



Minnesota Board of Pharmacy

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Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning **pharmacists** between the dates of September 10, 2011 and December 20, 2011:

Bentz, Robert H., License #114446. Mr Bentz allowed his Minnesota pharmacist license to lapse on March 1, 2011. Mr Bentz also admitted to the diversion of tramadol from his employer for his personal use. He also acknowledged that he had been discharged from the Health Professionals Services Program for noncompliance on May 4, 2011. Consequently, at its November 9, 2011 meeting, the Board issued a Stipulation and Consent Order that reprimands Mr Bentz and establishes conditions that he must meet before he will be allowed to renew his license.

Condon, John P., License #114558. Mr Condon admitted to diverting methadone, fentanyl, and hydromorphone from his employer for his personal use over a nine to 12-month period of time. He also admitted that he is unable to practice pharmacy in a dispensing setting at this time. Consequently, the Board adopted a Stipulation and Consent Order at its November 4, 2011 meeting, indefinitely suspending Mr Condon's license and setting conditions that he must meet in order for the suspension to be lifted.

Sporer, Amy E., License #117558. Ms Sporer was discharged from the Health Professionals Services Program after several toxicology screens were positive for metabolites of ethyl alcohol. She also admitted to ingesting a tablet containing morphine that was not prescribed for her. These were violations of an order that the Board issued on January 14, 2009. Consequently, at its November 4, 2011 meeting, the Board rescinded the previous order and adopted a new Stipulation and Consent Order that requires her to successfully complete the Health Professionals Services Program and abstain from the use of mood-altering chemicals. The order also prohibits her from serving as a pharmacist-in-charge.

The Board took the following disciplinary actions concerning **pharmacies** between the dates of September 10, 2011 and December 20, 2011:

Pharmerica, License #261548. Pharmerica admitted that 37 pharmacy technicians were allowed to continue working for approximately six weeks in January and February of 2011 even though their registrations had not been renewed by December 31, 2010. Consequently, at its November 4, 2011 meeting, the Board adopted a Stipulation and Consent Order that reprimands Pharmerica and imposes a civil penalty of \$5,550.

The Board considers the following **pharmacy technician** to have voluntarily surrendered his registration between September 10, 2011 and December 2, 2011: **McCabe, Caleb E., Registration #717333.**

Pharmacy Technicians Renewals

December 31, 2011, was the deadline for renewing pharmacy technician registrations. Any technicians who did not renew their registration by that date must now pay a late fee when their registration is renewed, and are not allowed to work as technicians until it is renewed. The pharmacist-in-charge of each Minnesota pharmacy is responsible for making sure that all of the pharmacy technicians employed in his or her pharmacy have current technician registrations posted.

Among the rule changes recently adopted by the Board was this language: "An individual may not, under any circumstances, perform pharmacy tasks as a pharmacy technician prior to being registered as a pharmacy technician according to this part." This language was added to emphasize the long-standing requirement for individuals to be actively registered while working as pharmacy technicians. Pharmacies and pharmacists-in-charge should take note of the fact that the Board recently disciplined a pharmacy for allowing 37 technicians to work for six weeks, even though their registrations had not been renewed.

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FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that “inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration.” Further, FDA clarifies its October 21, 2011 communication “to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector.” FDA also notes the following:

- ◆ Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- ◆ Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- ◆ At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit www.cdc.gov/flu.

‘Tell Back’ Works Best to Confirm Patient Understanding



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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 risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at

www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

In the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? *Ann Emerg Med*. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of “Tell Back-Collaborative Inquiry” to Assess Understanding of Medical Information. *J Am Board Fam Med* 2008;21(1):24-30). Researchers tested three types of inquiry about the patient’s understanding:

- ◆ Yes-No
- ◆ Tell Back-Directive
- ◆ Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: “I’ve given you a lot of information. Do you understand?”) The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: “It’s really important that you do this exactly the way I explained. What do you understand?”) The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I’ve given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers’ reluctance to put patients “on the spot” with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider’s care and concern for them personally, or evidence of the provider’s attention to detail and competence. So, when counseling patients about their medications, instead of asking “Do you have any questions?” or “Do you understand?” ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address “processing integrity” as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-



tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at www.deadiversion.usdoj.gov/e-comm/e_rx/thirdparty.htm#approved. Detailed background information is provided in the Federal Register Notice, available for download at www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at www.ScriptYourFuture.org. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medication-as-directed-133077423.html.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- ◆ Make a list of the medications they take
- ◆ Keep their medication list with them at all times
- ◆ Know the name of each medication, why they are taking it, how much to take, and when to take it
- ◆ Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement

liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at <http://rxpatrol.org/TrainingVideos.aspx>.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life-threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for \$195 by visiting the NABP Web site at www.nabp.net/publications.

The *Survey*, produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey*, please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

Technician Policies

Each pharmacist-in-charge must prepare written policies and procedures (P&Ps) governing the activities of pharmacy technicians. Copies of the P&Ps **do not** have to be submitted to the Board for approval, but must be kept on file in the pharmacy. The written P&Ps must be available for inspection by the Board upon request, and copies of the P&Ps must be given to each individual working as a pharmacy technician. The P&Ps must be updated at least every five years.

Pharmacist Renewals

Pharmacists are encouraged to use the secure online services section of the Board's Web site to renew their licenses. However, pharmacists can also print a renewal invoice after logging in to the online services section or they can contact the Board office to request a paper renewal application. Pharmacists should either renew their licenses online or complete and return a renewal application to the Board by February 1, 2012. Pharmacist licenses expire on March 1, of each year and a late fee is assessed for any renewal received after February 28. Pharmacists are not allowed to practice after February 28, without a valid license renewal.

Continuing Education Pharmacy Technicians

A pharmacy technician's registration renewal for calendar year 2014 will not be issued unless the technician has completed 20 hours of approved continuing pharmacy technician education (CPTe) during the two-year period between August 1, 2011 and July 31, 2013. Thereafter no annual pharmacy technician registration renewal will be issued unless the technician presents the Board with satisfactory evidence of completion of 20 hours of approved CPTe per two-year reporting period, with each period ending on July 31, of odd-numbered years. This means that all currently registered pharmacy technicians who plan on continuing to be registered should now begin completing approved CPTe programs.

CPTe must focus on the competencies that the technician must carry out and the specific duties that the technician performs. The Board accepts programs developed specifically for technicians by either Accreditation Council for Pharmacy Education-accredited or Board-approved providers. A technician may also apply for credit for attendance at programs developed by other organizations, provided that the technician completes a continuing education program approval form, obtainable from the Board's Web site, and submits it to the Board within 90 days after completing the program.

Pharmacists

Minnesota pharmacists are reminded that continuing education reporting is due no later than October 1, of every even-numbered year. There are now approximately

nine months left during which pharmacists can complete and report their continuing education for the period from October 1, 2010 to September 30, 2012. Upon completion of at least the required 30 hours of continuing education, a Certificate of Completion should be signed, dated, and returned to the Board of Pharmacy office. The Certificate of Completion can be found on the Board's Web site at www.pharmacy.state.mn.us/forms/cecert10.pdf.

Please note that the Board is in the process of enhancing its licensing and regulatory database to allow for the online reporting and certification of continuing education. When that feature is available, pharmacists and technicians will have the option of certifying the completion of their continuing education using the online services section of the Board's Web site.

Remotely Engaging in Dispensing Activities

The Board has become aware of pharmacists who remotely perform portions of the dispensing process from locales that are not licensed pharmacies. (For example, pharmacists logging in from home or from a corporate location not licensed as a pharmacy.) Please note that the process of dispensing a drug includes, among other things, prescription data entry, pharmacist review of such data entry, prospective drug utilization review, and certification of prescriptions. Per Minnesota Statute §151.15, it is "unlawful for any person to compound, dispense, vend, or sell drugs, medicines, chemicals, or poisons in any place other than a pharmacy." Since the activities mentioned above are part of the dispensing process, they must be done within a licensed pharmacy. Pharmacists should not log in remotely from unlicensed places, including their homes, to perform these activities.

In the case of hospitals that do not have pharmacies that are open 24 hours per day, the Board has approved variances that allow for one pharmacy to provide remote, after-hours order-entry for another pharmacy. The Board's rules concerning central service pharmacies (Chapter 6800.4650) also allow for certain dispensing functions to be performed remotely by a pharmacy that is working on behalf of another one. However, the Board cannot allow dispensing activities to be performed remotely from unlicensed places.