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Minnesota Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Actions

The following disciplinary actions were brought to conclusion by the Minnesota Board of Pharmacy during the three-month period of September, October, and November 2002.

Pliner, Michael T., License #112066-2. Licensee was found to be in violation of a previous Board Order relating to the personal use of prescription drugs that was not authorized by a licensed practitioner. Licensee diverted carisoprodol from his place of employment for his personal use.

Licensee's license to practice pharmacy was suspended for an indefinite period of time.

Drugs Exempt from Mandatory Generic Substitution

Under the terms of the generic substitution law in Minnesota, the Minnesota Department of Human Services (DHS) Drug Formulary Committee is to periodically review the list of drugs exempt from the mandatory generic substitution requirement. The DHS Drug Formulary Committee recently announced that, effective November 6, 2002, there are only two drug products listed as exempt from the mandatory generic substitution requirement. Those drugs are levothyroxine and phenytoin sodium 100 mg extended-release capsules.

Under the language of the generic substitution law, substitution is not required for these items when prescribed as a brand-name product. Pharmacists may still exercise their professional judgment; however, in determining whether a generically equivalent product might also be therapeutically equivalent and, if the pharmacists believe that to be the case, substitution can still occur. Substitution with a generically equivalent product is not required, however, as is the case for all other products for which a generic equivalent is available.

Installation of Automated Prescription-filling Technology Requires Variance

The Board wishes to remind pharmacists-in-charge (PICs) of all Minnesota pharmacies that Board of Pharmacy Rules require the pharmacist to check the original manufacturer's container from which the medication was withdrawn during the certification steps performed at the conclusion of the prescription-dispensing process. The use of automated medication counting devices of one kind or another generally makes it difficult, if not impossible, for pharmacists to comply with this requirement.

As a result, pharmacies installing automated prescription counting or dispensing devices must apply to the Board for a variance from this requirement. Variance request forms can be downloaded from the Board's Web site at www.phcybrd.state.mn.us. When

submitting a variance request for the use of automated dispensing equipment, the PIC should include with the variance request form a copy of the policies and procedures in place at the pharmacy for the use of this equipment.

In reviewing the variance requests, the Board's Variance Committee tends to pay particular attention to alternative safeguards that are part of the automated system. In addition, particular attention is also paid to the training process for pharmacy staff that will be operating the equipment.

Below is a copy of the guidelines the Board has developed for the implementation and use of these types of automated systems. The Board's Variance Committee will also use these guidelines during its review of variance requests it receives relating to the use of these automated systems.

Automated Counting Machine Guidelines

The Board of Pharmacy must be notified, in writing, before distributing, dispensing, or vending any legend drug by an automatic or vending machine. The written notification must include the name and address of the pharmacy responsible for control of the system, and the name of the pharmacist-in-charge (PIC) of the pharmacy. Policies and procedures should also be included with the notification. See **MN Rule 6800.2600**.

1. All filling of cells/cassettes need to be addressed as prepackaging, with compliance and documentation of all steps in **MN Rule 6800.3200, Subpart 1**.
2. All filling of cells/cassettes should be done with only one drug at a time.
3. When multiple stock bottles of a drug are used to fill a cell/cassette, all stock bottles used must be available for the pharmacist to check.
4. A system must be in place that addresses calibration, sanitation, and cross-contamination. Penicillin, sulfa, etc, should not be used in a system with a common spout. Drugs that can cause serious unintended harm to the pharmacy staff should not be used in any system without prior Board approval.
5. Labeling of the vials, cells, or cassettes must be addressed as required in **MN Rule 6800.3200, Subpart 2**, to prevent errors.
6. Certification as required in **MN Rule 6800.3100, Subpart 3**, must be complied with and documented. Specifically, how will a pharmacist check the original labeled container of a product from the automated counting machine? This must be determined and stated in your policies and procedures.
7. Those drugs that can be safely returned can only be returned to the cell/cassette by a pharmacist. Commingling of lot numbers must be tracked and documented. Lot numbers not tracked and documented shall result in such medication be-

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NABP Examination Security Group Detects FPGEE Security Breach, Halts Examination

The National Association of Boards of Pharmacy® (NABP®) Examination Security Group recently discovered a security breach in the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) improperly caused by a group of FPGEE candidates. As a result of the breach, administration of the FPGEE has been halted as of November 19, 2002, until a new examination can be established. The Association will notify candidates in writing concerning future examination dates in early 2003.

“Upon learning of this serious breach of security, NABP, in keeping with its responsibility of aiding the state boards in the protection of public safety and welfare, initiated a large-scale investigation and will pursue all workable remedies to the fullest extent as permitted by law,” states NABP President John A. Fiacco. “We deeply regret having to take such serious actions, but feel that it needs to be made clear to candidates that NABP does not tolerate such security breaches. We are also creating additional security measures to protect against possible future breaches.”

Although all sources of the cause of the security breach have not been determined, NABP is working to establish which scores have been compromised by the breach. Accordingly, NABP has been forced to take the following steps to protect the public health and welfare and ensure the integrity of its testing program:

1. Computer-based FPGEE scores affected by the compromise will be invalidated.
2. Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certificates awarded to candidates who passed the exam affected by the compromise will be invalidated.
3. All existing FPGEE appointments have been cancelled and no new appointments can be made at this time.

This incident is isolated to the FPGEE and does not affect NABP’s North American Pharmacist Licensure Examination™ (NAPLEX®), Multistate Pharmacy Jurisprudence Examination™ (MPJE®), or Disease State Management (DSM) examinations.

Candidates with questions may visit NABP’s Web site at www.nabp.net for updated information or e-mail the Customer Service Department at custserv@nabp.net. Individuals without Internet access may contact NABP’s Customer Service Department at 847/698-6227.

FDA Approves Subutex, Suboxone to Treat Opiate Dependence

The US Food and Drug Administration (FDA) announced on October 8, 2002, the approval of Subutex® and Suboxone® tablets for the treatment of opiate dependence. Both medications treat opiate addiction by preventing symptoms of withdrawal from heroin and other opiates. Based on the potential for abuse of the drugs, FDA and the Department of Health and Human Services recommended that Drug Enforcement Administration (DEA) place the active ingredient, buprenorphine, in Schedule III under the Controlled Substances Act (CSA).

These products represent two new formulations of buprenorphine and are supplied in 2 mg and 8 mg tablets that are placed under the tongue and must be allowed to dissolve. The first of these formulations, Subutex, contains only buprenorphine, and is intended for use at the beginning of treatment for drug

abuse. The other, Suboxone, contains both buprenorphine and the opiate antagonist naloxone, and is intended to be the formulation used in maintenance treatment of opiate addiction. Naloxone guards against intravenous abuse of buprenorphine by individuals physically dependent on opiates.

Subutex and Suboxone are the first narcotic drugs available for the treatment of opiate dependence that can be prescribed in an office setting under the Drug Addiction Treatment Act (DATA) of 2000. Under this new law, medications for the treatment of opiate dependence that are subject to less restrictive controls than those of Schedule II can be prescribed in a doctor’s office by specially trained physicians.

The sponsor, Reckitt Benckiser Pharmaceuticals, in collaboration with FDA and with input from other Health and Human Services agencies, has developed a comprehensive risk-management program designed to deter abuse and diversion from its legitimate use in patients and physicians regarding proper use of these drugs, close monitoring of drug distribution channels, and child-resistant packaging.

The risk-management program also provides for active and passive surveillance to identify if and when the drugs are being abused. The surveillance will include interviews with substance abusers, monitoring local drug markets, data collection, and the monitoring of adverse event reports. Reports of the results of these surveillance efforts will enable FDA to identify untoward effects from the availability of buprenorphine and, if indicated, to take appropriate actions to protect the public health.

In addition, the provisions of the DATA include limits on the number of patients individual physicians are allowed to treat and a special DEA registration for the use of this drug, thus providing additional safeguards as this drug enters the office-based treatment setting.

USP Launches New Dietary Supplement Verification Program

The United States Pharmacopeia (USP) announced the launch of its new Dietary Supplement Verification Program (DSVP) that will help inform and guide pharmacists when recommending a dietary supplement.

Currently, some dietary supplement products bear the USP initials that are placed on a label voluntarily by a manufacturer. By placing the USP initials on a dietary supplement product’s label, a manufacturer states that they have complied with USP standards for one or all of the following: strength and potency, dissolution and disintegration, and purity, which are met by meeting a USP analytical monograph standard.

DSVP is a program that manufacturers join voluntarily. Unlike the USP initials, the DSVP mark represents that a participant’s product was submitted for review and meets USP’s rigorous criteria. Under DSVP, USP evaluates and certifies dietary supplements according to stringent standards for purity, accuracy of ingredient labeling, and proper and sanitary manufacturing practices. The DSVP mark helps assure pharmacists that the dietary supplements they recommend:

- ◆ Contain the ingredients stated on the label;
- ◆ Have the declared amount of strength of ingredients;
- ◆ Will dissolve effectively to release the contents of the dietary supplement for absorption into the body;

Compliance News

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- ◆ Was tested for harmful contaminants such as heavy metals, E. coli, and pesticides; and
- ◆ Have been manufactured using safe, sanitary, and well-controlled procedures.

Once a product has been certified, USP will periodically conduct random off-the-shelf tests on verified products to ensure they continue to meet DSVP's strict standards. USP also will continue to conduct audits of manufacturer sites for compliance with DSVP requirements.

Dietary supplement products bearing the DSVP mark began to appear on retailer and pharmacy shelves in December 2002. Currently, several companies have joined DSVP: Pharmavite's Nature Made, Weider Nutrition International Inc's Schiff brand of Move Free joint care products, and Inverness Medical Innovations.

For a list of DSVP-certified products or for further information about DSVP, visit www.usp-dsvp.org.

Accutane Medication Guide Changes

The updated version of the Accutane Medication Guide (MedGuide), distributed to pharmacists in early September 2002, is now printed on **tan** paper and replaces all other versions of the MedGuide. Pharmacists should discard **all** MedGuides printed on white, yellow, or green paper, and distribute only those printed on the tan paper. This Medication Guide for Accutane summarizes, in simple language, the professional package insert, including the approved indication for Accutane and major adverse events reported in the package insert. The revision to the MedGuide was developed in conjunction with the US Food and Drug Administration (FDA), and replaces the MedGuide released in July 2002.

Misidentification of Alphanumeric Characters

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with US Pharmacopeia (USP) and the 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, then publishes its recommendations. 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.



A potentially serious medication error was reported recently because a lower case "L" was the end letter in a drug name and was misread as the number 1. An order for 300 mg of **TEGRETOL** (carbamazepine) BID was misinterpreted as 1300 mg BID. The letter "L" at the end of Tegretol had been written very close to the numerical dose of 300 mg on a prescription for the patient (Tegretol300 mg). The pharmacist was unfamiliar with the medication and the pharmacy computer system did not alert him that the dose exceeded safe limits. The patient received only one dose in error before another pharmacist caught

the mistake and the patient was informed. The single dose made the patient lethargic, but not seriously toxic. It is not uncommon to read a letter or number differently than the writer intended. Recently, a pharmacist read the word "IODINE" in a space on a patient profile for allergy alerts. Yet, a second pharmacist read the allergy as "LODINE."

Computerized physician order entry (CPOE) can overcome most problems with poor handwriting and, fortunately, use of such technology is growing. However, even typed or computerized physician orders may not help prevent all problems. Anyone familiar with e-mail knows how easy it is to misidentify a computer-generated lower case letter L (l) in an e-mail address as the numeral one (1), or the letter O as a zero (0)! Even when using character recognition software, drug names may be translated incorrectly. For example, when we tested Lodine, typed with a lower case L, the software recognized the drug name as Iodine. Likewise, it's easy to confuse the upper case letter Z with the number 2. In fact, research conducted by Bell Laboratories found that some symbols are more vulnerable than others to misidentification (Nierenberg GI. Do it right the first time. New York: John Wiley and Sons 1996). The previously mentioned characters (I/1; O/0 and Z/2) plus the number 1, which can look like a 7, accounted for over 50% of the errors caused by character misidentification in the study.

Adequate spacing between the drug name and the dose is crucial on prescriptions and electronic formats such as pharmacy computer selection screens, computer-generated medication labels and records, printed forms and communications, shelf labels, etc. For example, even a clearly typed order for 25 mcg of **LEVOXYL** (levothyroxine) could be misread as 125 mcg if it appears without proper spacing as Levoxy125 mcg, especially since both strengths are available.

Many drug name recognition errors can be reduced with block printing using upper case characters. We've seen some prescription forms incorporate shaded blocks for this purpose. Pharmacists should encourage this style of writing and use of such forms. Symbolic differentiation is another way to distinctively convey a symbol's meaning. Throughout Europe, it's common to see a zero written with a slash through it to differentiate it from the letter "O." The number 7 can be written with a bar through it to prevent confusion with the number 1. The letter "Z" with a bar through it also can prevent confusion with the number 2. Stricter adherence to these principles would help reduce character misidentification. The potential for name-related errors is greatly reduced when pharmaceutical manufacturers incorporate practitioner testing of drug names and doses into their new drug development process. By using samples of cursive and printed characters practitioners can often recognize potential problems, which can help manufacturers avoid dangerous product names. Finally, the drug and dose have to make sense to the pharmacist; otherwise follow up with the prescriber is necessary. However, the context in which the order is being read may not always be helpful in properly identifying alphanumeric characters. While it would be unlikely to read ZETAR as "2TAR," it would be easy to read an order for "HCTZ50mg" as either hydrocortisone 250 mg or hydrochlorothiazide 50 mg (and yes, this has actually happened!). Avoiding drug name abbreviations is a subject we will tackle in the future.

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ing deemed misbranded and subject to embargo under **MN Statutes, §151.38**.

8. Implement a Quality Assurance/Quality Improvement monitoring system with concurrent corrective measures when necessary. See **MN Rule 6800.2400, Subpart 1. J.**, which states that the PIC must ensure that staffing and operational quality assurance policies, including training, are developed, implemented, and followed for the purpose of decreasing and monitoring prescription errors. Training in the use of the equipment shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with operational policy requirements applicable to them. This training should be documented.
9. Any proposed variance request that is a deviation from these rules must follow **MN Rule 6800.9900**, which states that any alternative measure taken must be equivalent or superior to current rules.
10. Failure to provide notification to the Board of Pharmacy, as required by **MN Rule 6800.2600**, may result in the Board of Pharmacy prohibiting use of the automated counting machine.

The Health Professionals Services Program: A Unique Alternative

Health professionals, like anyone else, are susceptible to substance abuse as well as psychiatric and medical disorders. Left untreated, these illnesses can put patients at risk. Until recently, the only options to address these illnesses were to ignore the potential impairment or file a report with the licensing board.

Created in 1994 as an alternative to Board discipline, the State of Minnesota's Health Professional Services Program (HPSP) offers a proactive way to get confidential help for these kinds of illnesses.

Many people are unclear about their reporting obligations and feel uneasy about reporting themselves, a colleague, or an employee to HPSP. Getting involved in the personal issues of another professional is a difficult decision. Yet, there is the ethical duty to protect patients from potential harm. All referrals made to HPSP are regarded as privileged data and kept confidential. Anyone who submits a report "in good faith" is immune from civil liability or criminal prosecution (Minn. Stat. 214.34).

Pharmacists refer themselves to HPSP at a higher rate than most other professionals, which can be attributed to the hard work and dedication of Jim Alexander, the director of the Pharmacy Recov-

ery Network (PRN). He has been instrumental in ensuring that pharmacists get the help they need and refer themselves to HPSP.

Nearly 2,000 health professionals have enrolled in HPSP since the program's inception eight years ago. HPSP currently provides monitoring services to approximately 480 licenses. Of these, 64% either reported themselves to the program or were referred by a third party, usually a coworker or employer. Because pharmacists are often the first health care providers to identify symptoms of drug abuse, they act as an important referral source. Licensing boards also make referrals to HPSP, sometimes in conjunction with disciplinary actions.

The program monitors treatment progress, work quality, and medications, along with attendance at support groups and random urine screens if alcohol or drug use is part of the illness. HPSP might also require counseling, work limitations, or other individualized conditions that address the person's needs and public safety. Typically, agreements are for 36 months.

All eligible health care professionals licensed in Minnesota can receive HPSP monitoring services as long as they comply with program expectations. Participants are responsible for the cost of their own evaluation, treatment, and toxicology screens if necessary.

To learn more about HPSP and how to refer someone who may have an illness, call 651/643-2120, visit their Web site at www.hpssp.mn.state.us, or write for information at 1885 University Ave, Suite 229, St Paul, MN 55104.

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