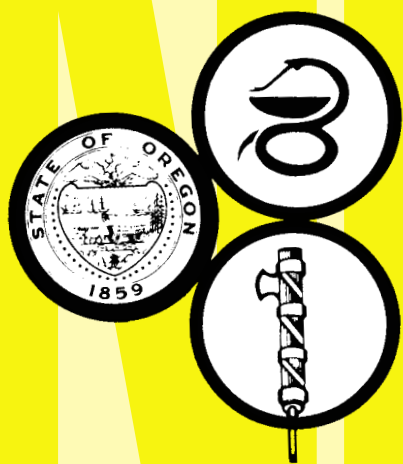


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NEWS

Oregon State Board of Pharmacy

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No. 373: Restrictions on Pseudoephedrine Sales

On October 13, 2004, the Oregon State Board of Pharmacy adopted a temporary rule that restricted the sale of pseudoephedrine (PE) products. This rule required that products which have PE as the sole active ingredient may be sold only from behind the pharmacy counter. The rule also required that PE combination products may be sold by a pharmacy or a non-prescription drug outlet from behind the counter. Liquid and gel cap PE products are exempt from the rule and may be sold by a pharmacy or non-prescription drug outlet.

This step was taken by the Board at the request of Governor Ted Kulongoski, who made a personal appearance before the Board to present the recent findings and recommendations of his Methamphetamine Task Force. He described what he believed to be emergency conditions caused by the proliferation of clandestine methamphetamine manufacturing labs in neighborhoods throughout the state and asked the Board to adopt emergency rules to restrict the sale of PE in a manner similar to the restrictions recently adopted by the state of Oklahoma.

The temporary rule has a life span of 180 days and will expire on May 13, 2005. Since the adoption of the temporary emergency rule, the Board convened a task force to study the issue and develop language for a permanent rule regarding the sale of PE. This task force provided a recommendation and the Board adopted a permanent rule through the normal rule making process including written notice, comment period, and public hearing.

Under the new permanent rule, both single entity and combination PE products are restricted to sale only from the pharmacy counter. Liquid and gel cap products remain exempt from the restrictions and may still be sold by a non-prescription drug outlet. The pharmacy must require the purchaser of PE products in the tablet or capsule form to produce a valid photo identification (ID) issued by a government or school and must keep a log, either electronically or in hard copy form, containing specific information. The log must include the purchaser's name, driver's license or other ID number, date of birth, and the amount purchased. The ID and log requirements do not apply to the sale or transfer of a PE product pursuant to a valid prescription.

The permanent rule becomes effective on May 14, 2005. A period of time has been designated to allow retailers to take the

necessary steps to come into compliance before enforcement action will be taken. Enforcement of the rule will begin on July 16, 2005. Check the Board of Pharmacy's Web site for more details.

No. 374: Oregon Death With Dignity Act – Pharmacist Reporting Requirement

The August 2003 edition of this *Newsletter* contained an article about the Death With Dignity Act. This article made reference to the requirement for pharmacists who dispense prescriptions pursuant to the Act. An article appeared in the *Newsletter* in 1999 that provided details about how to file the pharmacy dispensing report. The process for submitting that report has changed slightly since 1999. Information on physician-assisted suicide and a downloadable pharmacy reporting form can be found on the Oregon Department of Human Services Web site at <http://egov.oregon.gov/DHS/ph/pas/pasforms.shtml>. Any pharmacist who dispenses a prescription pursuant to the Act is required to complete this report and send it to Oregon Health Services, Center for Health Statistics, PO Box 14050, Portland, OR 97293-0050.

No. 375: Gaps Between PIC Appointments

The compliance staff has noticed an increase in the number of cases in which a pharmacy has been without a designated pharmacist-in-charge (PIC) for a period of time. OAR 855-041-0020 requires that a change in PIC at the pharmacy must be reported to the Board within 15 days. This is a time window for reporting the change, not for making the change. No provision exists for a time lag between the old and new PIC. The Board believes that the PIC requirement is very important for continuity, accountability, and security within the pharmacy.

The rule also states that a pharmacist may serve as the PIC for up to two pharmacies and requires that any pharmacist designated as the PIC in more than one pharmacy is required to personally conduct and document a monthly compliance audit. A pharmacist may apply to the Board for approval to serve as PIC for more than two pharmacies by submitting in writing a detailed implementation plan that includes, at a minimum, a monthly compliance audit report form, geographic area covered by the PIC, address of the pharmacies, hours dedicated to PIC duties at each location, and hours dedicated to dispensing and other duties. This represents the Board's more liberal view on the PIC responsibilities and expectations for pharmacy manage-

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Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretinoin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.



Metronidazole and Metformin: Names Too Close for Comfort

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (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, then publishes its recommendations. 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: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®



(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association (JAMA)* published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at <http://www.connectlive.com/events/genericdrugs/>.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

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ment. This expanded view of the PIC's responsibility increases the importance of having a designated PIC at all times. Each day a pharmacy opens for business without a designated PIC is a violation of the rule and the pharmacy could be subject to disciplinary action by the Board.

No. 376: More Staff Changes in the Board Office

The Board continues to add and subtract names as it attempts to stabilize its staffing. Currently, two vacancies exist in the Compliance section for healthcare investigator/pharmacist positions. Recruiting has been under way since the departure of pharmacist Larry Martin, the former chief inspector who left after 14 years with the Board. More recent vacancies have occurred with the departure of pharmacists Paul Mattson, who left after 10 years as a pharmacy inspector, and Gregg Hyman, who left after two and a half years as a pharmacy inspector.

Reorganization of the Compliance staff is nearly complete. Inspector Gary Miner has accepted the position of compliance director and is undergoing an accelerated orientation and training schedule. Inspector Joe Ball is now the chief investigator, which is a version of the former chief inspector title that has been rewritten to more appropriately reflect the responsibilities of the position.

Pharmacist Mike Beck started as healthcare investigator/pharmacist in February. He is undergoing an orientation and training program and it is anticipated he will be spending the majority of his time on the road getting inspections caught up. Mike lives in Corvallis and has a background in compounding and retail pharmacy.

No. 377: Help For Patients Without Health Insurance

If you have or know of patients who do not have health insurance, a program exists that might be able to provide help. Patients without health insurance can be referred to the state's Family Health Insurance Assistance Program (FHIAP). FHIAP pays 50% to 95% of monthly premiums for eligible Oregonians so that they can afford to purchase private health insurance. Applicants must be uninsured for six months, not counting Oregon

Health Plan coverage, and they must meet income, residence, and citizenship guidelines. For information call 1-888/564-9669. The agency will provide FHIAP brochures and brochure stands to pharmacies that request them.

No. 378: New CE Program Approval Form

A new form to request approval for continuing education (CE) programs has been developed to reflect the provisions of new rules adopted in 2004. The new form is available to view and download from the Board's Web site. Please use the new form if you are applying for approval for CE programs.

No. 379: New Phone, Fax, and Look for Web Site

The state is consolidating agency telephone systems and the Board of Pharmacy office is the first to be upgraded. Our old numbers will forward for the next few months. Our new phone number is 971/673-0001 and our new fax number is 971/673-0002. Please make a note.

If you have accessed the Board's Web site recently you have noticed a new look. The Web site address has not changed (www.pharmacy.state.or.us), but the appearance and content have been upgraded. Check it out and let us know if you have comments or suggestions.

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