

July 2006



North Carolina Board of Pharmacy

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Item 2115 – Board Election Results

Pharmacists voted for North Carolina Board of Pharmacy representatives from Districts 1 and 2 in April and May 2006. Board staff tallied the results on May 15, 2006, as follows:

District 1

Rebecca W. Chater 1418
Michael Overman 1172

District 2

Betty H. Dennis 1421
Jack G. Watts 1210

The Board certified Rebecca W. Chater as the winner for District 1, and Betty H. Dennis as the winner for District 2, at the May 2006 meeting. The Board extends congratulations to Ms Chater and Dr Dennis, and heartfelt appreciation for the candidates Messrs Watts and Overman.

Item 2116 – Board Overhauls Web Site

By the time this *Newsletter* goes to press, the Board will have unveiled a redesigned and overhauled Web site. The Board's Web site (www.ncbop.org) has always been a repository of a lot of useful information for practitioners. That information has, however, not always been easy to locate on the Web site. Kristin Moore of the Board's staff has invested many hours, with the able assistance of Tom Buedel, redesigning and streamlining the Web site. Board staff appreciates the many pharmacists who took the time to provide suggestions for improvement. The end result is a significantly more attractive Web site that should be much more user friendly. Board staff welcomes your additional input on improving the Web site.

Among future efforts to continue to streamline our electronic resources, Board staff will now study the feasibility of allowing online original license and permit applications. As you know, online renewals are already available and encouraged. Any pharmacists with suggestions about how original license and permit applications should be handled online should contact Kristin Moore or Tom Buedel at the Board office.

Item 2117 – Internet Pharmacy Issues Continue

The Board of Pharmacy continues to take action against pharmacies that fill prescriptions generated pursuant to online "consultations," "questionnaires," or "surveys." Federal regulators are also taking an active role in stopping this practice. In January 2006, David Work, past executive director of the Board, sent out a reminder to all pharmacists in the state that, under Rule .1801, the filling of any prescription that a pharmacist knows or should know was issued without a physical

examination or without a prior prescriber-patient relationship is prohibited.

The Board is aware that certain online "pharmacies" are actively soliciting pharmacists in this state (targeting principally independent pharmacists) to fill a set number of "online" prescriptions per week, usually in exchange for significant payments. The Board reminds pharmacists that filling these prescriptions is illegal and is a serious threat to the public health and safety. The Board urges pharmacists who receive these offers to report them to the Board office.

Item 2118 – New Rule Allows Temporary Pharmacist-Managers

An amendment to Rule .2502 permitting "temporary" pharmacist managers took effect on April 1, 2006. This amendment was strongly supported by community pharmacists, who are constantly dealing with the "pharmacist shortage" when staffing stores. Under Rule .2502, a permit may employ for a single 90-day period a temporary pharmacist-manager who need only be present in the pharmacy for 20 hours per week. The "temporary" pharmacist-manager responsibilities do not otherwise differ from any other pharmacist-manager. This amendment should aid permittees who are having difficulty bridging from one pharmacist-manager to the next.

Different paperwork is not required for installing a temporary pharmacist manager. Permittees should fill out the same change of pharmacist-manager form (available at the Board Web site) and remit the appropriate fee. Permittees should note on the form or in an accompanying letter that the pharmacist-manager will be "temporary."

Board staff frequently receive requests for extensions of the 30-day deadline by which a permittee must install a new pharmacist-manager, with the result being that a store may go two months or more without any pharmacist-manager. Please take note that Board staff will now look upon such requests with disfavor. For obvious reasons, the Board much prefers that a permittee operate with a temporary pharmacist-manager for 90 days, rather than operate with no pharmacist-manager for 30 or 60 days.

Item 2119 – DEA Numbers on Non-Controlled Prescriptions/Medicaid Audits

Board staff has received several recent inquiries about the need for a prescriber's Drug Enforcement Administration (DEA) number on a prescription for a non-controlled substance. NCGS §134.1 requires that written prescriptions for all legend drugs "must bear the printed or stamped name, address, telephone number, and DEA number of the prescriber in addition to his legal signature."

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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.

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Pharmacists should, of course, use their professional judgment when presented with an otherwise valid prescription for a non-controlled substance that lacks the prescriber's DEA number. Often, the prescriber's DEA number will already be found in the pharmacy's computer system. And, in any event, pharmacists should not unduly obstruct a patient's access to necessary prescription drugs on this basis.

Pharmacists should also be aware, however, that Medicaid auditors apparently are enforcing the requirement of DEA numbers on non-controlled prescriptions for purposes of payment. Medicaid auditors also are apparently refusing to pay for prescriptions on which a medical resident does not include their personal "suffix" to the health care facility's DEA number on written prescriptions.

Item 2120 – Pharmacist-Manager Responsibility To Verify Licensure/Registration Status of Staff Pharmacists and Technicians

The Board reminds pharmacist-managers that they bear personal responsibility to ensure that all staff pharmacists employed at their site are currently licensed by the Board and that all technicians are currently registered with the Board. The Board recently heard a disciplinary matter in which a pharmacist was allowed to practice at a site for several months despite his having failed to renew his license. The pharmacist-manager reported her belief that checking licensure status was primarily the responsibility of the corporate permittee. Remember that under North Carolina law (NCGS §90-85.21), a pharmacy permit is issued jointly to the owner and to the pharmacist-manager. Accordingly, the pharmacist-manager has a corresponding personal responsibility to ensure that all operations at the permitted site are carried out in accordance with state law.

Item 2121 – Medicare Part D Plans and NTI Drugs

The Board has received several complaints that Medicare Part D payors are refusing to reimburse pharmacists for dispensing one particular generic version of a Narrow Therapeutic Index (NTI) drug versus another plan-preferred generic version of an NTI drug. Under North Carolina law (NCGS §90-85.28(b1)), a "prescription for an [NTI] drug shall be refilled using only the same drug product by the same manufacturer that the pharmacist law dispensed under the prescription, unless the prescriber is notified by the pharmacist prior to the dispensing of another manufacturer's product, and the prescriber and the patient give documented consent to the dispensing of the other manufacturer's product." Drugs currently on the NTI list are: carbamazepine, cyclosporine, digoxin, ethosuximide, levothyroxine

sodium tablets, lithium, phenytoin, procainamide, theophylline, and warfarin.

Pharmacists should advise payors of these limitations on substituting NTI drugs and should resist being forced to make a substitution that would violate state law. If a payor refuses to adjust their expectations, please advise Board staff.

Item 2122 – Electronic Signatures on Controlled Substance Prescriptions

Electronic prescribing is an increasing fact of life in pharmacy practice today. Many pharmacists are confused, though, about whether or not and under what circumstances e-prescribing is permissible for controlled substances (CS).

The Board understands that DEA continues to take the position that e-prescribing for Schedule II substances is never appropriate. Federal law permits faxing of Schedule II prescriptions in limited circumstances (such as for residents of long-term care facilities and hospices). But beyond these narrow cases, e-prescriptions for Schedule II substances are prohibited.

The Board also understands that DEA continues to take the position that the only permissible "electronic" prescription for a Schedule III, IV, or V substance is a faxed copy of a paper prescription that the prescriber actually signed. In other words, "electronic signatures," though permitted by state law, are not acceptable for Schedule III, IV, or V prescriptions.

These positions may change in the coming months. DEA has for a number of years pledged to take a fresh look at e-prescribing issues, with no visible result. Medicare Part D, however, specifically directs Centers for Medicare and Medicaid Services (CMS) to develop uniform standards for e-prescribing, a practice that the statute encourages as a potential cost-savings and patient safety improvement. CMS and DEA have jointly noticed a conference among their agencies to discuss e-prescribing issues as they relate to CS. It seems almost certain that DEA will be forced to critically reevaluate its position on these issues.

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