2012. Following is a brief summary of the rules.

OAR Chapter 855, Division 041 – Drug Outlets: The rule amendments reorganize and renumber Division 041. Some rules are repealed because they are old and outdated. In addition, other rules have been amended to provide greater clarity and consistency with federal regulations. Amendments also change the lifespan of a non-controlled substance prescription from two years back to one year.

Division 041 – Emergency Department Distribution: These rule amendments update labeling and record keeping requirements. Also, some new rules are being adopted that establish specific requirements for the use of automated dispensing machines within the emergency department.

Division 065 – Pharmaceutical Wholesaler Definition: This rule amendment modifies the definition of Class II Wholesaler to include Oxygen USP and other medical gases.

Division 110 – Fees: This new rule establishes a permanent annual licensing fee of \$300 and delinquent fee of \$75 for supervising physician dispensing outlets.

The actual text of these new and amended rules can be found on the Board's Web site at www.pharmacy.state.or.us under "What's Hot: Certificate of Permanent Rulemaking."

No. 516: Duty to Cooperate

At a recent Board meeting, several Board members observed that they have been seeing an increase in the number of cases that involve dishonesty and a lack of cooperation with the Board's investigations. The Board is required by law to investigate every consumer complaint it receives. It is the Board's expectation that licensees will be truthful with the Board and will fully cooperate with the inspectors during an investigation.

OAR 855-001-0035 Duty to Cooperate states, "Every licensee and registrant of the Board shall cooperate with the Board and shall respond fully and truthfully to inquiries from and comply with any requests from the Board, subject only to the exercise of any applicable right or privilege." It is your responsibility as a licensee of the Board to cooperate and be truthful with the Board when completing applications or responding to questions during an investigation. If you are asked to respond to questions or allegations during a Board investigation, it is imperative that you answer truthfully and as completely and thoroughly as possible. Furnishing untruthful or incomplete responses to these questions may be considered by the Board as failure to cooperate, which could result in disciplinary action.

No. 517: Duty to Report

The Board has suggested it is time to revisit and review pharmacists' and pharmacy technicians' duty to report suspected violations. Sometimes referred to as the "Snitch Rule," the duty to report is actually a statute, **ORS 689.445 Report of suspected violations; liability for reporting; confidentiality of report.** This law states:

- ◆ A pharmacist or pharmacy technician shall report to the State Board of Pharmacy any suspected violations of this chapter (ORS Chapter 689) or of ORS 4475.005 to 475.285 and 475.940 to 475.999.



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



Compliance News to a particular state or jurisdiction should not be assumed (regarding the law of such state or jurisdiction.)

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.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and
Register for CPE Monitor Today!

CPE Monitor™ integration is underway. Most Accreditation Council for Pharmacy Education (ACPE)-accredited providers should now be requiring you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity.

Visit www.MyCPEmonitor.net to set up your e-Profile, obtain your e-profile ID, and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

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- ◆ Any pharmacist or pharmacy technician who reports to the board as required by subsection (1) of this section in good faith shall not be subject to an action for civil damages as a result thereof.
- ◆ Any information that the board obtains pursuant to ORS 689.405 or 689.445 or this section is confidential as provided under ORS 676.175.

ORS Chapter 475 referred to in the first bullet point is the Oregon Uniform Controlled Substances Act.

ORS Chapter 676 referred to in the last bullet point relates to “Health Professions Generally” and details the issues around complaints and disciplinary action against health care professionals. **ORS 676.070 Immunity of information providers states**, “A person who reports or supplies information in good faith to a health professional regulatory board or to a committee reporting to a health professional regulatory board shall be immune from an action for civil damages as a result thereof.”

These statutes can be found on the Board Web site under “Quick Links: Laws & Rules.” All pharmacists and pharmacy technicians should be familiar with them.

No. 518: Pharmacist-in-Charge Training Class

The Board began offering a pharmacist-in-charge (PIC) training course in September 2007. Since then, 1,135 pharmacists have taken the three-hour course. It is being attended by pharmacists newly assigned to a PIC position, new pharmacists who want to be prepared in the event they get a PIC position, and experienced pharmacists who are or have been in the PIC position. Even though the duties of a PIC are spelled out in OAR 855-019-0300, many pharmacists find themselves in the position but are not entirely prepared to take on the PIC duties confidently and competently. This course is an excellent starting point or refresher for anybody in the position of PIC. You can share your experiences and hear first-hand experiences from other pharmacists and the Board inspectors. The course lasts about three hours and you can obtain three hours of continuing education including one hour of law, one hour of patient safety/medication error prevention, and one hour of “other.”

The regular course is held in the Board conference room and is limited to 15 participants in order to facilitate more effective dialogue among the inspectors and participants. It is also being offered at the Oregon State Pharmacy Association Annual

Convention. It has been taken to the pharmacy schools at both Oregon State and Pacific Universities for pharmacy students who are near graduation. The inspectors facilitate a review and discussion of the PIC responsibilities, other rules, and the PIC self-inspection form. As time allows, they also review current Board issues and common compliance questions. The course provides a forum for questions and answers as well as discussions about best practices and standards of pharmacy practice. If you are interested in attending one of these classes, contact the Board’s compliance office to reserve a seat. You can check the Board’s Web site for the date, time, and place for the next upcoming class. And, best of all, there is no cost for the class beyond your commitment of time and attention.

No. 519: New Inspector Joins Compliance Staff

Inspector Jennifer Zanon left the compliance staff in 2011 to take her current position with the Oregon Health & Science University. Following a broad recruitment effort, the Board hired pharmacist Fiona Karbowicz. Fiona comes with an extensive background in community pharmacy practice. She graduated from the University of Connecticut in 1997 and worked at independent pharmacies in Connecticut prior to relocating to Oregon. She also worked at Walgreen’s for 13 years. Inspector Karbowicz has been with the Board since March 2011. She has taken on her duties with enthusiasm, and she possesses the curiosity and attention to detail that is so important to an investigator. Besides doing inspections, investigations, and consulting, Fiona is being assigned a variety of other projects such as research, rule writing, and acting as a preceptor for the Board’s pharmacy interns. She recently attended Drug Enforcement Administration’s Annual Conference on Chemical and Drug Diversion in November 2012. When she is not working, Fiona enjoys skiing and spending leisure time with her family on the slopes of Mt Hood.

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Gary A. Schnabel, RN, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor
Larissa Doucette - Communications Manager

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1600 Fehanhville Drive
Mount Prospect, IL 60056
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