



# Idaho Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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## Future Law Continuing Education Programs

The following scheduled continuing education (CE) programs will satisfy the annual requirement as mandated by rule 134.02. One clock hour (0.1 CEU) must be Idaho Board of Pharmacy approved jurisprudence (pharmacy law) programs. Also, rule 134.05 allows for CE accrued in June, which is in excess of that licensing period's requirements, to be carried over to the next licensing period. This schedule is subject to change; please verify on the Board of Pharmacy Web site prior to attending.

**6/1/08:** 11:30 AM: Coeur D'Alene Resort, 115 S Second St 11: ISPA NW Convention

**6/24/08:** 7 PM: St Luke's Hospital, Anderson Center, 190 E Bannock St, Boise, ID

**8/2/08:** 9:30 AM Idaho State University, Leonard Hall, Pocatello, ID

**9/26/08-9/28/08:** Sun Valley Resort: ISHP Fall Meeting

## Online, 24/7 Access to Prescription Monitoring Program Data

The Board of Pharmacy has implemented a 24/7 online program where authorized practitioners and pharmacists may check controlled substance (CS) prescriptions filled for specified individuals. Practitioners and pharmacists must register to access the Web site. Applications may be obtained by contacting the Board of Pharmacy at 208/334-2356 or e-mail Teresa Anderson at [teresa.anderson@bop.idaho.gov](mailto:teresa.anderson@bop.idaho.gov).

## Renewal Season: 2008-2009

We are in the home stretch of the current renewal season. If you have not renewed your license you only have a few more days to do so without penalty. Late fees are assessed beginning July 1 and are determined by postmark. If you sent your renewal form and fee and have not received your renewed certificate contact [ellen.mitchell@bop.idaho.gov](mailto:ellen.mitchell@bop.idaho.gov), and we will research the issue. Renewal forms are available on our Web site at [www.idaho.gov/bop/renew/](http://www.idaho.gov/bop/renew/). You may fax the renewal form with the Credit Card Transmittal form for faster processing. Due to the increased workload during this time of year we are unable to fax license cards. Please return your forms with payment prior to June 30 to ensure your license does not expire. Pharmacists: Be sure you have completed your CE prior to renewing your license as you are certifying that you have met the requirements. You do not need to send copies of CE certificates with your renewal, although you may be audited up to three years back, so keep complete records. During the upcoming year, please keep us informed of any address changes. The Board spends an extraordinary amount of money on returned mail due to bad addresses. We desire to be good stewards of the funds we receive, and you can help by keeping us informed!

## Online Ordering Now Available

We have made a few changes to our Web site that will now allow you to order several items online using a credit or debit card. Law Books, Controlled Substance Inventory books, Official Idaho Registers, Duplicate Wall Certificates, Hours Transfers (Interns), and several Commercial Lists

are currently available. Please visit our Web site at <http://idaho.gov/bop/>, click on Shop, then click on Order Now to be directed to our online catalog. You may also access the catalog by clicking on the highlighted items on the shop page. From the catalog page you can also set up a free account with Idaho.gov that will allow you to view your order history and reprint receipts. To set up this account click on the sign-in button and then "New Users start here" to set up your account. If you have any questions about online ordering you can e-mail Misty at [misty.lawrence@bop.idaho.gov](mailto:misty.lawrence@bop.idaho.gov) or Sharon at [sharon.treese@bop.idaho.gov](mailto:sharon.treese@bop.idaho.gov). We are always looking for suggestions for the Web site; please direct these to [ellen.mitchell@bop.idaho.gov](mailto:ellen.mitchell@bop.idaho.gov) or Misty at the e-mail above.

## Is Your Inventory in a Bound Book and Available for Inspection?

The annual CS inventory as required in IDAPA 27.01.01.0496 must be a written record resulting from a physical (or actual) count of all CS on hand and contain the date the inventory is taken. Upon completion, the inventory must be dated as of the day taken, indicating whether it was taken at the opening or closing of business and signed by the party that took the inventory. The bound inventory book shall be in written, typewritten, or printed form and available for inspection at the registered location. The inventory shall be kept in a bound inventory book provided by the Board or in another bound book suitable to meet the requirements of inventory reporting. Loose leaf notebooks, spiral notebooks, and stapled pages do not meet Board requirements for a bound book and are unacceptable. The Board permits pharmacies to generate and use their own inventory reports so long as they have them professionally bound and all chain pharmacies use the same method for maintaining their inventory books.

## Wholesale Drug Distribution Act

While the Wholesale Drug Distribution Act (statute 54-1751 through 54-1759) and subsequent rules (321 through 332) mainly affect wholesale distributors, certain acts by retail pharmacies are addressed. The following examples do not comprise a complete listing. Without licensure as a wholesale distributor, retail pharmacies are allowed to sell minimal quantities of prescription drugs to licensed practitioners for office use. This replaces language that allowed for as much as 5% of one's sales to be sold in this capacity. Also, while intracompany sales of prescription drugs are allowed without wholesale distributor licensure, intercompany sales, purchases, distribution, trade, and transfer without wholesale distributor licensure is only permitted for emergency medical reasons. For example, anticipatory sales, in the absence of a legitimate patient's prescription, is not considered an emergency medical reason. Additionally, each person who is engaged in the wholesale distribution of a prescription drug, which leaves the normal distribution channel, shall provide a pedigree. While most transactions are within the normal distribution channel, repackaged prescription drugs (excluding those completed by the pharmacist for product dispensing directly to the patient) specifically require a pedigree upon wholesale distribution. If one attempts to further distribute repackaged



## **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).

prescription drugs they shall affirmatively verify that each transaction listed on the pedigree has occurred.

### **Controlled Substance Prescriptions Written By Out-of-State Prescribers**

CS prescriptions written by out-of-state practitioners are not required to be written on uncopyable paper in order for the prescription to be considered valid. If a patient sees a doctor in Oregon and is given a prescription for CS and returns to Idaho to have the prescription filled, the prescription need not be written on uncopyable paper.

### **Volunteer Opportunities**

Calling all Boise-based pharmacists and pharmacy technicians. The Garden City Community Clinic (GCCC) is provided by volunteer health care professionals with the goal to provide free medical services and dental care to those who are economically disadvantaged and without health insurance in the Treasure Valley. GCCC operates medical clinics on Tuesday and Thursday evenings, Wednesday mornings, and dental clinics on Monday, Thursday, and Friday mornings. Medical services include treatment of acute non-emergent and limited chronic illnesses, limited medications, referrals for X-rays and laboratory tests, and referrals to specialists, counseling, social work visits, and durable medical equipment and supplies as necessary. Dental services include dental screening examinations, dental hygiene/cleaning preventative maintenance, and limited procedures (fillings, root canals, and extractions). The medication room is typically staffed by one pharmacist and one pharmacy technician. We offer a defined drug formulary, patient counseling, computer patient profiling with thermal labeling of all prescriptions, and a collaborative practice between our medical director and pharmacist Elaine Ladd involving intensively managed patients on insulin therapy for their diabetes. For more information contact Gus Catherman at 208/384-5200 or one of the volunteer pharmacists (Dawn Berheim, Mike Dickens, Debra Evans, Les Gieselman, Brian Tollinger, or Victoria Wallace) from Saint Luke's Regional Medical Center at 208/381-2490 or Elaine Ladd from Saint Alphonsus Regional Medical Center at 208/367-4577.

### **Disciplinary Actions from March 7, 2008 Meeting**

**J.T., RPh**, violation of Statute 54-1704: failure to provide proper and safe storage of drugs, rule 180.02: improperly removing drugs from the pharmacy, and rule 496.04: failure to complete a CS inventory. A fine of up to \$600 is to be imposed, pending results of an additional audit.

**Pharmacists, P.B., T.G., B.R., R.J., and M.A.**, violations of rule 291.01: failure to renew CS registration, resulted in \$200 fines.

**W.I.I., VDO**: violation of rule 359.01: allowing access to legend drugs to individuals not registered as veterinary drug technicians and rule

357.04: telephone orders to be signed by the veterinarian within 72 hours, resulted in a \$200 fine.

**J.J., RPh**, violation of existing order and statute 37-2734 (a) (3), 37-2718 (c)(2), 54-1732(3)(a)(1), 54-1726(f), 54-1726(a), rule 184.08, 184.09, and 184.13: removing CS from place of business for personal use, resulting in an indefinite suspension of license and CS registration.

**D.B., RPh**, violation of statute 54-1732(3)(c), 37-2732(c): possessing a CS without a valid prescription, 37-115 (b): adulterating a drug, and 54-1726(a), rule 184.13: inappropriate conduct, resulting in an indefinite suspension of license and CS registration.

**R.S., RPh**, violation of statute 54-1726 (a): unprofessional conduct and (b): incapacity, rule 184.07: addicted or habituated to the use of alcohol and 184.13: inappropriate conduct, resulting in indefinite suspension of license and CS registration.

**S.B., MD**, mirrored order with Board of Medicine.

**A.R. pharmacy technician**, violation of 37-2732(c): possession of CS without valid prescription, 37-2732C(a): being under the influence of CS while on property open to the public, and 54-1732(3)(c): possession of legend drug without a valid prescription, resulting in revocation of technician registration.

### **Special Notice**

The *Idaho Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy intern/externs, and pharmacy technicians registered by the Board. Please read them carefully. We encourage you to keep them filed in your pharmacy, preferably in your Idaho Pharmacy Law book, for future reference.

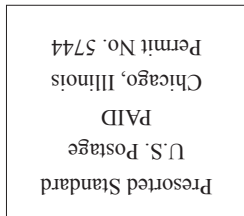
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