



Minnesota Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning **pharmacists** between the dates of December 13, 2007 and March 5, 2008.

Bullerman, Miles, License #111765. Mr Bullerman admitted to violating his probation by consuming alcohol, and his license was suspended indefinitely. He may petition for reinstatement of his license after he demonstrates six consecutive months of sobriety. If reinstatement is granted, Mr Bullerman will be placed on probation until he successfully completes participation in the Health Professionals Services Program.

Snyder, Timothy B., License #112876. Mr Snyder admitted to the habitual consumption of alcohol in a manner that could cause conduct endangering public health. He may petition for reinstatement of his license after he demonstrates 12 consecutive months of sobriety. If reinstatement is granted, Mr Snyder will be placed on probation until he successfully completes participation in the Health Professionals Services Program.

The following pharmacy technicians had their registrations suspended between December 13, 2007 and March 5, 2008: **Cook, Kimberly A., Registration #707639; Engebretson, Heidi, Registration #704433; Larmore, Sarah, Registration #702090; Theobald, Chelsea, Registration #711886.**

Continuing Education

Minnesota pharmacists are reminded that continuing education (CE) reporting is due no later than October 1 of every even-numbered year. There are now approximately six months left during which Minnesota pharmacists can complete and report their CE for the period from October 1, 2006 to September 30, 2008. Upon completion of at least the required 30 hours of CE, the Certificate of Completion, which is mailed to all pharmacists, should be signed, dated, and returned to the Board of Pharmacy office.

Continuing Education for Preceptors

In order to renew registration as a preceptor, a pharmacist must have participated in an instructional program specifi-

cally for preceptors, provided or approved by the Board, within the previous 24 months. At its March 5, 2008 meeting, the Board designated an additional CE program as being acceptable for this purpose. Please refer to the "Interns and Preceptors" portion of the Board's Web site for additional information. There are now three online CE programs approved for the preceptor CE requirement:

- ◆ "Prescription Errors: Legal Consequences and Patient Safeguards." David B. Brushwood, RPh, JD. Powerpak. Accreditation Council for Pharmacy Education (ACPE) #430-000-05-104-H03.
- ◆ "The Community Pharmacist Preceptor Education Program." Developed by American Pharmacists Association and National Association of Chain Drug Stores. ACPE # 206-202-07-008-H04.
- ◆ The *Pharmacist's Letter* online three-part CE "Precepting in Pharmacy" series.

All three programs are available online; the first two programs are ACPE approved and are free. Links to the program are available on the Board's Web site: www.phcybrd.state.mn.us/preceptorce.htm. In addition to the online CE programs, the University of Minnesota College of Pharmacy periodically holds CE programs for preceptors.

Pharmacist Interns and Preceptors

Approximately 150 pharmacy students will become eligible to work as pharmacy interns this summer. Many of these students will be seeking employment in order to obtain their required internship hours. Minnesota pharmacists who will be hiring pharmacy students as pharmacist interns over the summer must be sure that students are registered with the Board of Pharmacy as interns and that the pharmacists under whose supervision the interns will be working are properly registered with the Board as pharmacist preceptors. Failure of students to properly register as interns or failure of pharmacists to properly register as preceptors will result in loss of intern hours for the student and the potential for disciplinary action involving the pharmacist.

Please also note that every year some interns are found to be working in Minnesota based on an intern registration in another

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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 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.



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.

state. Registration as an intern in another state is not valid in Minnesota. A student of a college of pharmacy located in another state, who is employed in a Minnesota pharmacy as an intern, must be registered as an intern in Minnesota.

Licensure Verification

The Board was recently notified about an individual who was practicing pharmacy without a license. That individual has never been licensed by this, or any other, board of pharmacy. In addition, Board inspectors frequently encounter individuals performing the duties of a pharmacy technician without being registered as such. It is the duty of each pharmacist-in-charge (PIC) to verify that individuals who are working as pharmacists, interns, or technicians possess valid and current licenses or registrations. The online portion of the Board's Web site has a feature that allows for verification of licensure or registration. This feature can be accessed at www.hlb.state.mn.us/mnbop/glsuiteweb/homeframe.aspx. Verification can also be accomplished by calling the Board's office at 651/201-2825. Pharmacists must be licensed, and technicians and interns must be registered **before** they can work in a pharmacy. The Board has the authority to take disciplinary action against the license of a PIC (or against the license of the pharmacy itself) permitting unlicensed or unregistered individuals to work as pharmacists, interns, or technicians.

Facsimile Transmission of Prescriptions Written or Printed on Tamper-Resistant Paper

Last year, Congress enacted a section of law that requires all paper Medicaid prescriptions to be written or printed on tamper-resistant pads or paper. (Unless they are transmitted electronically or telephoned to the pharmacist.) Per a Provider Update issued on March 4, 2008, by the Minnesota Department of Human Services (DHS):

Centers for Medicare and Medicaid Services has set two deadlines for this requirement:

- ◆ Beginning April 1, 2008, all prescription pads/paper for prescriptions written for Medicaid fee-for-service recipients/members are required to have at least one of the tamper-resistant characteristics from one of the tamper-resistant categories. Prescriptions generated by an automated medical record, that print a unique number on each prescription, would satisfy this requirement.
- ◆ Beginning October 1, 2008, prescription pads/paper will be required to have at least one of the tamper-resistant characteristics from all three tamper-resistant categories. At this point, prescriptions generated by an automated medical record, that prints a unique number on each prescription, would not satisfy the requirement of meeting all three categories.

Additional information on DHS policies concerning this issue can be found on that department's Web site.

The Board has been receiving calls from pharmacists concerning the facsimile transmission of prescriptions that have been written or printed on tamper-resistant paper. The word "VOID" commonly appears printed on the faxed copy of such prescriptions. Pharmacists have asked if such prescriptions can be filled. The answer is, no – the Board does not consider prescriptions with "VOID" appearing on them to be legally valid. A pharmacist receiving such a prescription should contact the prescriber to verify its validity and note the verification on the prescription.

Pharmacist Participation in Managing and Modifying Drug Therapy

Minnesota Statutes §151.01, subd. 27 provides a definition of the "practice of pharmacy" that includes: "participation in the practice of managing drug therapy and modifying drug therapy, according to section 151.21, subd 1." Such participation requires a written protocol between a specific pharmacist and an individual dentist, optometrist, physician, podiatrist, or veterinarian. The Board regularly receives questions about this provision, and the following information may be helpful to pharmacists and others interested in this issue.

Please note that there is no mention of nurse practitioners or physician assistants in the law. Consequently, pharmacists cannot enter into a protocol with those individuals. Also, the law very plainly states that a protocol must be between a **specific** pharmacist and an **individual** dentist, optometrist, physician, podiatrist, or veterinarian. So, for example, a protocol between a physician and "all pharmacists working for Pretty Good Pharmacy" would not be valid. Nor would a protocol between pharmacist Sven Svenson and "all family physicians practicing at Acme Clinic."

The Board recently received a question from the Minnesota Department of Health (MDH) concerning the validity of an order signed by a pharmacist. MDH had cited a home health agency for accepting orders that were not signed by a practitioner. They had been signed by a pharmacist, who claimed to have the legal authority to sign the orders. The above-mentioned section of law does not authorize pharmacists to issue legally valid prescriptions or drug orders. The section of law that defines which individuals are allowed to prescribe drugs is MS §151.37, subd. 2. There is no mention in that section of a practitioner being able to delegate prescribing to a pharmacist. Consequently, for an order to be valid, it must be signed (or counter-signed) by a practitioner authorized to prescribe pursuant to MS §151.37, subd. 2.