

Oregon State Board of Pharmacy

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No. 447: As I See It

By Bernie Foster, Public Member, Oregon State Board of Pharmacy

The Oregon State Board of Pharmacy may look different next year. Changes have been discussed that could alter the makeup of the Board and the disciplinary procedures for pharmacists. For the past five years as a public member, I have had the privilege of representing ordinary Oregon citizens on the Board, and I would like to thank the Board for allowing me to share my views with you – Oregon pharmacists. I do not intend to represent the Board of Pharmacy as a whole here. This is simply the way I see it.

In light of these discussions in Salem, I wonder, “Where is the Oregon State Pharmacy Association, and where are the other pharmacy organizations on these issues?” Pharmacists who care about their profession and about the public safety should be concerned. Why? Because the Board of Pharmacy has a highly successful disciplinary program that should not be undermined by short sighted politicians dreaming of “one size fits all” regulatory programs for the health professions.

The Board of Pharmacy sees about eight or nine cases a year involving pharmacists and unprofessional conduct for drug abuse. Violations range from being under the influence of alcohol or drugs while dispensing prescriptions, to abusing drugs, such as Vicodin[®]. I do not need to dwell on the obvious danger this represents to the public. That is why, under our current system, the offending pharmacists are immediately taken off the job and disciplinary procedures begin. Here is how it works.

The first step for an addicted or chemically dependent pharmacist is a meeting with the state’s Pharmacy Recovery Network (PRN), followed by a full and independent drug and alcohol evaluation. Next, any pharmacist determined eligible by the evaluation who wants to keep his or her license must sign a five-year stringent monitoring contract which typically includes:

- ◆ No return to work until approved by the Board of Pharmacy, PRN, and the rehabilitation counselor;
- ◆ Completion of a 30- to 90-day residential treatment program, targeted to professionals, such as Serenity Lane or Hazelden Springbrook;
- ◆ Follow-up treatment sessions at least three times a week for three months – after that the meetings gradually decrease in frequency over time, providing the pharmacist remains clean and sober;
- ◆ Alcoholics Anonymous or Narcotics Anonymous or other approved self-help meetings four times a week for the first year then three times a week; and
- ◆ 30 random urine tests a year for the first two years, then 24 a year for three years or longer.

These are just highlights from a rigorous program that reports an 85% success rate. The program is in line with other rehabilitation programs across the nation. Pharmacists who enter the PRN program pay for the treatment and for the urine tests. If, at any time, the PRN monitor is concerned, the pharmacist may be taken out of the workplace. The PRN monitor makes decisions under the supervision of an independent five-person Supervisory Council.

The Board of Pharmacy makes decisions about restoring or revoking licenses with recommendations from PRN, but the Board is not bound to follow these recommendations. On occasion the Board has revoked a license, even when PRN has recommended continuing to work with a pharmacist. If a pharmacist in the program relapses, and some do, they must start the entire process again from the beginning.

Why do we want to give pharmacists a chance to rehabilitate themselves? Pharmacy training is expensive and pharmacists are valuable professionals. This system prevents unnecessary waste of important health care workforce resources while maintaining public safety.

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FDA Web Site Upgrades Support MedWatch's Patient Safety Goal

Two recently launched additions to the Food and Drug Administration's (FDA) Web site are intended to support the "Patient Safety" goal that MedWatch shares in public health efforts to protect patients from serious harm and improve outcomes. The entry pages assist health care professionals and patients to locate timely safety information for FDA-regulated human medical products and assist them in making diagnostic and therapeutic decisions.

The content and links on the new FDA entry page specifically for health care professionals allows busy doctors, pharmacists, nurses, and other health care professionals to find information to make point-of-care decisions. There is information that is specifically safety-related, such as easy access to reporting adverse events or finding new safety alerts, warnings, and recalls. Users can also find content regarding new approvals information, or access to the current version of the label, or prescribing information in "DailyMed." This page can be accessed through www.fda.gov/healthprofessionals.

FDA's other new page is specifically for patients and provides two patient-friendly articles about reporting adverse events and product quality problems to FDA and to the patient's caregivers. These articles are also available to pharmacists in printer-friendly PDF versions that can be downloaded and distributed to patients. FDA relies on properly and timely reporting of serious and unexpected drug and device-related adverse events, use errors, and quality problems. Pharmacists can ascertain and teach their patients to understand the "what, why, and how" to report to FDA and also learn about what happens to each received report and whether it leads to FDA action that may make product use safer for both patients and providers. FDA's patient specific page can be found at www.fda.gov/consumer/default.htm.

Retail Pharmacies Now Providing Medical Clinics to Improve Public Safety



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with USP and FDA in analyzing 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 recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**® Community/Ambulatory Edition by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 200 Lakeside Dr;

Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Retail pharmacy corporations have set up medical clinics within pharmacies. These nurse-practitioner or physician-assistant run clinics aim to rapidly diagnose and treat a limited number of health problems. Many also offer vaccination programs. The first pharmacy-based medical clinics were opened in Minnesota as QuickMedx in 2000, later becoming MinuteClinic in 2002. Currently there are approximately 1,000 sites in 37 states representing almost three million cumulative visits.

The emergence of pharmacy-based medical clinics offers a unique set of opportunities to improve the safety in prescribing and dispensing medications. Do you have a clinic opening in your store? If so, consider these safety recommendations:

- ◆ Meet the nurse practitioners and physician assistants and introduce them to your staff. Show them how your operation works and invite them in for a tour.
- ◆ If you have prescription scanning capabilities, show them how a scanned prescription displays on your monitor. Show them how different prescription blanks scan (eg, colored prescription blanks, blanks with water marks or seals for diversion) and what to avoid using so as not to distort the actual order.
- ◆ If they are using a device that allows them to send prescriptions electronically, have them send test prescriptions to you, invite them in to see how their prescriptions display on your computer and send them back test refill requests.
- ◆ Work together on any issues that arise, such as conflicting directions and special instructions, where the automatic sig indicates one set of patient directions and then the free text special instructions contradict the sig (see image below).

R Sig:	LORAZEPAM 0.5MG TABLET 1 Tablet(s) PO Q6-8H PRN anxiety, insomnia x 30 days
Dispense:	90 Tablet(s)
Special Instructions:	Take one tab as needed for anxiety or insomnia, may repeat x1.
Refills:	5
Signature:	_____

- ◆ Ask prescribers to include the indication for use whenever they write or call in a prescription.
- ◆ Educate them that it is your policy to read back the entire prescription order to them after transcribing it in the pharmacy including spelling the medication name. Let them know you will be using "cock-pit" language, for example, "one six" for "16."
- ◆ Ask them to include both the generic and brand names on all written orders for medications with look-alike and/or sound-alike names.
- ◆ Share with them ISMP safety tools (eg, List of Error Prone Abbreviations, List of Confused Drug Names) found at www.ismp.org/Tools.



- ◆ Let them know you will dispense measuring devices every time they order a liquid medication.
- ◆ Let them know that safety is your priority when filling prescriptions, and invite them to be part of your safety team.

FDA Launches Web Sites on Promotion of Medical Products

On September 3, 2008, FDA launched two new Web sites to provide information for consumers and industry about how FDA regulates the promotion of medical products. Pharmacists can obtain useful information regarding prescription drug advertising regulations as well as refer their patients who may have questions to the site.

The "Advertising Prescription Drugs and Medical Devices" Web site provides a "one-stop shop" portal to information on FDA regulation of medical product promotion. Pharmacists access relevant laws, regulations, and guidances. This site can be found at www.fda.gov/oc/promotion/.

The direct-to-consumer Web site, "Be Smart about Prescription Drug Advertising: A Guide for Consumers" is designed to educate consumers about how to view such advertising to help inform their discussions with health care providers, and consequently to help improve patient's understanding and medical care. This site was created in collaboration with EthicAd, an independent, nonprofit organization dedicated to helping consumers, health care professionals, and the pharmaceutical and advertising industries with direct-to-consumer advertising for prescription drugs. More information can be found at www.ethicad.org.

The direct-to-consumer site provides interactive example ads for fictitious drugs to illustrate the different requirements for the various types of ads. It also includes a list of questions patients should ask themselves when they see a prescription drug ad. This list can be printed for patients to use while discussing questions with their health care providers. This site can be found at www.fda.gov/cder/ethicad/index.htm.

FPGEE Returns to Computer-based Format

As advancements in secure testing technology forge ahead, the push for more electronically based systems and less use of the traditional paper-and-pencil mechanisms continues. With this in mind, NABP will soon be returning the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) to a computer-based format, eliminating the paper-and-pencil examination.

The FPGEE is the third computerized examination to be developed by NABP, after the North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®). The new computerized FPGEE will debut at the April 14, 2009 administration.

The computerized FPGEE examination will continue to be administered one day in the spring and one day in the fall; however, instead of limiting the available testing locations to three sites, applicants will be able to choose from more than

200 Pearson VUE testing sites located within the continental United States. In addition, it is anticipated that applicants will be able to schedule their test sites electronically 48 to 72 hours after having been accepted to take the FPGEE.

The NABP test vendor, Pearson VUE, will administer the computerized FPGEE as it does with the NAPLEX and the MPJE. Demonstrating a record of solid customer service combined with a secure and consistent test center network, Pearson VUE is committed to providing a reliable and professional testing environment for applicants on behalf of NABP.

The FPGEE is one component of the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certification process. In addition to passing the examination, FPGEC applicants are required to have certain documents submitted from educational and licensure institutions that present their educational backgrounds and licensure and/or registration to practice pharmacy. Applicants must also pass the Test of English as a Foreign Language™ (TOEFL®) and the Test of Spoken English™ (TSE®), or the TOEFL Internet-based Test (iBT). The FPGEC certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the 50 United States and the District of Columbia where the certification is recognized.

To prepare for the FPGEE, NABP recommends that applicants take the Pre-FPGEE®, the official FPGEE practice examination written and developed by NABP. This practice examination is designed to help familiarize applicants with the FPGEE by exhibiting the types of questions provided on the actual examination as well as providing a score estimate.

Additional information on the FPGEE as well as the Pre-FPGEE is available in the Examination Programs section on the NABP Web site at www.nabp.net.

Updated 2009 Survey of Pharmacy Law Now Available

The NABP 2009 *Survey of Pharmacy Law*, providing a concise research source for key regulatory questions in pharmacy practice for all 50 states, the District of Columbia, and Puerto Rico, is now available.

The *Survey* updates, graciously provided by the state boards of pharmacy, consist of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Also, a new question in Section VII, "Issuance of Initial Pharmacist Licensure," asks whether or not states require criminal history record checks for initial licensure as a pharmacist.

To order the *Survey*, visit the NABP Web site at www.nabp.net and download an order form; the *Survey* costs \$20.

All final-year pharmacy students receive the CD-ROM free of charge through the generous sponsorship of Purdue Pharma LP.

More information on the *Survey* is available by contacting customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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What is more, in my view the current system works. It is rigorous yet responsive. It protects the public, yet it allows for rehabilitation. As part of the treatment team, the monitor works confidentially with pharmacists, but reports to the Supervisory Council or the Board when relapses or relapse behaviors occur. The way I see it, a “one size fits all” program would be a loss for pharmacists and the public across our state.

Other discussions that floated around the state capitol during the interim recommend changing the makeup of the Board of Pharmacy, along with the other health professional regulatory boards. Bills have not yet been drafted as of this writing, so it is not clear which proposals will become bills and actually make their way to the legislative committees. One recommendation would maintain the Board of Pharmacy as a seven-member board but would increase the number of public members from two to three, and decrease the number of pharmacists from five to four. I believe this would be a mistake.

Lay members can, and do, make useful contributions. However, when it comes to discussions about drug regulation, pharmacy education, and many other technical areas that we cover, I am frequently awestruck by the depth and breadth of the knowledge and understanding displayed by the pharmacists on the Board. I do not think the Board should be weakened by diluting it with fewer expert members. I am all for democracy, but after all it is the Board of Pharmacy, so pharmacists should guide its work.

During my tenure the Board has worked on issues that affect all of you in your day-to-day work, such as licensing requirements, professional standards, pain relief rules, and disciplinary actions. And I am sure you already know that the Board of Pharmacy championed the law requiring prescriptions for pseudoephedrine medications – a law that has played a key role in reducing methamphetamine manufacture and abuse across the state.

For the last six years the Board has been working with the legislature to:

- ◆ Create a controlled substance prescription monitoring program so that drug seekers will not be able to present multiple prescriptions from multiple medical providers
- ◆ Regulate Internet prescriptions

Similar measures have been successfully adopted in other states, and the Board works hard to ensure Oregon standards keep pace.

Lastly, I have been surprised that more of you do not bring your concerns to our public meetings. Everyone knows what happens to the squeaky wheel – so come along and make your voices heard.

And that's the way I see it.

No. 448: License Fee Increases Proposed for 2009-2011 Budget

License fee increases are being considered for several of the Board's license categories for the upcoming 2009-2011 budget cycle. No one is fond of the idea of imposing increased fees on licensees but the truth is that the Board of Pharmacy's operating revenue comes solely from its licensees and registrants. It receives no funding from the state. Predictably, as expectations and expenses increase over the years, fixed revenues eventually are unable to support a balanced budget for agency operation. The long-term plan is to implement increases for the selected categories this session and for others, including pharmaceutical wholesalers and manufacturers, during the 2011-2013 legislative session.

To put this into perspective, the last time any fees were increased was 2001. At that time, annual fees were raised for pharmacists, pharmacies, pharmacy technicians, pharmaceutical wholesalers, and pharmaceutical manufacturers. To put it in an even broader perspective, the previous fee increase for pharmacists occurred in 1989. The current proposed fee increase would be their second in **20 years**. For pharmacies, the previous increase occurred in 1980 making this only their second increase in **29 years**. By the time the manufacturer and wholesaler increases are proposed in 2011-2013, it will be only their second increase in over **30 years**. By all standards, that is a commendable track record for any state agency.

The proposed fee increases are being presented to the legislature as part of the governor's recommended budget. Assuming the Joint Ways & Means Committee approves and the legislature adopts the budget, the increases will be phased in over the two-year budget cycle. The proposed annual fees are as follows: pharmacist, \$175; pharmacy, \$300; pharmacy technician, \$50; controlled substance registration, \$100; and reciprocity, \$300. The intent, as was the case in 2001, is to spread the increases over as many license categories as possible to lessen the burden on any one category.

No. 449: Board of Pharmacy Appointment

On July 1, 2009, a vacancy will exist on the Board of Pharmacy for a pharmacist member. Cathryn Lew, who has been a Board member since 2001, will complete her second and final four-year term on June 30, 2009. The Board, by law, is composed of seven members including five pharmacists and two public members who are not pharmacists. Members are appointed by the governor and confirmed by the state Senate to serve a four-year term on the Board, and may be reappointed for a second four-year term. No Board member may serve more than two consecutive full terms.

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To qualify for the pharmacist member position on the Board a person must, at the time of appointment, be an Oregon resident, be licensed in good standing to practice pharmacy in the state, be engaged in the practice of pharmacy in the state and have five years' experience in the practice of pharmacy in the state after licensure.

Under Oregon Law, ORS 689.115, the Oregon State Pharmacy Association (OSPA) may assemble a task force to develop and provide a list of five nominations for recommendation to the governor. If you are qualified and interested in being considered for a position on the Board, you may contact OSPA or contact the Governor's Office of Executive Appointments directly. For information on the governor's boards and commissions, interest forms, and instructions, visit the governor's Web site at www.oregon.gov/Gov/boards.shtml.

No. 450: Duty to Report

Following its December meeting, the Board suggested it is time to revisit and review the pharmacist's and pharmacy technician's duty to report suspected violations. Sometimes referred to as the "snitch rule," the duty to report is described in ORS Chapter 689, of the *Oregon Pharmacy Act*. **ORS 689.455 Report of suspected violations; liability for reporting; confidentiality of report** states:

- (1) A pharmacist or pharmacy technician shall report to the State Board of Pharmacy any suspected violations of this chapter or of ORS 475.005 to 475.285 and 475.940 to 475.999.
- (2) 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.
- (3) 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 section 1 is the *Oregon Uniform Controlled Substances Act*. ORS Chapter 676 referred to in section 3 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 state of Oregon Web site at www.oregon.gov/ under the Government/State Government section, State Laws and Regulations. All pharmacists and pharmacy technicians should be familiar with them.

No. 451: Adult Prescription Dispensed to Four Year Old

A recent complaint that resulted in a case being presented to the Board illustrates a common break down in the most basic principles of pharmacy practice. Case No. 08-0400 begins with a mother presenting a prescription for an otic suspension for her four-year-old child and requesting a refill of her husband's Ambien® prescription. The technician correctly entered the child's prescription into the computer, entered a new prescription for Concerta® for another person under the child's name and failed to enter the Ambien refill. The Concerta prescription had come from the same medical clinic and had been placed in the technician's inbox. The pharmacist who checked the technician's work did not detect the error.

Circumstances leading to the error include the fact that both new prescriptions, each intended for a different person, were put into an inbox together, and the fact that these were electronically generated prescriptions from the same clinic that were all identical in appearance. The breakdown began when the technician failed to read and enter the appropriate name on each prescription. It continued when the pharmacist failed to compare the name printed on each label with the name printed on each electronic prescriptions. The cascading error was completed when the pharmacist failed to perform the required drug utilization review and to provide adequate counseling, which should have led to the discovery that one adult prescription had been erroneously prepared and labeled for a child and was bagged for and dispensed to another adult. No injury resulted to either the child or his father since the father discovered the error at home before any doses were taken.

What can be learned from this case? It is this. There is no substitute for vigilance. There is no substitute for dispensing procedures that focus attention on these basics. Remember to:

1. read the patient's name;
2. compare the label with the prescription;
3. perform your DUR (review the appropriateness of each prescription for each patient);
4. do your counseling; and
5. do not let this happen to you or one of your patients!

No. 452: Oregon's First Accredited Compounding Pharmacy

The Pharmacy Compounding Accreditation Board (PCAB) notified the Board of Pharmacy that it has provided accreditation status to Broadway Apothecary, located at 1712 Willamette Street in Eugene. The pharmacy was reviewed and accredited in July 2008 and is the first in the state to become PCAB-accredited. PCAB

is a voluntary accreditation body formed by pharmacy organizations to establish high quality standards for compounding pharmacies.

No. 453: Board Adopts Position Statement on Patient Safety

The Board expects all pharmacists and pharmacy technicians to engage in practices that provide appropriate, accurate, and professional patient care and ensure patient safety. All pharmacies should take proactive measures to prevent errors and adopt a “culture of safety,” which provides for sharing of information to promote best practices.

At its October 15, 2008 meeting in Eugene, the Board adopted a position statement, *Optimizing Patient Safety and Reducing Medication Errors in Oregon*. This new position statement includes “Recommendations for Optimizing Patient Safety and Reducing Medication Errors,” a 23-point document that was developed by the Board’s Research Council and is based on a review of current literature and work done in other states. The recommendations have been modified and edited specifically for use in Oregon pharmacies.

While the document is not intended to be a comprehensive list of goals that are completely achievable on a continual basis, it does suggest a number of specific procedures that can be implemented in pharmacy practice settings in an effort to enhance existing quality improvement programs. This list is not exclusive of other improvements and may be supplemented by the Board from time to time.

It is the Board’s position that all pharmacies and pharmacists should review these recommendations as a high priority and should consider implementation of those measures that are appropriate to the particular pharmacy setting. The Board believes that adoption

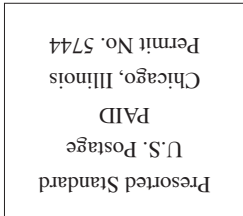
and institution of these practices will lead to optimal patient safety through enhanced pharmacy medication dispensing systems, improved performance generally and, ultimately, a significant reduction in medication errors.

The Board would like to acknowledge the work done by the National Association of Boards of Pharmacy® 2007-08 Task Force on Continuous Quality Improvement, Peer Review, and Inspecting for Patient Safety, the Massachusetts Board of Registration in Pharmacy, and the Institute for Safe Medication Practices.

Please take time to familiarize yourself and others with these recommendations. The position statement and the 23-point document, as well as other position statements adopted by the Board, can be found on the Board’s Web site at www.pharmacy.state.or.us/Pharmacy/Position_Statements.shtml.

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OREGON STATE BOARD OF PHARMACY
National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056