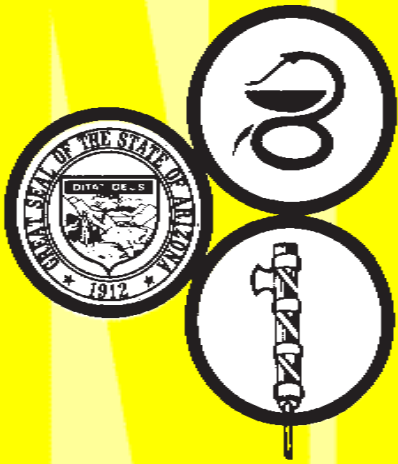


April 2008



# Arizona State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## **Governor Napolitano Appoints Two New Board Members**

In January, Governor Janet Napolitano appointed two new members to the Arizona State Board of Pharmacy. Chuck Dutcher from Snowflake, whose term expired, was succeeded by Gilbert resident Dan Milovich as the newest pharmacist member. Dan is a graduate of the University of Michigan and is currently the vice president of pharmacy operations for Bashas' Inc. He has been a pharmacist in Arizona for over 30 years and has been a longtime member and supporter of the Arizona Pharmacy Association and its successor the Arizona Pharmacy Alliance. He has won numerous pharmacy awards throughout his career. Dan is an active member of the Chandler Rotary Club and has served on the Board of Director's for the Crisis Nurseries in Phoenix and the Arizona Pharmacy Foundation. He is also a charter member of Phi Lambda Sigma, the Beta Tau Chapter.

Eloy resident Josephine Anne (JoAnne) Galindo is an honors graduate in criminal justice from Central Arizona College and leads the merchant education component for the Pinal County Tobacco Use Prevention Program, which certifies merchants on the legal sale of age restricted products such as alcohol and tobacco. JoAnne is new to the Board of Pharmacy but has served on the Arizona Department of Liquor Licenses and Control Board for four years and is also a member of the Santa Cruz Valley Union High School governing board.

The Board staff looks forward to working with these extensively qualified members in the coming years.

## **Board Compliance Officer – Update on Vacant Position**

The governor issued an order that freezes hiring by state agencies until further notice. Due to a coincident medical leave, the compliance staff is down to only three active officers. Pharmacy inspections will continue on a reduced basis, and the compliance staff will cover the whole state rather than a smaller regional territory. Complaint investigations will take priority over inspections.

## **Reminder – Requirement to Report Change of Address/Employment**

Board statutes and rules require all licensees (pharmacists, interns, and technicians) to report to the Board office in writing within 10 days of any change in address.

The requirement to provide written notice of address changes may seem at best inconsequential and at worst a nuisance to licensees. The requirement is designed to save the Board and the licensee time, expense, and embarrassment, however.

License renewal reminders are mailed (**as a courtesy**) to all licensees scheduled for renewal about 45 days before the renewal date of the license. An old or incorrect address may result in the renewal notice being returned to the Board undelivered. The cost for the courtesy mailing is currently over \$10,000 annually, and several hundred notices are returned to the Board offices each renewal cycle. If a licensee does not receive the courtesy notice due to an old or incorrect address on file, chances are the licensee will fail to renew and be subject to a late fee of one half the renewal fee and be unable to work until the renewal and late fee is paid and a new renewal receipt issued. Remember that professional license renewal is the responsibility of the licensee as is the case with motor vehicle operator (drivers) licenses.

Pharmacy interns usually graduate and are licensed as pharmacists before their intern licenses expire and are therefore not subject to renewal, while technician trainees may only renew once if approved by the Board.

The applicable statutes are as follows:

### **Arizona Revised Statutes §32-1926. Notice of change of employer or home address; termination of responsibility**

- A. Except as prescribed in subsection B, a pharmacist, intern, pharmacy technician or pharmacy technician trainee within ten days after changing that person's employer or home address shall give written notice to the executive director of the new employer or new home address.
- B. Pursuant to board rule, a pharmacist designated as the pharmacist in charge for a permit issued under this chapter shall give immediate notice of the initiation and termination of such responsibility.

### **ARS §32-1925. Renewal of license of pharmacists, interns and pharmacy technicians; fees; expiration dates; penalty for failure to renew; continuing education**

- A. Except for interns and pharmacy technician trainees, the board shall assign all persons licensed under this chapter to one of two license renewal groups. A holder of a license certificate ending in an even number shall renew it biennially on or before November 1 of the even numbered year, two years

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## **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).

from the last renewal date. A holder of a license certificate ending in an odd number shall renew it biennially on or before November 1 of the odd numbered year, two years from the last renewal date. **Failure to renew and pay all required fees on or before November 1 of the year in which the renewal is due suspends the license. The board shall vacate a suspension when the licensee pays all past due fees and penalties. Penalties shall not exceed three hundred fifty dollars. The board may waive collection of a fee or penalty due after suspension under conditions established by a majority of the board.**

- C. A person shall not apply for license renewal more than **sixty days** before the expiration date of the license.

### **Disciplinary Actions – Board of Pharmacy (Actions Since January 2008 Newsletter)**

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

#### **Pharmacist Discipline Actions**

**Bach, Jon (S009345)** – License reinstated. Five years probation. Lifetime Pharmacists Assisting Pharmacists of Arizona contract. Effective January 23, 2008.

**Balikian, Paul (S004434)** – Request to reinstate closed license denied pending action from Osteopathic Board. Effective January 23, 2008.

**Hahn, Robert (S010250)** – Probation terminated. Effective January 23, 2008.

**Hogan, Elizabeth (S015072)** – Revoked. Effective January 23, 2008.

**Isaacson, Alan (S007599)** – Probation terminated. Effective January 23, 2008.

**Pillon, Richard (S006697)** – Consent Amended – No longer required to work with another pharmacist. Effective January 23, 2008.

**Wilcox, Robert (S012472)** – Suspended between four to 10 months, followed by probation to last between four to four and a half years. Effective January 23, 2008.

#### **Technician Discipline Actions**

**Dinovo, Julia (T007753)** – Revoked. Effective January 23, 2008.

**Garcia, Sophia (T003053)** – Revoked. Effective January 23, 2008.

**Kendrick, Brandon (T011274)** – 18 months probation. Treatment Assessment Screening Center program. Effective January 23, 2008.

**Perez, Jose (T009642)** – Revoked. Effective January 23, 2008.

**Ronizo, Jonathan (T011697)** – Revoked. Effective January 23, 2008.

### **Disciplinary Actions – Other Boards**

#### **Arizona Osteopathic Medical Board**

##### **(DO – Osteopathic Physicians)**

**LeBlanc, Erol (DO 3452)** – Respondent placed on probation for five years with set terms and conditions. Effective February 25, 2008.

**Wray, Jeremy W. (DO 3638)** – Respondent placed on probation for five years with set terms and conditions. Effective February 20, 2008.

#### **Arizona Board of Medicine (MD – Allopathic Physicians and Physician Assistants)**

**Austein, Mark R. (MD 14196)** – Request for license inactivation with cause and order inactivating license with cause. Effective December 11, 2007.

**Chavis, Robert M. (PA 3421)** – License surrendered to the Board. Effective November 14, 2007.

**Foley, Nils E. (MD 32906)** – Respondent issued a Letter of Reprimand. Respondent shall not practice anesthesia for two years. Respondent placed on probation for five years with set terms and conditions. Effective December 14, 2007.

**Hsu, Unen D. (MD 8373)** – Respondent issued a Decree of Censure. Respondent placed on probation for 15 years with set terms and conditions. Effective October 12, 2007.

**Levitt, Keith N. (MD 26382)** – License surrendered to the Board. Effective December 14, 2007.

**Normann, Peter J. (MD 33254)** – License revoked. Effective October 11, 2007.

**Strickland, Jeffery D. (MD 34244)** – License surrendered to the Board. Effective December 14, 2007.

**Menon, Venu G. (MD 12360)** – *Interim Findings of Fact* – Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended pending a formal hearing. Effective August 13, 2007.

**Miller, Eric J. (MD 19279)** – *Order Vacating Interim Consent Agreement for Practice Restriction Dated January 9, 2007*. Effective June 4, 2007.

**Moody, Warren (MD 31152)** – *Interim Findings of Fact* – Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended pending a formal hearing. Effective October 16, 2007.

**Morford, Pamela A. (MD 17926)** – License surrendered to the Board. Effective October 11, 2007.

**Plumb, David I. (MD 37523)** – *Interim Findings of Fact* – Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended pending a formal hearing.