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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** and **pharmacies** between the dates of September 10, 2008 and December 3, 2008.

Schultz, Lyndon, License #111267. Mr Schultz petitioned the Board for reinstatement of an unrestricted license to practice pharmacy. The Board had suspended his license on May 5, 2004, based on his diversion of controlled substances. The Board granted the petition and issued an Order of Reinstatement.

Jordan, Marjorie, License #114180. Ms Jordan was found to have engaged in the habitual indulgence in narcotics and intoxicating liquors in a manner that could endanger the public. At its September 10, 2008 meeting, the Board issued a stipulation and consent order that placed Ms Jordan on probation and referred her to the Health Professional Services Program. Ms Jordan subsequently offered to voluntarily surrender her license. The Board accepted her offer and issued an Order of Voluntary Surrender at its December 3, 2008 meeting.

The Internet and the Abuse of Prescription Drugs (Part 2)

As was noted in the last quarterly *Newsletter*, the Board recently disciplined five pharmacists and one pharmacy for involvement with Internet Web sites that offered to arrange for the sale of legend drugs. The Web sites paid physicians and a physician assistant, licensed in other states, to write prescriptions based on their review of questionnaires filled out by customers. Those purported prescriptions were then made available electronically to the pharmacists who worked at two licensed Minnesota pharmacies. The pharmacists shipped legend drugs to customers located across the country. Controlled substances were shipped by one of the pharmacies. The actions of the pharmacists violated a number of state and federal laws and rules.

The last *Newsletter* contained information about a law passed by the Minnesota Legislature earlier this year that establishes that prescriptions for controlled substances and certain other drugs (butalbital, tramadol, muscle relaxants, and erectile dysfunction drugs) are not valid unless the prescriptions or orders are based on a documented patient evaluation, including an **in-person** examination, adequate to establish a diagnosis and identify underlying conditions and contraindications to treatment. Pharmacists are prohibited from knowingly dispensing prescriptions that do not meet the criteria for a valid prescription. The ways in which the requirement for an in-person examination can be met were explained in the October 2008 *Newsletter*.

Congress passed a similar law in October 2008 – the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. This law specifies that “no controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.” It defines “valid prescription” to mean a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one **in-person** medical evaluation of the patient. (That is, the patient must be in the physical presence of the prescribing practitioner.) A practitioner who has not conducted an in-person evaluation is allowed to write a controlled substance prescription for a patient – but only at the request of a practitioner who has conducted an in-person evaluation of that patient.

Under this new federal law, the requirement for an in-person evaluation does not apply when a practitioner is engaged in the practice of telemedicine. Some illegitimate Internet Web sites try to legitimize their actions by claiming that the physicians working for them contact customers by phone and are therefore engaged in the practice of telemedicine. However, Minnesota law is stricter than the federal law in this regard. First, physicians in other states who wish to provide telemedicine to Minnesota residents must pay a fee and register with the Minnesota

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FDA Web Site Upgrades Support MedWatch's Patient Safety Goal

Two recently launched additions to the Food and Drug Administration's (FDA) Web site are intended to support the "Patient Safety" goal that MedWatch shares in public health efforts to protect patients from serious harm and improve outcomes. The entry pages assist health care professionals and patients to locate timely safety information for FDA-regulated human medical products and assist them in making diagnostic and therapeutic decisions.

The content and links on the new FDA entry page specifically for health care professionals allows busy doctors, pharmacists, nurses, and other health care professionals to find information to make point-of-care decisions. There is information that is specifically safety-related, such as easy access to reporting adverse events or finding new safety alerts, warnings, and recalls. Users can also find content regarding new approvals information, or access to the current version of the label, or prescribing information in "DailyMed." This page can be accessed through www.fda.gov/healthprofessionals.

FDA's other new page is specifically for patients and provides two patient-friendly articles about reporting adverse events and product quality problems to FDA and to the patient's caregivers. These articles are also available to pharmacists in printer-friendly PDF versions that can be downloaded and distributed to patients. FDA relies on properly and timely reporting of serious and unexpected drug and device-related adverse events, use errors, and quality problems. Pharmacists can ascertain and teach their patients to understand the "what, why, and how" to report to FDA and also learn about what happens to each received report and whether it leads to FDA action that may make product use safer for both patients and providers. FDA's patient specific page can be found at www.fda.gov/consumer/default.htm.

Retail Pharmacies Now Providing Medical Clinics to Improve Public Safety



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with USP and 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: 200 Lakeside Dr;

Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Retail pharmacy corporations have set up medical clinics within pharmacies. These nurse-practitioner or physician-assistant run clinics aim to rapidly diagnose and treat a limited number of health problems. Many also offer vaccination programs. The first pharmacy-based medical clinics were opened in Minnesota as QuickMedx in 2000, later becoming MinuteClinic in 2002. Currently there are approximately 1,000 sites in 37 states representing almost three million cumulative visits.

The emergence of pharmacy-based medical clinics offers a unique set of opportunities to improve the safety in prescribing and dispensing medications. Do you have a clinic opening in your store? If so, consider these safety recommendations:

- ◆ Meet the nurse practitioners and physician assistants and introduce them to your staff. Show them how your operation works and invite them in for a tour.
- ◆ If you have prescription scanning capabilities, show them how a scanned prescription displays on your monitor. Show them how different prescription blanks scan (eg, colored prescription blanks, blanks with water marks or seals for diversion) and what to avoid using so as not to distort the actual order.
- ◆ If they are using a device that allows them to send prescriptions electronically, have them send test prescriptions to you, invite them in to see how their prescriptions display on your computer and send them back test refill requests.
- ◆ Work together on any issues that arise, such as conflicting directions and special instructions, where the automatic sig indicates one set of patient directions and then the free text special instructions contradict the sig (see image below).

	LORAZEPAM 0.5MG TABLET
Sig:	1 Tablet(s) PO Q6-8H PRN anxiety, insomnia x 30 days
Dispense:	90 Tablet(s)
Special Instructions:	Take one tab as needed for anxiety or insomnia, may repeat x1.
Refills:	5
Signature:	_____

- ◆ Ask prescribers to include the indication for use whenever they write or call in a prescription.
- ◆ Educate them that it is your policy to read back the entire prescription order to them after transcribing it in the pharmacy including spelling the medication name. Let them know you will be using "cock-pit" language, for example, "one six" for "16."
- ◆ Ask them to include both the generic and brand names on all written orders for medications with look-alike and/or sound-alike names.
- ◆ Share with them ISMP safety tools (eg, List of Error Prone Abbreviations, List of Confused Drug Names) found at www.ismp.org/Tools.



- ◆ Let them know you will dispense measuring devices every time they order a liquid medication.
- ◆ Let them know that safety is your priority when filling prescriptions, and invite them to be part of your safety team.

FDA Launches Web Sites on Promotion of Medical Products

On September 3, 2008, FDA launched two new Web sites to provide information for consumers and industry about how FDA regulates the promotion of medical products. Pharmacists can obtain useful information regarding prescription drug advertising regulations as well as refer their patients who may have questions to the site.

The "Advertising Prescription Drugs and Medical Devices" Web site provides a "one-stop shop" portal to information on FDA regulation of medical product promotion. Pharmacists access relevant laws, regulations, and guidances. This site can be found at www.fda.gov/oc/promotion/.

The direct-to-consumer Web site, "Be Smart about Prescription Drug Advertising: A Guide for Consumers" is designed to educate consumers about how to view such advertising to help inform their discussions with health care providers, and consequently to help improve patient's understanding and medical care. This site was created in collaboration with EthicAd, an independent, nonprofit organization dedicated to helping consumers, health care professionals, and the pharmaceutical and advertising industries with direct-to-consumer advertising for prescription drugs. More information can be found at www.ethicad.org.

The direct-to-consumer site provides interactive example ads for fictitious drugs to illustrate the different requirements for the various types of ads. It also includes a list of questions patients should ask themselves when they see a prescription drug ad. This list can be printed for patients to use while discussing questions with their health care providers. This site can be found at www.fda.gov/cder/ethicad/index.htm.

FPGEE Returns to Computer-based Format

As advancements in secure testing technology forge ahead, the push for more electronically based systems and less use of the traditional paper-and-pencil mechanisms continues. With this in mind, NABP will soon be returning the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) to a computer-based format, eliminating the paper-and-pencil examination.

The FPGEE is the third computerized examination to be developed by NABP, after the North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®). The new computerized FPGEE will debut at the April 14, 2009 administration.

The computerized FPGEE examination will continue to be administered one day in the spring and one day in the fall; however, instead of limiting the available testing locations to three sites, applicants will be able to choose from more than

200 Pearson VUE testing sites located within the continental United States. In addition, it is anticipated that applicants will be able to schedule their test sites electronically 48 to 72 hours after having been accepted to take the FPGEE.

The NABP test vendor, Pearson VUE, will administer the computerized FPGEE as it does with the NAPLEX and the MPJE. Demonstrating a record of solid customer service combined with a secure and consistent test center network, Pearson VUE is committed to providing a reliable and professional testing environment for applicants on behalf of NABP.

The FPGEE is one component of the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certification process. In addition to passing the examination, FPGEC applicants are required to have certain documents submitted from educational and licensure institutions that present their educational backgrounds and licensure and/or registration to practice pharmacy. Applicants must also pass the Test of English as a Foreign Language™ (TOEFL®) and the Test of Spoken English™ (TSE®), or the TOEFL Internet-based Test (iBT). The FPGEC certificate allows foreign graduates to partially fulfill eligibility requirements for licensure in the 50 United States and the District of Columbia where the certification is recognized.

To prepare for the FPGEE, NABP recommends that applicants take the Pre-FPGEE®, the official FPGEE practice examination written and developed by NABP. This practice examination is designed to help familiarize applicants with the FPGEE by exhibiting the types of questions provided on the actual examination as well as providing a score estimate.

Additional information on the FPGEE as well as the Pre-FPGEE is available in the Examination Programs section on the NABP Web site at www.nabp.net.

Updated 2009 Survey of Pharmacy Law Now Available

The NABP 2009 *Survey of Pharmacy Law*, providing a concise research source for key regulatory questions in pharmacy practice for all 50 states, the District of Columbia, and Puerto Rico, is now available.

The *Survey* updates, graciously provided by the state boards of pharmacy, consist of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Also, a new question in Section VII, "Issuance of Initial Pharmacist Licensure," asks whether or not states require criminal history record checks for initial licensure as a pharmacist.

To order the *Survey*, visit the NABP Web site at www.nabp.net and download an order form; the *Survey* costs \$20.

All final-year pharmacy students receive the CD-ROM free of charge through the generous sponsorship of Purdue Pharma LP.

More information on the *Survey* is available by contacting customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

Board of Medical Practice. In addition, prescriptions for controlled substances, butalbital, tramadol, muscle relaxants, and erectile dysfunction drugs are valid when issued by a consultant practitioner who is providing services by means of telemedicine – but **only** if a referring practitioner has performed an in-person examination. Typically, customers of the illegitimate Web sites have not been referred to the physicians working for the Web site.

The Ryan Haight Act also requires Internet pharmacy Web sites to identify the business, pharmacists, and physicians who are associated with the Web site. This information must be displayed on the home page of the Web site. The new law also empowers a state attorney general to shut down an illegitimate Web site across the country, rather than only barring sales to consumers of his or her state.

The Minnesota Pharmacists Foundation (MPF) recently launched a program designed to increase awareness about the dangers of prescription drug abuse. The program is called AWA_Rx_E and it was inspired by the death of St Cloud resident Justin Pearson. Justin passed away on Christmas Day in 2006 from an overdose of prescription drugs – which he ordered online and obtained from pharmacies around the country, including at least one in Minnesota. The Minnesota Board of Pharmacy is one of several organizations that is partnering with the MPF in this effort. Among other activities, AWA_Rx_E is partnering with the DARE program to connect local pharmacists and physicians with DARE officers to provide education in schools and communities. Pharmacists wishing to learn more about volunteering or about AWA_Rx_E in general can visit the Web site at www.awarx.org.

E-Prescribing and Controlled Substances

The Board frequently receives questions from pharmacists concerning the legal validity of controlled substance prescriptions that have been electronically “signed.” Such prescriptions may have the electronically captured signature of the prescriber printed on them. Or a phrase such as “electronically signed by the prescriber” may be printed on the prescription. They are sometimes directly faxed to the pharmacy, sometimes sent via true e-prescribing to the pharmacy’s computer, and sometimes are printed out and given to the patient. Regardless of how an electronically “signed” controlled substance prescription arrives at the pharmacy, it is not legally valid. Current federal laws and rules do not permit electronic signatures for controlled substance prescriptions.

This may change because the United States Drug Enforcement Administration (DEA) recently published proposed rules for the electronic prescribing of controlled substances. There are indications that those rules may be adopted by April 2009. However, here is an excerpt of DEA’s description of the rules that are **currently** in place. This description clearly indicates that DEA inter-

prets current federal laws and rules to prohibit electronic signatures for controlled substances:

A pharmacist may dispense a Schedule III or IV controlled substance only pursuant to a written and **manually** signed prescription from an individual practitioner, which is presented directly or transmitted via facsimile to the pharmacist, or an oral prescription, which the pharmacist promptly reduces to writing containing all of the information required to be in a prescription, except the signature of the practitioner (21 U.S.C. 829, 21 CFR 1306.21). (Emphasis added).

Schedule II controlled substance prescriptions must also be manually signed by the prescriber but can only be phoned or faxed to a pharmacy in the limited circumstances allowed under federal law and rules. Further information is available on the Board’s Web site at www.phcybrd.state.mn.us/faq.htm#9.

Note that a **manually** signed Schedule III or IV controlled substance prescription can be presented directly to the pharmacist. A **manually** signed Schedule III or IV prescription can also be faxed to the pharmacist. However, there is nothing that allows an **electronically** signed controlled substance prescription to be “directly” faxed from an electronic medical record to a pharmacy. Instead, the Board advises pharmacists that an electronically generated prescription for a controlled substance drug is not valid unless it has been printed out and manually signed by the prescriber. A pharmacist that receives an electronically signed Schedule III or IV controlled substance prescription is allowed to contact the prescriber and take the prescription as an oral order. The Board understands that it can be inconvenient and time-consuming to do this. However, until DEA adopts the proposed rules mentioned above, the Board has no choice but to advise pharmacists to obey the current federal laws and rules. Board staff has provided information about this issue to the boards that license prescribers, to the Minnesota Medical Association, and to some of the health care systems that are using electronic prescribing systems – in hopes that the prescribers would be notified of the requirement for controlled substance prescriptions to be manually signed.

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