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New Jersey Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Patient Profile

NJSA 45:14-68 and NJAC 13:39-7.19 require that all pharmacies maintain a Patient Profile Record System (PPRS) to enable the dispensing pharmacist to identify previously dispensed medication at the time a prescription is presented for dispensing. One profile may be maintained for all members of a family with the same family name living at the same address. Each profile must include the following information: 1) family name and patient first name; 2) patient address and telephone number; 3) patient age, date of birth, or age group (infant, child, or adult) and gender; 4) date of each dispensing and initials of dispensing pharmacist (unless initials are recorded on the back of the original prescription or other New Jersey Board of Pharmacy-approved record); 5) prescription number; 6) name of prescriber; 7) drug name, strength, and quantity dispensed; 8) the individual history, if significant, including known allergies and drug reactions, known diagnosed disease states and a comprehensive list of medications and relevant devices (if no relevant allergies or medical conditions exist this must be noted in the profile); and 9) pharmacist comments relevant to drug therapy.

Each time a new or refill prescription is presented for dispensing, the PPRS must permit the dispensing pharmacist to immediately retrieve any information necessary to identify previously dispensed medications for that patient. The dispensing pharmacist must review the profile, determine if any adjustment to the profile is indicated, and attempt to identify any potential drug interactions, adverse effects, or drug misutilization. Should any potential drug interactions, adverse effects, or drug misutilization be identified the dispensing pharmacist must take the appropriate action prior to dispensing, which may include consultation with the patient and/or prescriber.

Each patient profile must be maintained for at least five years from the date of last entry. If the PPRS is maintained as an electronic database, the system must be capable of producing retrievable and readable documents of all original and refilled prescription data. For the oldest four years of information these documents must be retrievable and readable within two weeks. For the most recent one year these documents must be retrievable and readable immediately.

Drug Addiction Treatment Act of 2000

The Drug Addiction Treatment Act of 2000 (DATA 2000) grants a waiver to qualifying physicians (doctor of medicine or doctor of osteopathy) allowing them to treat opioid-addiction

with certain Food and Drug Administration (FDA)-approved Schedule III, IV, and V narcotics. Subutex® (buprenorphine hydrochloride) and Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride dihydrate) were given an FDA-approved indication for the treatment of opioid addiction on October 8, 2002. To qualify for a waiver physicians must meet special requirements. Prior to dispensing these agents it is recommended that you consult the following Web site: www.suboxone.com/hcp/pharmacists/. Pharmacists receiving a prescription for Suboxone or another approved narcotic to treat opioid addiction should verify that the prescriber has been granted a waiver. The following can be used to verify that the prescriber is approved to prescribe Suboxone or Subutex for opioid addiction: 1) check the prescriber's Drug Enforcement Administration (DEA) number; physicians granted a waiver under DATA 2000 are issued a special DEA number that always begins with "X"; as of July 2005 physicians are required to include this special DEA number on all prescriptions for Suboxone or Subutex; 2) check the Substance Abuse and Mental Health Services Administration (SAMHSA) physician locator at: www.buprenorphine.samhsa.gov; 3) call SAMHSA at 1-866/287-2728 (physicians can elect not to be listed on the Web site); or 4) call the prescriber and ask to have the DEA registration certificate faxed to you. **Please Note:** Federal regulations require a greater degree of confidentiality regarding patient information pertaining to patients who are being treated for substance abuse; therefore, when verifying a prescriber's waiver, it is a violation of federal regulations to disclose the identity of the patient for whom the prescription was written, even if you are speaking directly to the prescribing physician.

Health Care Professional Responsibility and Reporting Enhancement Act

The Health Care Professional Responsibility and Reporting Enhancement Act requires a health care professional to promptly notify the Division of Consumer Affairs or Board if he or she is in possession of information that reasonably indicates that another health care professional has demonstrated an impairment, gross incompetence, or unprofessional conduct, which would present an imminent danger to an individual patient or to the public health, safety, or welfare (see NJSA 45:1-37). The act also includes language that provides immunity from civil liability for anyone who provides information in good faith and without malice and provides for confidentiality of information pending final disposition of the inquiry or investigation.



Generic Substitution Issues

This is a reminder to pharmacists regarding the legal generic substitution of certain drug products. Recent practices by pharmaceutical manufacturers involving the reformulation of drugs into alternative dosage forms (eg, tablets to capsules) seem to have caused some confusion.

Generic substitution is the act of dispensing a different brand or unbranded drug product than the one prescribed. Generic substitution is only allowable when the substituted product is therapeutically equivalent to the prescribed innovator product. Generic drug manufacturers must provide evidence to Food and Drug Administration (FDA) of therapeutic equivalence, which means that both products are pharmaceutically equivalent (eg, have the same active ingredients in the same dosage form and strength, and use the same route of administration) and bioequivalent (eg, have more or less the same rate and extent of absorption). Therapeutically equivalent drugs are expected to produce the same clinical benefits when administered for the conditions approved in the product labeling.

FDA assigns two-letter therapeutic equivalence codes to generic products when the products meet both the aforementioned requirements, are approved as safe and effective, are adequately labeled, and are manufactured in compliance with current Good Manufacturing Practice regulations. The primary reference guide for pharmacists on therapeutic equivalence is FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book." Drug products determined to be therapeutically equivalent to innovator drugs are assigned an "A" for the initial letter of their therapeutic equivalence code. The second letter provides additional information regarding the product: products rated AA, AN, AO, AP, or AT are those with no known or suspected bioequivalence problems (rating depends on dosage form). An AB rated product indicates that actual or potential bioequivalence problems have been resolved with adequate in vivo and/or in vitro evidence. In contrast, drugs assigned a "B" for the initial letter are not considered therapeutically equivalent because bioequivalence problems have not been resolved to the satisfaction of FDA.

A recent example of improper substitution has been brought to the attention of several boards of pharmacy by Acorda Therapeutics, the maker of Zanaflex[®] tablets, who recently released Zanaflex Capsules[™] (tizanidine hydrochloride). Although the active ingredient in Zanaflex Capsules is the same as the active ingredient in Zanaflex tablets and generic tizanidine tablets, their formulations are different. For this reason, FDA has deemed there to be no therapeutic equivalent to Zanaflex Capsules and has not assigned a therapeutic equivalence code.

A similar situation existed in 1995 when the manufacturer of Sandimmune[®] (cyclosporine) capsules and oral solution, Sandoz, (now Novartis), came out with NEORAL[®] (cyclosporine) capsules and oral solution for microemulsion. Due to differences in bioavailability, Sandimmune and Neoral, and their accompanying generic versions, were not, and still are not, rated as substitutable.

It must be emphasized that generic substitution mandates are found in individual state laws and regulations. In states where generic substitution is allowed only for "Orange Book" A-rated

products, pharmacists may not substitute a generic product for a non-A-rated product. Some states may have developed their own generic substitution lists or formularies. Pharmacists are encouraged to review the laws and regulations in their states to determine the appropriate legal methods by which to perform generic substitution.

Preventing Errors Linked to Name Confusion



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 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.

The Institute for Safe Medication Practices (ISMP) regularly hears about confusion between products with similar names. One such pair is OMACOR (omega-3-acid ethyl esters) and AMICAR (aminocaproic acid) an antifibrinolytic. Omacor is indicated as an adjunct to diet to reduce very high triglyceride levels (500 mg/dL or more) in adult patients. The drug is also being studied as adjuvant therapy for the prevention of further heart attacks in patients who have survived at least one. A pharmacist reported an error in which a telephone order for Omacor 1 gram BID was interpreted and dispensed as Amicar 1 gram BID. Counseling was not provided, but fortunately the patient read the drug information sheet for Amicar before taking any medication and called the pharmacy stating that he was expecting a medication to reduce his triglyceride levels.

While this case illustrates why manufacturers should review and test new trademarks for error potential before the product reaches the market, there are some things that practitioners can do to help prevent errors with products that have look-alike or sound-alike names.

- ◆ Look for the possibility of name confusion before a product is used. Use the concepts of failure mode and effects analysis (FMEA) to assess the potential for error with new medications that will be prescribed or added to your inventory. If the potential for confusion with other products is identified, take the steps listed below to help avoid errors.
- ◆ Prescriptions should clearly specify the drug name, dosage form, strength, complete directions, as well as its indication. Most products with look- or sound-alike names are used for different purposes. If the indication is not available, pharmacists and nurses should verify the purpose of the medication with the patient, caregiver, or physician before it is dispensed or administered.
- ◆ Reduce the potential for confusion with name pairs known to be problematic by including both the brand and generic name on prescriptions, computer order entry screens, prescription labels, and MARs.



- ◆ When accepting verbal or telephone orders, require staff to write down the order and then perform a read back (or even spell back) of the medication name, strength, dose, and frequency of administration for verification.
- ◆ Change the appearance of look-alike product names on computer screens, pharmacy product labels, and MARs by emphasizing, through bold face, color, and/or tall man letters, the parts of the names that are different (eg, hydrOXYzine, hydrALAzine).
- ◆ Pharmacists should work under good lighting and use magnifying lenses and copyholders (keep prescriptions at eye level during transcription) to improve the likelihood of proper interpretation of look-alike product names.
- ◆ Install computerized reminders for the most commonly confused name pairs at your site so that an alert is generated when entering prescriptions for either drug. If possible, make the reminder auditory as well as visual.
- ◆ Store commonly confused products in different locations. Avoid storing both products in a "fast-mover area." Use a shelf sticker to help find relocated products.
- ◆ Affix "name alert" stickers to areas where look- or sound-alike products are stored (available from pharmacy label manufacturers) or to the actual product containers.
- ◆ Employ at least two independent checks in the dispensing process (one person interprets and enters the prescription into the computer and another compares the printed label with the original prescription as well as the manufacturer's product).
- ◆ Open the prescription bottle or package in front of the patient to confirm the expected appearance of the medication and review the indication. Caution patients about error potential when taking a product that has a look- or sound-alike counterpart. Encourage patients to ask questions if the appearance of their medication changes. Take time to fully investigate any patient concerns.
- ◆ Encourage reporting of errors and potentially hazardous conditions with look- and sound-alike names to the ISMP-USP Medication Errors Reporting Program and use the information to establish priorities, as listed above, for error reduction. Maintain an awareness of problematic product names and error prevention recommendations provided by ISMP (www.ismp.org), FDA (www.fda.gov), and USP (www.usp.org).

If you are interested in learning what look-alike and sound-alike name pairs have been published in the ISMP Medication Safety Alert!®, a free list is available at www.ismp.org/Tools/confuseddrugnames.pdf.

Combat Methamphetamine Epidemic Act Phasing In

This year, new requirements of the federal Combat Methamphetamine Epidemic Act passed by Congress for the sale of all single and multi-ingredient pseudoephedrine and ephedrine-containing products will become effective. The new law places non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine in a new Controlled Substances Act category of "scheduled listed chemical products." Drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine are subject to sales restrictions, storage requirements, and record keeping requirements.

A 3.6-grams-per-day base product sales limit, 9-grams-per-30-days base product purchase limit, a blister package requirement, and mail-order restrictions went into effect on April 8, 2006,

for all sellers of these products. All other provisions of the law require compliance by September 30, 2006. If a state has more stringent requirements, the stronger requirements remain in place. A summary of this Act's requirements can be found on the United States Drug Enforcement Administration's (DEA) Web site at www.dea diversion.usdoj.gov/meth/cma2005.htm.

Explanation of DEA Regulations on Partial Refilling of Prescriptions

Pharmacists often question the DEA rule regarding the partial refilling of Schedule III, IV, and V prescriptions as stated in Section 1306.23 of the Code of Federal Regulations. Confusion lies in whether or not a partial fill or refill is considered one fill or refill, or if the prescription can be dispensed any number of times until the total quantity prescribed is met or six months has passed. According to DEA's interpretation, as long as the total quantity dispensed meets the total quantity prescribed with the refills and they are dispensed within the six-month period the number of times it is refilled is irrelevant. The DEA rule is printed below:

Section 1306.23 Partial Filling of Prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible provided that:

- (a) Each partial filling is recorded in the same manner as a refilling,
- (b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
- (c) No dispensing occurs after 6 months after the date on which the prescription was issued.

[21 CFR 1306.23]

Electronic Version of DEA Form 106 Now Available

DEA has announced that a secure, electronic version of the DEA Form 106 (Report of Theft or Loss of Controlled Substances) is now available to DEA registrants. The electronic form may now be completed online through a secure connection and submitted via the Internet to DEA Headquarters. Copies of the letter from DEA and the 2005 Final Rule were published in the *Federal Register*. The new interactive form is located at the Diversion Control Program's Web site and may be accessed at www.DEAdiversion.usdoj.gov.

Patients Rely on Pharmacists' Recommendations

Patients consider their pharmacists a trusted source for medication recommendations, as evidenced by the result of a poll recently conducted by the American Pharmacists Association (APhA). APhA polled 3,000 community pharmacists and found that pharmacists were asked about over-the-counter (OTC) products an average of 32 times each week. Of those pharmacists surveyed, 55% said they spend three to five minutes with each patient who asks about an OTC. And patients are listening, for during this consultation time, according to the survey, 81% of patients purchased OTC products recommended by the pharmacist.

The results of the poll was published in APhA's *Pharmacy Today*. Other topics researched in the poll include recommendation habits of pharmacists in leading OTC therapeutic areas including treatments for allergies, adult cold symptoms, adult headache remedies, heartburn, pain relief, and tooth whitening products among others.

Dispensing Alert

A February 24, 2006 "Dear Pharmacist" letter from Reliant Pharmaceuticals, Inc urges pharmacists to be particularly cautious regarding potential "sound-alike" dispensing errors involving Omacor® capsules (omega-3 acid ethyl esters; Reliant Pharmaceuticals, Inc) and Amicar® tablets (aminocaproic acid; Xanodyne Pharmaceuticals, Inc). Omacor capsules are indicated to lower serum triglyceride levels and are available as 1 gram transparent, gold gelatin capsules. Amicar tablets are indicated to enhance blood clotting when fibrinolysis contributes to bleeding, and are available as 500 mg or 1000 mg round white tablets and 250 mg/5 mL oral solution. The following steps are recommended to reduce the likelihood of a dispensing error: 1) install an alert in the computer system; 2) verify both the generic and trade name with the prescriber; 3) for telephone prescriptions ask the prescriber to spell the drug name or state the drug's indicated use; 4) verify the dosage form (Omacor capsule or Amicar tablet) with the prescriber; and 5) match the drug's indication to the patient's diagnosis prior to dispensing.

Should a dispensing error occur, pharmacists are asked to report them using the following telephone numbers: for Omacor capsules, Reliant Pharmaceuticals, Inc at 1-877/311-7515; for Amicar tablets, Xanodyne Pharmaceuticals, Inc at 1-513/636-5145. Medication errors should also be reported to the United States Pharmacopeia Medication Error Reporting Program at 1-800/23ERROR, or the FDA MedWatch Adverse Event Reporting Program at 1-800/FDA-1088.

Disciplinary Actions

The actions listed below include only those where the individual's license to practice has been revoked, surrendered, suspended, restricted, or reinstated and do not include any other actions taken by the Board. Information regarding the current status of a pharmacist's license may be obtained either at the Division of Consumer Affairs Web site or by calling the License Verification Line at 973/273-8090.

License Suspensions/Surrenders/Revocations

Steven Kim, RPh – Respondent engaged in unauthorized practice as a registered pharmacist. Specifically, he utilized fraudulent prescriptions in order to obtain Prescription Legend Drugs for family members and to acquire manufacturer's rebates; committed Medicare fraud by submitting claims utilizing fraudulent prescriptions issued in the name of Respondent's brother; and diverted money from his employer by voiding cash sales or by directly keeping money from cash sales. **Ordered:** Respondent's license to practice pharmacy has been revoked for a period of no

less than two (2) years from the entry date of this Order. (Filed on January 12, 2006.)

Barbara Ann Pesciotta, RPh – Respondent had been working as a pharmacist from August 2004 to April 2005 while her license to practice was surrendered. She presented a false letter to investigators indicating her license had been restored; and had obtained Schedule II controlled dangerous substance (CDS) through the use of stolen and forged prescription blanks. **Ordered:** Respondent's license to practice pharmacy has been surrendered to be deemed a revocation, with prejudice to any re-application. (Filed on January 26, 2006.)

Richard T. Kuk, RPh – Respondent allegedly diverted CDS from his employer for his own consumption by issuing and dispensing pursuant to fraudulent prescriptions for himself and his parents.

Ordered: Respondent's license to practice pharmacy has been revoked with no right to make application for reinstatement prior to the termination of his criminal probation. (Filed on February 22, 2006.)

Doris Seavey, RPh – Respondent continued to work as a pharmacist from April 30, 2001 to November 10, 2005, after her license to practice had expired as a result of her failure to renew in April 2001.

Ordered: Respondent's license to practice has been surrendered to be deemed a revocation, with prejudice to any re-application prior to three (3) years from the date of entry of this Order. Respondent shall pay to the Board of Pharmacy a civil penalty of \$10,000 for engaging in the unlicensed practice of pharmacy. (Filed on February 22, 2006.)

Catherine Fee, RPh – Respondent allegedly filled unauthorized prescriptions for Schedule III and IV CDS. Respondent was charged with obtaining prescription medications by fraud and conspiracy to obtain prescription medications by fraud. **Ordered:** Respondent's license to practice pharmacy in the state of New Jersey has been suspended. (Filed on February 15, 2006.)

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