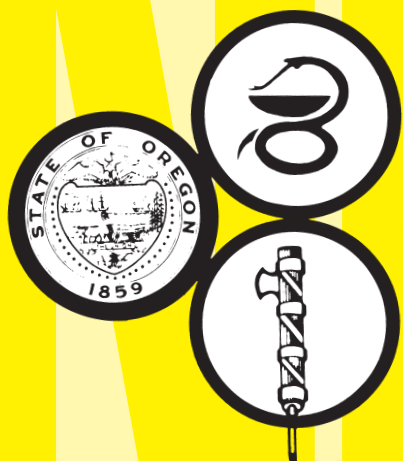


May 2008



# Oregon State Board of Pharmacy

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## **No. 431: Tamper-Resistant Prescription Pads**

Following a six-month delay in implementation, the Medicaid tamper-resistant prescription pad requirement became effective April 1, 2008. The November 2007 *Newsletter* contained article **No. 423: Tamper-Resistant Prescription Forms** describing the requirements. The Oregon State Board of Pharmacy Web site now contains all the information one should need to maintain compliance with the law. This is simply a reminder.

The new law applies only to written prescriptions for covered outpatient medications. Oral, facsimile, or electronically transmitted prescriptions are not affected by this requirement. The law applies only to reimbursement when Medicaid pays any portion of the cost of a prescription. It is not a dispensing requirement under Board of Pharmacy regulations.

To view the latest Centers for Medicare and Medicaid Services communication to the Boards of Pharmacy regarding the tamper-resistant requirement, visit the Board's Web site under "What's New" at [www.pharmacy.state.or.us/Pharmacy/TamperProofRx.shtml](http://www.pharmacy.state.or.us/Pharmacy/TamperProofRx.shtml). You will find the most recent information available including answers to questions such as, "What can pharmacists do if they are not sure whether a prescription meets the requirements?"

## **No. 432: Do You Know Why You Are Taking This Medication?**

*By Ann Zweber, Board of Pharmacy President*

The most common consumer complaints received by the Board are complaints about medication errors. In many cases, the error could have been prevented with appropriate and effective patient counseling by the pharmacist or intern. The following recent cases illustrate this point:

- ◆ atenolol was dispensed for Septra®;
- ◆ Cortisporin® Otic suspension was dispensed instead of Cortisporin® Ophthalmic drops;
- ◆ methotrexate was dispensed instead of medroxyprogesterone.

In each case, if the pharmacist had shown the patient the medication and asked why the patient was taking it, the error could have been quickly identified. More importantly, the patient would not have left the pharmacy with the wrong medication.

Counseling is most effective when patients are engaged in a dialogue about their medication therapy. Involving the patient in the discussion, including asking questions, helps the pharmacist to verify the correct medication is being dispensed. It will

also help the pharmacist to assess the patient's understanding about how to use the medication and what to expect.

Some pharmacists may be concerned that asking open ended questions will demand too much time. Others may be uncomfortable with trying a new technique. Start by simply showing the patient the medication and the product identification note on the label, and asking, "What did your doctor tell you about this medication?" or "What do you know about this medication?"

You will discover that patient counseling becomes more rewarding and more effective as you establish a relationship with your patient. Learn about what your patient already knows, and tailor the type of information you provide to meet the individual's needs. In many cases this type of counseling takes less time than reading directions and listing side effects. In some cases it may take a little more. In any case, how much time is it worth if you prevent a serious medication error? Try it!

It should also be mentioned here that new administrative rules adopted by the Board in Division 019 (OAR 855-019-0230c) require pharmacists and interns to document patient counseling beginning July 1, 2008.

## **No. 433: Oregon PRN**

*By Edwin Schneider, PRN Program Director*

The Oregon Pharmacy Recovery Network (OR PRN) was established by the Oregon legislature in 1989 to allow the Board of Pharmacy to work with licensees (pharmacists, pharmacy interns, and pharmacy technicians) whose health and effectiveness has been adversely affected and whose professional practice may become compromised by chemical dependency. Concerned and dedicated pharmacists helping with the OR PRN program strive to assist colleagues before chemical dependency causes impairment, or before impairment becomes a danger to the community and a threat to an individual's license to practice pharmacy or assist the pharmacist in the practice of pharmacy.

The role of the OR PRN program is one of advocacy, rehabilitative support, and monitoring. In the case of voluntary or self referrals, the program may even shield a participating individual from disciplinary action by the Board of Pharmacy. Some behavioral clues or characteristics of chemical dependency include:

- ◆ substances often taken in larger amounts than the person intended;
- ◆ one or more unsuccessful efforts to cut down or control substance use;

*Continued on page 4*



## **NABP Launches Pharmacy Curriculum Outcomes Assessment Program**

NABP launches its Pharmacy Curriculum Outcomes Assessment™ (PCOA®) mechanism in April 2008 for use by schools and colleges of pharmacy in evaluating their curricula. NABP invited schools and colleges of pharmacy to participate in the 2008 administration of the PCOA, scheduled for April 7-18. There will be no fee for participation in this first year of administration.

Those schools and colleges of pharmacy that participate in the April 2008 administration will receive detailed score reports for their students that sit for the assessment, as well as national comparative data. NABP developed the PCOA at the request of schools and colleges of pharmacy and accreditation stakeholders that have expressed a need for a national assessment that is psychometrically validated to assist with measuring curriculum development and student performance.

Details are posted under Assessment Programs on the NABP Web site, [www.nabp.net](http://www.nabp.net), or by contacting NABP Customer Service at [custserv@nabp.net](mailto:custserv@nabp.net).

## **An e-Educated Consumer is Your Best Customer (Patient)**



*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 Food and Drug Administration (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](http://www.ismp.org). If you would like to report a problem confidentially to these organizations, go to the ISMP Web site ([www.ismp.org](http://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](mailto:ismpinfo@ismp.org).*

According to the Pew Internet and American Life Project, Online Health Search 2006, 80% of American Internet users, or some 113 million adults, have searched for information on at least one of 17 health topics. Many Americans turn to the Internet before, or instead of, seeking information from their doctor or pharmacist. People want to make better decisions in their lives and therefore seek more in-depth research, research that is offered online.

Patients and caregivers have a vested interest to keep up-to-date on their own or their loved ones' medical conditions. The average doctor's appointment is just 10 minutes – hardly enough time to get into lengthy conversations about treatment options and medication side effects. Long lines, busy and distracted pharmacists, and lack of privacy and confidentiality deter patients from seeking more information from their community pharmacists. It is no wonder then, when patients do not understand medical terminology or want to explore the medication treatment options that are available, they do not call their doctor or pharmacist – they just log on. In the privacy of their home they can find practical information such as lists of foods they should or should not take with certain medical conditions or certain medications. Instead of bothering busy pharmacists

who do not appear to have the time to answer questions, they can get peace of mind when dealing with chronic conditions. They surf the net for reassurance and answers to their questions.

But what about the quality of those online sources? Some are better than others; obviously, Medline offered by the National Institutes of Health is a reliable source, but what if the site is sponsored by a pharmaceutical company? How does the consumer know which information to trust? Research suggests that most health information seekers do not check the source and date of the information they find online. Most Internet users use a search engine and key words from their own limited medical knowledge and rely on the algorithms of the search engines to find them reliable Web sites and scientific articles.

How can you, the pharmacist, help your patients find a credible health care information site? Patients need an easy-to-use, comprehensive medical Web site where they can learn about health conditions and medications. Patients should look for Web sites that offer unbiased health information written by medical professionals.

Tell patients to always check sources and dates of the information provided. For example, information on hormone replacement therapy has changed significantly in the last few years. Articles offering advice and recommendations on drug therapy from 10 years ago could be detrimental to the reader.

The patient-doctor-pharmacist triad has changed. We now live in an era of the square – the patient, doctor, pharmacist, and Internet. Help patients understand what they are reading. Go to the sites yourself and confirm the information is reliable and timely. And of course, find time to answer their questions. Look for a soon to be released consumer Web site being developed by ISMP.

## **FDA Warns against Using OTC Cold Medicines in Babies**

FDA issued a public health advisory on January 17, 2008, recommending that over-the-counter (OTC) cough and cold medicines should not be used to treat infants and children younger than 2 years of age, citing the risk of "serious and potentially life-threatening side effects." FDA held a public advisory committee meeting October 18-19, 2007, to discuss the issue, after which many pharmaceutical manufacturers voluntarily withdrew cough and cold medicines marketed for use in this age group.

FDA says the agency is in the process of evaluating the safety of OTC cough and cold medicines in children 2-11 years of age and will announce its recommendations "in the near future."

The public health advisory is available on the FDA Web site at [www.fda.gov/cder/drug/advisory/cough\\_cold\\_2008.htm](http://www.fda.gov/cder/drug/advisory/cough_cold_2008.htm).

## **Bayer Diabetes Care Recalls Contour Test Strips**

Bayer Diabetes Care recently recalled test strips (sensors) for use with the Contour TS Blood Glucose Meter. The company recalled the product because test strips from specific lots could result in blood glucose readings with a positive bias that could demonstrate 5% to 17% higher test results.

This issue is unrelated to the Contour TS meter itself and pertains only to certain test strips used with the meter. Strips used with other Bayer meters are unaffected.

Health care professionals are advised to check the lot number of the Contour test strips in their inventory and contact Bayer Diabetes Care for information on the return and replacement of strips.

More information is available in the manufacturer's press release at [www.fda.gov/medwatch/safety/2007/contourTS\\_recall.htm](http://www.fda.gov/medwatch/safety/2007/contourTS_recall.htm).



## **FDA Takes Action against Compounded BHRT Drugs**

FDA sent letters warning seven pharmacy operations that the claims they make about the safety and effectiveness of their so-called bio-identical hormone replacement therapy, or BHRT, products are unsupported by medical evidence, and are considered false and misleading by the agency. FDA has expressed concern that unfounded claims like these mislead women and health care professionals.

The pharmacy operations receiving warning letters use the terms "bio-identical hormone replacement therapy" and "BHRT" to imply that their drugs are natural or identical to the hormones made by the body. FDA regards this use of "bio-identical" as a marketing term implying a benefit for the drug, for which there is no medical or scientific basis.

The FDA news release is available at [www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html](http://www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html).

## **Manufacturers to Restrict Distribution of Methadone**

As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution of this formulation to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. Manufacturers will discontinue supplying this formulation to any facility not meeting these criteria.

The 5 mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies. The 40 mg methadone formulation is indicated for the treatment of opioid addiction; it is not FDA-approved for use in the management of pain. This measure comes in response to the reported increase in methadone-related adverse events.

For more information, see "Studies Show Increased Methadone-Associated Mortality Related to Pain Management" in the January issue of the *NABP Newsletter*, available on the NABP Web site at [www.nabp.net](http://www.nabp.net).

## **New Compounding Standards Effective June 1; USP Offers Webinars**

New standards for sterile compounding will become effective on June 1, 2008. United States Pharmacopeia (USP) published the revised General Chapter 797, "Pharmaceutical Compounding – Sterile Preparations" on its Web site in December 2007 to give the compounding community time to implement changes before the effective date.

These revisions tighten standards and conditions for sterile compounding over the previous version of Chapter 797 to help improve patient safety. (See "Sterile Compounding 'Checklist' Revised to Better Protect Patient Health" in the February 2008 issue of the *NABP Newsletter*.) The revisions are included in USP 32–NF 27 and in the second edition of the *Pharmacists' Pharmacopeia*, published in March 2008.

USP is offering a series of educational Webinars and workshops to help compounding professionals appropriately interpret and implement the newly revised standard. The Webinars will provide direct dialogue with two compounding experts and ample time to address questions related to the standard. The workshops will provide added interaction plus hands-on demonstrations related to environmental monitoring, contamination control, and aseptic testing.

Full details on these programs are available on the USP Web site at [www.usp.org/hottopics/generalChapter797.html?hlc](http://www.usp.org/hottopics/generalChapter797.html?hlc).

## **Moving? Need to Transfer Your License?**

It is easy – go to the Licensure Programs section of [www.nabp.net](http://www.nabp.net).

Questions? Call Customer Service at 847/391-4406.

*NABP – Serving Pharmacists with Licensure Transfer Since 1904*

## **CMS Names MSAs, Products for Round Two of DMEPOS Bidding**

Centers for Medicare and Medicaid Services (CMS) recently announced the metropolitan statistical areas (MSAs) and product categories for the second round of the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program.

All suppliers must meet quality standards and be accredited by a CMS-recognized accreditation organization, such as NABP, to obtain a contract under the Medicare DMEPOS competitive bidding program. The final deadline for all suppliers to obtain accreditation is September 30, 2009. However, CMS encourages suppliers to seek accreditation as soon as possible to avoid any potential difficulties that would affect their ability to bid.

The competitive bidding program is designed to improve the effectiveness of Medicare's DMEPOS payments, reduce beneficiary out-of-pocket costs, and save the Medicare program money while ensuring beneficiary access to quality DMEPOS items and services. More information, including the lists of MSAs and product categories, is available on the CMS Web site at [www.cms.hhs.gov/CompetitiveAcqforDMEPOS](http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS).

## **Adverse Event Reporting Requirements in Effect for OTC Products**

FDA recently issued new adverse event reporting requirements for manufacturers, packers, and distributors of dietary supplements and over-the-counter (OTC) drug products marketed without an approved application. The new reporting requirements, as described in Public Law 109-462, became effective on December 22, 2007.

The act, as well as the FDA *Guidance for Industry: Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed without an Approved Application*, is available via the FDA MedWatch site at [www.fda.gov/medwatch/otc.htm](http://www.fda.gov/medwatch/otc.htm).

## **FDA Rule Calls for Toll-Free Number for Adverse Events on Drug Labels**

FDA recently issued an interim final rule requiring certain medication labels to include a toll-free number for reporting adverse events. The interim final rule codifies provisions of the proposed rule "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products" that became effective on January 1, 2008, under the FDA Amendments Act of 2007. The rule does not apply to over-the-counter medications approved as new drugs if the product packaging includes a manufacturer's or distributor's toll-free number for reporting complaints.

To allow manufacturers, dispensers, and pharmacies time to update their labeling and systems to comply with the new requirements, FDA will delay enforcement actions regarding these regulations until January 1, 2009.

More information is available in the *Federal Register* (Docket No. 2003N-0342) at [www.fda.gov/OHRMS/DOCKETS/98fr/E7-25426.pdf](http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-25426.pdf).

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- ◆ excessive time spent in activities for obtaining substances (eg, theft or hook-up or bar hopping);
- ◆ frequent intoxication when substance use is physically hazardous (eg, driving while intoxicated);
- ◆ continued use despite adverse consequences (eg, hangover, cocaine-induced depression, divorce, peptic ulcer flare up, jeopardized professional license);
- ◆ marked tolerance (need to increase the amount of substance taken to achieve desired effect); and
- ◆ substances often taken to relieve or avoid withdrawal symptoms (eg, quick drink to avoid hangover, small opiate dose to fight cravings, muscle relaxant to relieve pain).

The OR PRN program is sponsoring the annual Northwest PRN Conference at the Salem Convention Center on May 3, 2008. The conference will feature recovery information, and 8.7 hours of continuing education, including 1.5 hours of pharmacy law and 4.2 hours of pain management. Follow the OR PRN Web site for the details and registration information for this annual spring conference.

If you are interested in information about the program, please contact Edwin Schneider, RPh, by phone at 971/563-3893 or by e-mail at [EdwinS@PRNofOregon.org](mailto:EdwinS@PRNofOregon.org), or Pam Aldersebaes by phone at 971/673-1141 or by e-mail at [PamA@PRNofOregon.org](mailto:PamA@PRNofOregon.org). Further information about referral, advocacy, and other options under the program can also be found on the OR PRN Web site at [www.PRNofOregon.org](http://www.PRNofOregon.org).

#### **No. 434: Letter to Oregon Pharmacists**

The Board received a letter dated March 7, 2008, from Douglas B. Kirkpatrick, MD, vice chair of the Oregon Medical Board. The letter was addressed to Board of Pharmacy President Ann Zweber, asking her to consider placing the following statement in the next *Newsletter*.

At a recent meeting of the Oregon Medical Board (formerly known as the Oregon Board of Medical Examiners) we commented on how often we receive helpful information from Oregon pharmacists about Oregon physicians who are mis-prescribing, self prescribing or abusing medication. This information is extremely helpful to us and always triggers an appropriate investigation.

We would like to thank each and every pharmacist in Oregon. It would be very difficult for physicians to treat their patients without the diligent and professional work of the pharmacists. Furthermore, the Oregon Medical

Board itself greatly appreciates the vigilance and ethical standards of the pharmacists who let us know about the occasional physician who transgresses appropriate standards of prescribing.

The Board would like to thank Dr Kirkpatrick for recognizing the efforts of Oregon's pharmacists on behalf of the Medical Board. Receiving letters or communications such as this is not an every day occurrence at the Board of Pharmacy. Pharmacists should be proud to know that their hard work and dedication is noticed and acknowledged by the medical community.

#### **No. 435: Pharmacist-in-Charge Training Classes**

The Board's compliance staff continues to provide training classes for pharmacists-in-charge (PIC). Over the past year, classes have been attended by new and expectant PICs as well as mature and seasoned PICs. Follow the Board's Web site for the schedule of classes, and register early as the classes fill up quickly. The staff is reporting that pharmacies under the control of a PIC who has attended one of the classes tend to have fewer problems. They are taking less time to get through their inspections and are passing their inspections with fewer incidents.

The classes are also open to staff pharmacists who are not PICs. This training is valuable for staff pharmacists since they are usually involved in the on-site inspection process. They will become better equipped to accompany the inspector throughout the inspection in the absence of the PIC and more competent in the area of pharmacy law.

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