



# SC Department of Labor, Licensing & Regulation – Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

## Board Elections

At its June 2005 meeting, the South Carolina Board of Pharmacy members elected Terry T. Lewis, RPh, as its new chairman. Mr Lewis is a pharmacist representing the Sixth Congressional District. Mr Marvin A. Hyatt, Sr, RPh, was elected to serve as the vice chairman. Mr Hyatt is a pharmacist representing the Fifth Congressional District. Each member will serve a one-year term from July 1, 2005 through June 30, 2006. Congratulations!

## Pharmacy and Hurricane Season

By Leighann Lucas, PharmD Candidate, University of South Carolina College of Pharmacy on rotation with the South Carolina Pharmacy Association

South Carolina is one of the most vulnerable states in the nation to be impacted by hurricanes and tropical storms. Of the state's 46 counties, six have coastlines, which border the Atlantic Ocean.<sup>1</sup> Hurricane season begins June 1 and ends November 30. Meteorologists and weather experts expect a busy year. If a hurricane comes ashore near your area, will your pharmacy be prepared? Even though we need to prepare ourselves and our homes, we have a corresponding responsibility to do all that we can to protect our pharmacies as well. Here are a few tips to get you prepared...

### I. Prepare Ahead of Time<sup>1,2</sup>

- ◆ Prepare a list of all employees with contact information including cell phone numbers, home phone numbers, and e-mail addresses.
- ◆ Assemble a broadcast fax or e-mail list of local radio and television stations with their news phone number.
- ◆ Assemble a broadcast fax or e-mail list of local physician offices and hospitals.
- ◆ Obtain from the County Manager's Office a contact at the South Carolina Emergency Management Division (803/737-8500).
  - ◆ To locate the shelters in your area, go to [www.scemd.org/library/brochures/05hurricaneguide/shelters.html](http://www.scemd.org/library/brochures/05hurricaneguide/shelters.html) for a list of all the area shelters.
- ◆ Make lists of contact information for wholesalers and delivery services such as United Parcel Service and Federal Express.
- ◆ Obtain waterproof covering material for later use. Also make sure to enclose the above lists in waterproof material (eg; Ziploc® bag).
  - ◆ Note: After August 1, 2005, Carolina Pharmacy Network (CPN) (800/865-3699) can be contacted for a Pharmacy Hurricane Prep Kit that will include a checklist of reminders, forms, and contact list prepared for your area. Contact CPN for more details.

### II. Before and After the Storm<sup>1,2,3,4</sup>

- ◆ If controlled substances are lost in a disaster the pharmacist-in-charge (PIC) needs to contact the Drug Enforcement Administration (DEA) District Office in Columbia (803/765-5251) immediately and the Department of Health and Environmental Control Bureau of Drug Control (803/896-0636).
  - ◆ DEA Form 106 and/or a disposal form DEA 41 may need to be completed.
- ◆ Losses must be completed for the Board of Pharmacy (803/896-4700)
  - ◆ All permit holders shall report to the Board of Pharmacy within 10 working days of the discovery of the occurrence of disasters, accidents, destruction, or loss of records required to be maintained by state or federal law (SC State Practice Act, Section 40-43-91).
- ◆ If the pharmacy is to be closed and/or evacuated, the appropriate legal supervisory personnel should be notified.
- ◆ Anticipate power outages. In some cases a portable generator may be advisable. Ice and coolers should be available to store refrigerated products such as insulin. Also make sure to store flammable materials appropriately.
- ◆ If the pharmacy computer is down, prescriptions may be dispensed manually. Labels can be typed or handwritten using a waterproof pen if possible. Patient counseling should clarify any questions the patient may have since printed drug information may not be available.
  - ◆ South Carolina Practice Act 40-43-86 (I-4) states "All drugs dispensed to ambulatory or outpatients shall contain a label affixed to the container in which the drug is dispensed including:
    - (a) the name and address of the pharmacy dispensing the drug;
    - (b) the name of the patient for whom the drug is prescribed;
    - (c) the name of the prescribing practitioner;
    - (d) such directions as may be stated on the prescription drug order;
    - (e) the date of dispensing;
    - (f) any cautions which may be required by federal or state law;
    - (g) the serial number of the prescription drug order;
    - (h) the name or initials of the dispensing pharmacist;
    - (i) the proprietary or generic name of the drug dispensed and its strength, if more than one strength of the drug is marketed;

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## **New Board Will Oversee Management of Drug Safety Monitoring**

Food and Drug Administration (FDA) has unveiled a program that aims to improve oversight of drug safety monitoring and to bolster openness in agency product review and decision making. Included is the creation of an independent Drug Safety Oversight Board, made up of medical experts from FDA and other government agencies. Also planned are Web postings of emerging drug data and risk information as well as written materials that provide targeted drug safety information to the public. For more information, see [www.fda.gov/oc/factsheets/drugsafety.html](http://www.fda.gov/oc/factsheets/drugsafety.html).

## **ACPE Changes Provider Criteria Regarding Drug and Device Manufacturers**

In early 2005, the Accreditation Council for Pharmacy Education (ACPE) ceased accepting applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE). Effective July 1, 2005, the organization will no longer recognize pharmaceutical and biomedical device manufacturers as accredited providers. In addition, any CE issued by a pharmaceutical or device manufacturer after June 30, 2005, is not valid. These changes were approved by the ACPE Board of Directors at its January 2005 meeting after the organization determined that manufacturers could not meet both ACPE's requirements and the recommended restrictions as stated in a Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of the Inspector General of the United States (OIG).

In 2003, OIG stated that manufacturers could be subjected to liability under federal statutory provisions if they maintain any influence over CE subject matter or presenters, or provide funding for attendees or other incentives with respect to CE attendance. Strict compliance with OIG's guidelines would relegate manufacturers to solely providing educational grants to CE providers in order to be free of liability. Meanwhile, ACPE's Criteria for Quality require that the CE provider control the content speakers or authors of a CE program, putting ACPE's requirements in opposition to OIG's guidelines; hence, ACPE, out of responsibility to health regulatory boards, the profession, and the public, must now accredit only those providers who are in compliance with the ACPE criteria and the OIG guidelines.

In accordance with ACPE's new policies, organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations and non-health care-related companies, will not be eligible for ACPE accreditation status.

For more information, contact ACPE Executive Director Peter Vlasses at 312/664-3575, or via e-mail at [pvlasses@acpe-accredit.org](mailto:pvlasses@acpe-accredit.org).



## **Let's Get to the 'Point': Prescription Misinterpretations Due to Decimal Points**

*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](http://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](mailto:ismpinfo@ismp.org).*

**Problem:** Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (NCR) forms (often used in hospitals and long-term care facilities). If a decimal point is missed, an overdose may occur. The importance of proper decimal point placement and prominence cannot be overstated.

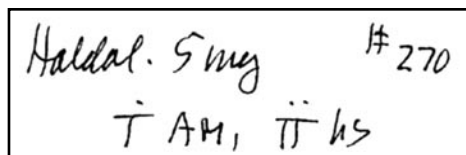
For one, a decimal point should always be preceded by a whole number and never be left "naked." Decimal expressions of numbers less than one should always be preceded by a zero (0) to enhance the visibility of the decimal. For example, without a leading zero, a prescription for "Haldol® .5 mg" (see image shown on next page) was misinterpreted and dispensed as "Haldol 5 mg." We have received similar reports with Risperdal® (risperidone) in which "Risperdal .5 mg" was prescribed (instead of Risperdal 0.5 mg), but the patient received several 5 mg doses because the decimal point was overlooked.

In addition, a whole number should never be followed with a decimal point and a zero. These "trailing zeros" (eg, "3.0") are a frequent cause of 10-fold overdoses and should never be used. For example, when prescriptions have been written for "Coumadin® 1.0 mg," patients have received 10 mg in error. Similarly, a prescription for "Synthroid® 25.0 mcg" could be misread as "Synthroid 250 mcg."

Dangerous use of decimals can also be problematic if they appear in electronic order entry systems or on computer-generated labels. A newly admitted hospital patient told her physician that she took Phenobarbital® 400 mg PO three times daily. Subsequently, the physician wrote an order for



the drug in the dose relayed by the patient. A nurse saw the prescription vial and verified that this was the correct dose. However, prior to dispensing, a hospital pharmacist investigated the unusually high dose. When he checked the prescription vial, he found that it was labeled as “phenobarbital 32.400MG tablet.” The label indicated that 30 tablets were dispensed with instructions to take one tablet three times daily.



The hospital pharmacist contacted the outpatient pharmacy and suggested that the computer expressions including trailing zeros be changed to avoid serious medication errors. The pharmacy management agreed that trailing zeros appearing on labels might pose a risk and made the change immediately.

## Safe Practice Recommendations

In order to avoid misinterpretations due to decimal point placement, pharmacists should consider the following:

- ◆ Always include a leading zero for dosage strengths or concentrations less than one.
- ◆ Never follow a whole number with a decimal point and a zero (trailing zero).
- ◆ Educate staff about the dangers involved with expressing doses using trailing zeros and naked decimal points.
- ◆ Eliminate dangerous decimal dose expressions from pharmacy and prescriber electronic order entry screens, computer-generated labels, preprinted prescriptions, etc.
- ◆ Avoid using decimals whenever a satisfactory alternative exists. For example, use 500 mg in place of 0.5 gram, 125 mcg instead of 0.125 mg, or 2 ½ mg instead of 2.5 mg.
- ◆ Identify drugs with known 10-fold differences in dosage strength (eg, Cytomel® 5 mcg and 50 mcg, Coumadin 1 mg and 10 mg, levothyroxine 25 mcg and 250 mcg) and place reminders in electronic order entry systems and on pharmacy shelves to alert practitioners to double-check the dosage strength.
- ◆ When sending and receiving prescriptions via fax, health care practitioners should keep in mind that decimal points can be easily missed due to “fax noise.” Whenever possible, encourage prescribers to give original prescriptions (with an indication that it has been faxed) to their patients to take to the pharmacy for verification. Pharmacists should carefully review faxed prescriptions and clarify prescriptions that contain fax noise.
- ◆ Eliminate the lines on the back copy of NCR forms so that a person receiving can clearly see decimal points or other marks that were made on the top copy.
- ◆ Notify prescribers of the potential for error if misinterpretations due to decimal point usage are discovered.

## DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from the following Web site address: [www.access.gpo.gov/su\\_docs/fedreg/a050401c.html](http://www.access.gpo.gov/su_docs/fedreg/a050401c.html).

## FDA Publishes Final Rule on Chlorofluorocarbons in Metered Dose Inhalers

FDA announced that albuterol metered-dose inhalers (MDI) using chlorofluorocarbon propellants must no longer be produced, marketed, or sold in the US after December 31, 2008.

The Health and Human Services (HHS) is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDI for patients for whom price could be a significant barrier to access to this important medicine. These programs include MDI giveaways, coupons for reducing the price paid, and patient assistance programs based on financial need.

In a final rule, published March 31, 2005, in the *Federal Register*, HHS stated that sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008, to allow the phasing out of similar, less environmentally friendly versions.

## FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medication online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on [www.nabp.net](http://www.nabp.net) to find out if a Web site has been checked to make sure it has met state and federal rules. Consumers also will know if an online pharmacy is VIPPS-accredited when they notice the VIPPS Seal on that particular Web site.

For more information on these PSAs visit [www.fda.gov/cder/consumerinfo/Buy\\_meds\\_online\\_all\\_resources.htm](http://www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm).

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- (j) the brand name of the drug product dispensed or the generic name of the drug product dispensed and its manufacturer or labeler, either written in full or appropriately abbreviated;
  - (k) when dispensing a prescribed medication, if a pharmacist selects an equivalent drug product for a name-brand prescribed drug, the generic drug name must either be listed on the prescription label first followed by the name-brand prescribed drug, or this information must be affixed to the container on an auxiliary label.”
- ◆ Refill authorizations may be difficult or impossible to obtain. If the governor declares a State of Emergency within your county, pharmacists may utilize the South Carolina State of Emergency Laws (Section 40-43-170) that allow for a one time emergency refill of up to a 15-day supply of a prescribed medication if:
    - ◆ The pharmacist has all prescription information necessary in order to accurately refill the prescription and;
    - ◆ In the pharmacist’s professional opinion the medication is essential to the maintenance of life or to the continuation of therapy and;
    - ◆ The pharmacist reduces the information to a written prescription marked “Emergency Refill,” files the prescription as required by law, and notifies the prescribing physician within 15 days of the emergency refill and;
    - ◆ The prescription is not for a controlled substance.
  - ◆ SC Practice Act (Section 40-43-170) also states that “a pharmacist not licensed in South Carolina but currently licensed in another state, may in a state of emergency dispense prescription medications in those affected counties without being licensed in South Carolina during the time that a state of emergency exists if:
    - ◆ the pharmacist has some type of identification to verify current licensure in another state and;
    - ◆ the pharmacist is engaged in a legitimate relief effort during an emergency situation.”
  - ◆ If the store is to be closed and evacuation is warranted the PIC should produce two sets of backup tapes or disks of all drug inventory and all prescription information. One set of information could be kept in a safe place and another kept off-site in the possession of the PIC.
  - ◆ Prior to evacuation, computers should be shut down and covered with waterproof material. If flooding is expected the computer should be disconnected from the terminals and moved to a safe area.

- ◆ Schedule II drugs should be moved to a locked, secure place. A safe may be used but is not required. Other products such as prescription drugs should be moved, if possible, above the floor level and covered with waterproof materials.
- ◆ Notify the following if the pharmacy is to be closed and when it will reopen:
  - ◆ Store personnel,
  - ◆ Local and television media,
  - ◆ Physicians and/or hospitals, and
  - ◆ South Carolina Emergency Management Division (803/737-8500).
- ◆ When the situation has stabilized, the pharmacy personnel should be notified on what steps to take to restore the integrity of the pharmacy setting.
- ◆ Most importantly, be careful not to hurt yourself while trying to assist in the needs of others.

Pharmacists in areas not affected by the natural disaster are encouraged to volunteer their services to disaster areas. In conjunction with state and county emergency officials, the Board of Pharmacy, Department of Health and Environmental Control, and the South Carolina Pharmacists Association (SCPhA) have joined efforts to assist if a disaster situation occurs.<sup>5</sup> You may contact the SCPhA (803/354-9977) to be added to the list of volunteers or sign-up on your pharmacist renewal application when sending it to the Board of Pharmacy.

#### References:

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