June 2008

Wyoming State Board of Pharmacy

Wyoming State Board of Pharmacy
632 S David St
Casper, WY 82601
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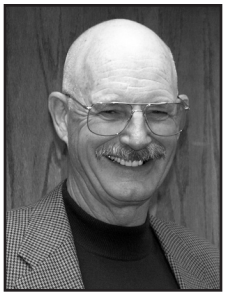
Published to promote voluntary compliance of pharmacy and drug law.

New Board Members Appointed

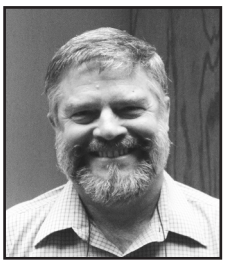
By Sarah Greer, 2008 PharmD Candidate



Recently, Charles Smith was appointed to the Wyoming State Board of Pharmacy as a public member. Charles is a retired school psychologist who spent over 30 years working with the Fremont County School District #1 in Lander, WY. Charles has a master's degree in special education from the University of Wyoming and became a board-certified school psychologist in 1989. He is a member of the Wyoming Association of School Psychologists and decided to apply to the Board of Pharmacy after completing a six-year term on the state AARP leadership team. Charles continues to live in Lander, WY, with his wife, Barbara. We are honored to have Charles as a Wyoming State Board of Pharmacy member.

Pharmacist Jennifer Nevins formerly served 12 years as a Wyoming State Board of Pharmacy member and has recently agreed to serve another three years. Jennifer graduated from the University of Wyoming with a bachelor of science degree in pharmacy and has experienced both retail and hospital pharmacy during her career. Jennifer is currently the pharmacy manager for Platte County Memorial Hospital where she has worked for the past 27 years. She is an avid supporter of the University of Wyoming Cowboys and has a strong commitment towards University of Wyoming pharmacy students by participating as a preceptor for fourth-year pharmacy students. Jennifer actively participates in Banner Health committees and is a member of the Wyoming Pharmacy Association (WPhA), National Association of Boards of Pharmacy® task forces, American Society of Health-System Pharmacists, American Association of Colleges of Pharmacy, and the University of Wyoming Alumni Board. Jennifer came to Wyoming during her sophomore year of high school. After graduating from college, Jennifer practiced pharmacy in Lincoln, NE, for five years before returning to Wyoming, where she has lived since. Jennifer is married to Zane Nevins and they are the proud parents of two children. We are thrilled to have Jennifer back as a Wyoming State Board of Pharmacy member.

Pharmacist Terry L. Carr has also been appointed as a new Wyoming State Board of Pharmacy member. Terry is currently employed at two locations part time including Medicap Pharmacy in Gillette, WY, and Platte County Memorial Hospital & Nursing Home in Wheatland, WY. He graduated with a bachelor of science



in 1974 and took a job in Sheridan, WY. Terry then moved to Gillette in 1976, where he has remained working retail and long-term care, with the exception of one year (2001) when he worked at the hospital in Wickenburg, AZ. Terry is a long time member of WPhA and has served as a member on its board. He is also a member of Wyoming Society of Health-System Pharmacy and the American Society of Consultant Pharmacists. Terry wished to join the Board because he would like to give back to the profession that has been his life. It is a pleasure to have Terry as a Wyoming State Board of Pharmacy member.

Also, Louann Weber has been appointed as the first technician Board of Pharmacy member in Wyoming history. Louann has been employed as a full-time pharmacy technician since 1987. She passed the Wyoming state certification examination with the first group certified in March of 1995 and became nationally certified in 1997. Louann is currently employed by Albertson's/Osco drug in Sheridan, WY, where she has worked since January 2005. Albertson's purchased the pharmacy Louann co-owned for six and one-half years. Louann also holds the first Wyoming pharmacy technician license ever issued. We are privileged to have Louann serving on the Wyoming State Board of Pharmacy.

April 2008 Board Meeting

Steve Hoffman, chief pharmacy officer for McKesson Patient Outreach Network Program, was present at the April Board meeting to explain how the program works. Health Mart is piloting the program and the Board determined there is no conflict with Wyoming Statutes or rules and regulations.

Tim Seeley was present to report on the work group for sterile processing regulations. This group is meeting via conference call with pharmacists, administrators, and representatives of the Wyoming Hospital Association to determine how to proceed with rulemaking based on the new standards in the United States Pharmacopeia Chapter 797, "Pharmaceutical Compounding – Sterile Preparations." One survey has been completed, and the group agreed to share information about remodeling and which products to use. Another conference call was planned in May, and a meeting at the Board's office is scheduled for June 25, 2008.

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,* or by contacting NABP Customer Service at 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. 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.*

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.*

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.*

Compliance News

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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.*

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.*

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.*

Moving? Need to Transfer Your License?
It is easy – go to the Licensure Programs section of *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.*

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.*

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.*

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Rulemaking was discussed and the motion carried to go forward with rulemaking in Chapter 8 (Distributor Rules), Chapter 10 (Pharmacy Technician Regulations), and in Chapter 16 (Immunizations). An emergency rule was enacted to add the zoster vaccine to the list of approved adult immunizations for pharmacists to administer in Wyoming. The proposed change for technicians is to make it easier to implement online renewals. The proposed rules for drug distributors, manufacturers, and wholesalers have extensive revisions to Chapter 8 because of the change to the statutes enacted by the Wyoming State Legislature in 2007. The proposed rule changes can be viewed on the Board Web site at *http://pharmacyboard.state.wy.us*. The public hearing will be held in Casper at the Board's office on June 26, 2008, beginning at 9 AM.

Election of new officers for a one-year term: Randy Harrop as president, Kay McManus as vice president, Terry Carr as secretary-treasurer.

Relocation of the Board office was discussed and the motion was made and seconded: "In the best interest of the people of Wyoming the Board of Pharmacy office will move to Cheyenne as smoothly and efficiently as possible." The motion carried.

Prescription Drug Monitoring Program

By Denise Embury, Records Analyst

We would like to thank all of the pharmacies who report each month in a timely manner. Just a few reminders, please do not put anything **but** the address in the address field. We have been receiving data with personal information, such as phone numbers, comments, city names, and zip codes. There is a separate field for zip codes, which automatically puts the name of the city in the data sent. We would also like to remind you that you still need to use the Drug Enforcement Adminstration (DEA) number for the pharmacy and the practitioner, **not** the National Provider Identifier number. This has not changed and it is very important, as our system uses the DEA number to bring in the practitioner and pharmacy name. If you need a DEA number, please do not make one up, call our office and we can provide you with the correct number.

Need Help with USP 797?

By Mollie Jay

A growing concern for most small and rural hospitals is compliance with USP Chapter 797. Not only does the task seem daunting but expensive as well, and most pharmacies just want to comply with the basics and get on with patient care. But what are those basics?

Several pharmacists have turned to the Board for answers; the Board is currently reviewing the matter. Until more definitive answers are in place, pharmacists with questions have a multitude of resources available to help them through this change.

The latest revision of the chapter is available on the USP Web site at *www.usp.org/pdf/EN/USPNF/generalChapter797.pdf*. Webinars, workshops, and a reader-friendly *Guidebook on USP <797> Pharmaceutical Compounding Sterile Preparations* are also available for varying fees. Other available tools include:

- *Assuring Continuous Compliance with Joint Commission Standards: A Pharmacy Guide* by Charles P. Coe and John P. Uselton is available at *www.ashp.org*.
- *Planning, Design, and Construction of Health Care Facilities* from the Joint Commission available at *www.jointcommission.org/*.
- *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings* from the National Institute for Occupational Safety and Health Publication No. 2004-165 is available at *www.cdc.gov/niosh/docs/2004-165/2004-165c.html*.
- American Society of Health-System Pharmacists additional resources for home, ambulatory, and chronic care pharmacies at *www.ashp.org/s_ashp/cat1c.asp?CID=1916&DID=1960*.

As challenging as it may seem, meeting compliance is achievable. Keep in mind that USP Chapter 797 was written to improve sterile product compounding, and once the initial hurdles of meeting the requirements are passed, patients and staff benefit as a result.

Special Notice about This Newsletter

The *Wyoming State Board of Pharmacy News* has been designated as the official method of notification to pharmacists and pharmacy technicians licensed by the Wyoming State Board of Pharmacy. Please read these *Newsletters* and keep them for future reference. These *Newsletters* will be used in hearings as proof of notification. *Newsletters* are available for review on the Board's Web page (*http://pharmacyboard.state.wy.us*).

The *Wyoming State Board of Pharmacy News* is published by the Wyoming State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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