

April 2008



Nevada State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

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2008 Board Meeting Schedule

April 16-17Las Vegas
June 4-5..... Reno
July 16-17Las Vegas
September 3-4 Reno
October 15-16Las Vegas
December 3-4 Reno

Return of Unit Dose Medications

It has been brought to the attention of Nevada State Board of Pharmacy staff that there is some confusion with regard to what medications are returnable to a pharmacy. Nevada Administrative Code 639.760 allows the return of non-Schedule II medication to the pharmacy that dispensed it **only** if the patient is a patient in a facility for skilled nursing or a facility for intermediate care as defined in chapter 449 of Nevada Revised Statutes **and** the medications **are packaged for unit dose by the original manufacturer.** Note: "bubble pack" or "bingo card" packaging is not returnable since they are not packaged by the original manufacturer.

Schedule II Issues

Effective December 19, 2007, Drug Enforcement Administration (DEA) announced that it will once again be legal for practitioners to write up to a 90-day supply of a Schedule II medication on multiple blanks dated the same day but with "do not fill until (date)" written on the face of the prescription. Again, these prescriptions must be tendered within 14 days of the date of issue.

As of January 1, 2008, manufacturers of methadone 40 mg tablets have voluntarily agreed to restrict distribution to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. The 40 mg methadone formula-

tion is approved by Food and Drug Administration for addiction treatment and not approved for the treatment of pain. The 5 mg and 10 mg formulations, which are approved for the treatment of pain, will continue to be available to all authorized registrants, including retail pharmacies. Adverse events, including an alarming increase of the death rate secondary to methadone overdosage has precipitated this action.

An Odd Diversion

Odd as it may seem, one of fastest climbing products on the list of diversion is promethazine with codeine syrup. The illicit recreational use of this product was popularized by a Houston, TX, music producer named DJ Screw who attributed the recreational use of the medication as the inspiration for the "chopped and screwed" subgenre of hip-hop music that originated in the southern United States. The concoction was introduced to a nationwide audience in June of 2000 by the Grammy and Academy Award-winning group Three 6 Mafia with lyrical references to the term "purple stuff" in the hit single entitled "Sippin On Some Sizzurp."

The purple hue to the concoction comes from the dyes in the cough syrup, and commonly is referred to as Purple Drank or Drank, Sizzurp, and Southern Lean, or Lean. The vernacular use of the new terminology might read, "2 - 4 ounces of Drank will make you lean." The original mixture is an equal ratio of promethazine with codeine syrup and soda pop with a Jolly Rancher candy added for further favoring. Alarming, the original mixture is evolving into a more dangerous combination by substituting the soda pop for alcohol, and by adding other ground opiates and benzodiazepines to the drink. Ron Peters, a professor at the University of Texas School of Public Health in Houston reported in a 2004 study that 30% of teens in the city had used the illicit purple concoction at least once.

Deaths have been attributed to the use of Purple Drank. DJ Screw died of a suspected codeine-alcohol overdose on November 15, 2000, several months after the video to Three 6 Mafia's single debuted. More recently, rapper Pimp C's December 2007 death was determined by the Los Angeles County Coroner's office as an accidental overdose of promethazine with codeine syrup in

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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, or by contacting NABP Customer Service at cust-serv@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.



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.

conjunction with a preexisting medical condition (sleep apnea).

The popularity of the promethazine with codeine concoction has spurred experimentation with other prescription cough medications as well such as Tussionex® and Tussigon®. It may be prudent for you to be more cognizant of your cough medication inventory.

Licensing Program

A new licensing program is on the horizon for the Board. Staff is currently in the process of designing and implementing a much needed and improved program that will make the process of renewing online even easier. The new program will allow for faster and more efficient online license verification as well. Our goal is to have the new program in place by September 2008.

Technician CE

It has been recently announced by the Accreditation Council for Pharmacy Education that continuing education programs specifically designed and accredited for pharmaceutical technicians will be assigned a course number ending with a "T." Likewise, a course accredited for pharmacists will end in a "P." The Pharmacy Technician Certification Board will accept "P" designated courses for technicians.

Please keep in mind that Nevada refers to continuing education for pharmaceutical technicians as "in-service training." Nevada statutes and regulations do not require pharmaceutical technicians to earn continuing education credits but rather only in-service training, which can be provided at the workplace level by pharmacy staff. Remember, continuing education credits may be used to satisfy in-service training.

Prescription Refills

Board staff often gets a call from either a patient or a pharmacist asking if it is OK for a pharmacist to fill multiple refills for the same prescription at the same time (eg, providing 90 tablets for a prescription written for a quantity of 30 with two refills). The

answer is "no," unless the practitioner is contacted and agrees (like in the instance of extended travel). Just a reminder, a patient is entitled to the entire quantity of a Schedule III through Schedule V prescription, regardless of the number of refills required within six months. DEA does not consider a refill to be complete until all of the quantity for the refill is dispensed. The pharmacist must be careful to ensure that no refill requested by a patient is dispensed sooner than the directions for use would allow.

Be Ready for Inspection

Increasingly, Board inspectors arrive at a pharmacy to conduct the annual inspection, and the pharmacy simply is unprepared. Pharmacy staff cannot locate the appropriate paperwork, the "purple sheets" are incomplete, technician training logs cannot be found, last year's inspection sheet is missing, DEA Form 222s are amiss, and on and on. It is the pharmacy manager's responsibility to ensure that his or her staff is prepared for the inspector when he or she arrives and that all of the appropriate paperwork is complete and accessible. Your pharmacy will always receive a preinspection packet the month prior to your inspection indicating that the inspector will be in sometime the following month. You are expected to be ready by the first of that month, and pharmacy staff is expected to be able to produce all of the documents and records necessary to conduct the inspection.

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