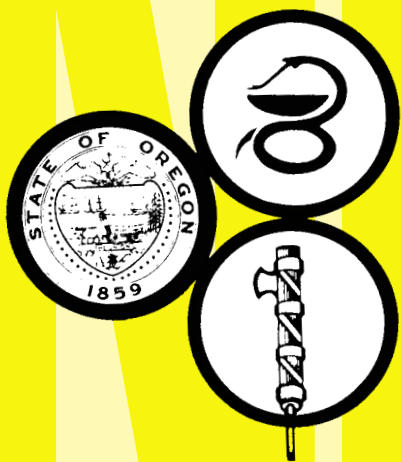


February 2005



Oregon State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

No. 369: Pharmacist License Fee During Military Service

During the past several years, a number of Oregon-based military units have been called to active duty for deployment to the Middle East or other areas of the world in support of the war on terrorism. Oregon law makes provisions for deferment of professional license fees under certain conditions for individuals called to active duty in the military service. The Oregon State Board of Pharmacy is aware that Oregon pharmacists have been deployed and might be eligible for license fee deferment.

ORS 408.450 states:

No person in the military or naval service of the United States, or any auxiliary corps thereof [sic], while exercising any privilege in this state by virtue of having paid an annual license of privilege fee to any state board or commission for the right to practice a profession or engage in a trade, shall lose such privilege because of failure to pay any such fee for any subsequent year during the period the person is in such service, unless dishonorably discharged there from. Upon being discharged from such service under honorable conditions and upon written application within 60 days of such discharge, every such person shall be restored to former status with respect to any such privilege without the necessity of paying the then current license fee.

The Board's licensing staff has confirmed with legal counsel for the Oregon Department of Veterans' Affairs that this law applies to individuals in the United States Army, Air Force, Navy, Marine Corps, Coast Guard, or their Auxiliary Corps. It also applies to National Guard and Reserve members called to active duty. It does not apply to anyone employed within the US Department of Health and Human Services (HHS). Employees of HHS are guided by statutes within "Title 34" and do not fall under the Privileges and Benefits of Veterans and Service Personnel under "Title 33."

You would not be required to pay the current renewal fee if you are a pharmacist who: a. is on active duty; or b. has been recently discharged; or c. has been recently released from active duty; and d. has submitted a renewal application within 60 days. Oregon's pharmacist license renewal application form contains a statement highlighted in red at the top right corner noting this fee exemption. If you qualify and want to take advantage of this fee exemption, simply circle the statement and enclose a copy of your discharge or release paper work with your renewal application.

No provision exists in this law, in the Oregon Revised Statutes Chapter 689, or in Oregon Administrative Rules Chapter 855 for deferring or waiving the requirement for continuing education (CE). A pharmacist who has not completed the 15-hour annual requirement while on active duty would have to catch up on CE for license renewal. OAR 855-019-0040(1)(b) describes this requirement for reinstatement of a lapsed license. General CE requirements are detailed in OAR 855-021-0005 to 0055. If you have questions, contact Michael Hunt at the Board's Licensing section via e-mail at michael.hunt@state.or.us.

No. 370: Pharmacy Self-Inspection Process

It is that time of year again. All pharmacies should have received a copy of the required Self-Inspection form. The form is also posted on the Board's Web site. It is important to remember that these need to be completed by February 1, 2005. It is also important to remember that that this form is more than just an "inspection form." It is an educational tool that clearly points out what is considered to be important by the Board, and it provides references to sources for the related information. The Board's staff takes pains to review and update this form annually in order to maintain a current and relevant process.

The most effective method for compliance with the Self-Inspection process is for the pharmacist-in-charge (PIC) to have a staff member do an inspection to complete the form providing accurate and honest responses. In this way, the PIC can get a clear overview of what is working and what needs to be addressed further before the Board's inspector appears for the on-site inspection. It is incumbent upon the PIC to take the necessary steps to bring the pharmacy into compliance where problem areas have been identified. The Board is not concerned with items checked as out of compliance on the form. The Board is, however, concerned that these items identified as out of compliance have been or are being addressed.

The form includes check boxes for the PIC to mark where problem areas have been addressed, and can be used as a valuable and effective component of the pharmacy's overall quality improvement program when used appropriately. If you have any questions, e-mail or fax the Board for clarification before you get inspected to avoid the risk of receiving an otherwise unnecessary warning notice.

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The Effects of the Flu Vaccine Shortage

In early October 2004, Chiron Corporation, one of two major pharmaceutical manufacturers of influenza vaccine, informed the Centers for Disease Control and Prevention (CDC) that it would be unable to distribute its estimated 48 million doses of Fluvirin® in time for the 2004-05 flu season. The United Kingdom's Medicines and Healthcare products Regulatory Agency temporarily suspended Chiron's license for its Liverpool facility that was scheduled to produce Fluvirin for distribution throughout the United States.

During the 2003-04 flu season, approximately 87 million doses of influenza vaccine were administered. Before Chiron's announcement, it was expected that 100 million doses would be available during this season, with Aventis, the other major influenza vaccine (Fluzone®) producer, contributing 54 million doses. Aventis has indicated that it will be able to produce an additional 2.6 million doses of influenza vaccine by January 2005.

Shortly after this announcement CDC convened its Advisory Committee on Immunization Practices to issue recommendations to prioritize the existing supply of influenza vaccine. In summary, the CDC recommends that the following priority groups be given available doses first due to their increased risk of complications from influenza infection:

- ◆ Persons aged 65 years or older;
- ◆ Children six to 23 months of age;
- ◆ Residents of long-term care facilities and nursing homes;
- ◆ Persons two to 64 years of age with chronic medical conditions;
- ◆ Health care workers involved in direct patient care;
- ◆ Household contacts and out-of-home caregivers of children less than six months of age;
- ◆ Children and teenagers between the ages of six months and 18 years who are receiving aspirin therapy; and
- ◆ Pregnant women.

Although not appropriate for everyone, FluMist® (MedImmune), the intranasal influenza vaccine, may be a good alternative for healthy persons between the ages of five and 49. Unlike Fluvirin and Fluzone injectables, which are inactivated influenza vaccines, FluMist is a live attenuated virus, which, if administered to at-risk groups, particularly those with compromised immune systems, may in rare instances actually cause disease.

Other alternatives include antiviral medications, which may be used to prevent and treat influenza infection. The antiviral agents rimantadine, Tamiflu® (oseltamivir), and amantadine are Food and Drug Administration (FDA) approved for treatment and prophylaxis of influenza. Relenza® (zanamivir) is only approved for influenza treatment. To help minimize resistance, CDC currently encourages the use of amantadine or rimantadine for influenza prevention while using the other antivirals oseltamivir or zanamivir for treatment.

Although vaccination and other pharmacologic interventions are extremely beneficial, health care professionals should educate patients on practical measures that can be taken to prevent the spread of influenza. These include:

- ◆ Washing your hands frequently to avoid the spread of viruses and bacteria;
- ◆ Avoiding contact with people who may be sick;
- ◆ Cleaning telephones, door knobs, and other environmental surfaces with disinfecting agents to help prevent the spread of viruses and bacteria;
- ◆ Covering your mouth and nose when coughing or sneezing;

- ◆ Staying home from work and/or school when you are sick and limiting/eliminating contact with those who have compromised immune systems.

In late August 2004, US Department of Health and Human Services (HHS) Secretary Tommy G. Thompson released preliminary plans for a National Pandemic Influenza Preparedness Plan that details a national strategy to prepare for and respond to an influenza pandemic and provides action steps that should be taken at the national, state, and local levels during a pandemic. At press time, the draft plan was located at www.hhs.gov/nvpo/pandemic-plan. Pharmacists have become increasingly active in efforts to increase the public access to immunizations; according to National Association of Board's of Pharmacy® (NABP®) 2003-2004 *Survey of Pharmacy Law*, more than half of the states allow pharmacists to administer immunizations.

Because of the influenza vaccine shortage, many have expressed concerns about the possibility of counterfeit influenza vaccines. Pharmacies and health care institutions should only secure product from reputable resources and immediately report any suspect product. Also, many pharmacies have reported that the price of influenza injectable vaccines from some distributors has more than doubled since the shortage. In mid-October 2004, HHS Secretary Thompson urged the state attorneys general to prosecute those who were price gouging the cost of influenza vaccines.

For more information visit these Web sites:

FDA Flu Information – www.fda.gov/oc/opacom/hottopics/flu.html.

CDC Influenza Information (including vaccination information and Antiviral Medication Usage Guidelines) – www.cdc.gov/flu.

FDA Urges Consumer Education About Counterfeit Drugs

In an interim report, FDA's Anti-Counterfeiting Task Force stressed the importance of increasing awareness and education of stakeholders including the public concerning counterfeit drugs. The report called for increasing efforts of FDA and other government agencies to educate consumers and health care professionals on how to reduce the risk of obtaining counterfeit drugs before the event occurs; educating consumers and health care professionals on how to identify counterfeit drugs; and improving and coordinating FDA and industry messages and efforts to address and contain a counterfeit event. At press time, FDA had available on its Web site (www.fda.gov/cder/consumerinfo/counterfeit_all_resources.htm) public service announcements that can be printed for consumers as well as educational articles to inform the public.

One recent high-profile case concerned Viagra® (sildenafil citrate) that was dispensed from two pharmacies located in California. The counterfeit product closely resembled genuine Viagra tablets with respect to size, shape, color, and imprinting; however, the counterfeit drugs had subtle differences in tablet edging, film coating, imprinting font, and packaging. At press time, FDA, along with Pfizer, Inc, the legitimate manufacturer of Viagra, was analyzing the counterfeit product to determine its true composition and whether or not it posed any health risks; fortunately, no injuries had been reported. For comparative photos of the counterfeit drug and genuine Viagra, refer to Pfizer's "Dear Pharmacist" letter posted on the company's Web site at www.pfizer.com as well as FDA's distributed a press release that is now available at www.fda.gov.

Compliance News

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



Exactly one month after the counterfeit Viagra product was discovered, FDA expressed concern regarding counterfeit versions of the prescription drugs Zocor® (simvastatin) and carisoprodol, which were imported from Mexico by US citizens. Tests of these products revealed that the counterfeit Zocor, reportedly purchased at Mexican border-town pharmacies and sold under the name Zocor 40/mg (lot number K9784, expiration date November 2004, and lot number K9901, expiration date December 2006), did not contain any active ingredient. Likewise, the counterfeit carisoprodol 350/mg (lot number 68348A) test results indicated that the products differed significantly in potency when compared to the authentic product. FDA continues to investigate this matter and is working with Mexican authorities to ensure that further sale and importation of these products are halted. For more information on counterfeit Zocor, visit www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html.



Diabetes or Alzheimer's Disease?

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.

Several reports of mix-ups have been reported in which the antidiabetic agent AMARYL® (glimepiride) had been dispensed to geriatric patients instead of the Alzheimer's Disease medication REMINYL® (galantamine). Each drug is available in a 4 mg tablet, although other tablet strengths are also available for each.

In one case, a 78-year-old woman with a history of Alzheimer's disease was admitted to the hospital with hypoglycemia (blood glucose on admission 27 mg/dL). A review of the medications she was taking at home revealed that her pharmacist dispensed Amaryl 4 mg, which she took twice daily instead of Reminyl 4 mg BID. In another case, an 89-year-old female received Amaryl instead of Reminyl for three days, eventually requiring hospitalization for treatment of severe hypoglycemia. A third patient received Amaryl instead of Reminyl while in the hospital, leading to severe hypoglycemia. All patients recovered with treatment. These events have been linked to poor prescriber handwriting and sound-alike, look-alike names. It is possible that prescriptions for Amaryl are more commonly encountered than those for Reminyl. Thus, confirmation bias (seeing that which is most familiar, while overlooking any disconfirming evidence) may lead pharmacists or nurses into "automatically" believing a Reminyl prescription is for Amaryl.

Obviously, accidental administration of Amaryl poses great danger to any patient, especially an older patient, who may be more sensitive to its hypoglycemic effects. Practitioners should be alerted to the potential for confusion between Amaryl and Reminyl. Prescribers should be reminded to indicate the medication's purpose on prescriptions. Consider building alerts about potential confusion into computer

order entry systems and/or adding reminder labels to pharmacy containers. Patients (or caregivers) should be educated about all of their medications so they are familiar with each product's name, purpose, and expected appearance. Most importantly, at all times pharmacists and nurses should confirm that patients are diabetic before dispensing or administering any antidiabetic medication, including Amaryl. FDA, Aventis (Amaryl), and Janssen Pharmaceutica Products LP (Reminyl) are aware of these reports and will be taking action to help reduce the potential for errors.

Medication Safety Videos Available Free

FDA's Center for Devices and Radiological Health has been producing a monthly series of patient safety videos available via the Internet. ISMP and FDA's Division of Medication Errors and Technical Support, Office of Drug Safety, has been cooperating in this effort. Access www.ismp.org/Pages/FDAVideos.htm for videos related to medication errors. See www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm for a complete list of all broadcasts.

2005 Survey of Pharmacy Law Now Available

NABP's 2005 Survey of Pharmacy Law CD-ROM is now available. Eight new questions were added to this year's Survey; topics include the formatting requirements of prescription pads, laws/regulations on the disposal of medications, and whether or not pharmacists are allowed to dispense emergency contraception without a prescription.

The Survey can be obtained for \$20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a check or money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from GlaxoSmithKline. If you do not have Web access or would like more information on the Survey, please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

NABP Headquarters Moves to New Location

NABP has moved its Headquarters to 1600 Feehanville Drive, Mount Prospect, IL 60056. The new phone number is 847/391-4406 and the new fax number is 847/391-4502. All printed communications can be sent to the Feehanville Drive address. If you have any questions concerning the Association's new Headquarters, please contact the Customer Service Department at custserv@nabp.net or call 847/391-4406.

Register Now for NABP's 101st Annual Meeting

Register now for NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel, New Orleans, LA, so you can take advantage of the chance to earn up to five hours of continuing education (CE).

This year, CE sessions will focus on topics that fall under the Meeting's theme, "A Medley for Patient Safety: Accreditation, Self Assessment, Quality Care." Other events include the Educational Presentation Area and Poster Session, the President's Welcome Reception, NABP's annual business sessions, and the Annual Awards Dinner. In addition, you and your spouse or guest will have the opportunity to participate in a special recreational tour and the annual Fun Run/Walk.

For more information visit NABP's Web site at www.nabp.net, or contact NABP at 847/391-4406 or custserv@nabp.net.

Continued from page 1

The Board considers the self-inspection and completion of this form to be very important, and it is required under the Board's rules. Failure to have the completed form available when the inspector arrives could result in disciplinary action.

No. 371: Continuing Education Completion Cycle

An impressive number of pharmacists were discovered through the Board's CE audit process to be out of compliance with the CE requirement for the current license renewal cycle this year. Some of these were out of compliance because they reported CE credits that fell outside the renewal cycle dates. The Board believes that the existing CE requirements are important and has taken disciplinary action against pharmacists for failure to meet the requirement and for indicating on the renewal form that they had met the requirement when they had not. Disciplinary action was taken by the Board against these pharmacists, which required them to take and pass the Multistate Pharmacy Jurisprudence Examination® at their own expense. It is the professional responsibility of pharmacists to ensure that they remain competent and up-to-date with current pharmacy practice standards and drug information. The annual CE requirement is an effort to assist pharmacists in meeting this responsibility for their public and their peers.

No. 372: Shake Well

It may come as a surprise to some (it should) to learn of the reason the Board has found it necessary to take disciplinary action against pharmacists in a number of cases in the past two years. These cases were related to complaints filed by patients or caregivers who were dispensed liquid suspension preparations. In one case, the powder for reconstitution was not reconstituted. The patient's mother followed the directions on the prescription bottle and gave her child a teaspoonful of un-reconstituted antibiotic powder. After several doses, the mother observed the child's reaction and called the doctor, who discovered the error.

Another equally disturbing case involved a liquid suspension of a common anti-seizure medication that did not require reconstitution. In this case, the pharmacist decanted the proper volume of suspension into the prescription bottle from the gallon stock bottle. The pharmacist had not shaken the stock bottle

prior to decanting the suspension, so the patient received a significantly diluted liquid suspension. To compound the problem the pharmacist failed to apply a "Shake Well" warning label to the prescription bottle or counsel the patient's mother to shake it. The bottle was not shaken prior to administration by the patient's mother and after several doses of diluted suspension, the patient began to have seizures. The doctor increased the dose on a new prescription to manage the renewed seizure activity, which the mother took to the pharmacy. This time the suspension was properly shaken and the warning label was applied by the pharmacist. After several doses at the increased level, the patient exhibited symptoms of overdose and received hospital treatment.

Still another case involved an otic suspension that was labeled and dispensed for administration into the eye.

This article is being written at the request of the Board members. Some practice settings may not provide optimum environments for concentration and focus, and some settings are very busy and put pressure on pharmacists. The point of this article is to remind pharmacists of what can happen when they respond to pressures to cut corners or multi-task, or move too fast or lose focus. All of these errors could have been prevented with proper counseling by the pharmacist. Reconstitute, shake well, and administer properly are concepts that should constantly be on the mind of any pharmacist in the process of dispensing prescriptions. Never mind the penalty for making this kind of error. Consider the experience of the patients and their families who rightfully depend on your professional expertise and judgment. The Board wants to stress the importance of making sure you are completely focused each time you dispense any medication. It is your job. It is your patients' health. And, it is your profession.

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