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

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Board of Pharmacy Welcomes New Inspector

Clelia Sanders joined the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy staff as an inspector on July 18, 2005. Ms Sanders lives in Edisto Beach, SC, and holds a bachelor of science degree from the University of South Carolina College of Pharmacy. Previously, she was coordinator of the Children's Hospital at Medical University of South Carolina and has extensive community and hospital pharmacy experience. She and her husband, Derek, have two adult children and are members of Edisto Beach Baptist Church.

Clarification Regarding Controlled Substance Prescribing

By John Pugh, PharmD Candidate, University of South Carolina College of Pharmacy on rotation with the South Carolina Board of Pharmacy

Pharmacists often find it difficult to remember whether or not a particular type of practitioner may prescribe controlled substances (CS). To issue a prescription in South Carolina for a scheduled medication, individual practitioners must be: 1) licensed by the appropriate board (Board of Medical Examiners, Board of Dentistry, etc); 2) acting in the regular course of professional practice; and 3) registered with Drug Enforcement Administration and the South Carolina Department of Health and Environmental Control (§503 of Regulation 61-4). Further, a prescription for a CS must be issued only for a legitimate medical purpose (ie, not to support an addiction). Physicians (medical and osteopathic), dentists, veterinarians, and podiatrists may prescribe Schedule II-V drugs. Nurse practitioners, certified nurse-midwives, and clinical nurse specialists may prescribe Schedules III-V if the medication is listed in the approved written protocol with the supervising physician (§40-33-34). Therapeutically certified optometrists may also prescribe Schedules III-V drugs provided the medication is used in treatment of a disease within the scope of practice of optometry and that analgesics are limited to a seven-day supply (§40-37-105). Physician assistants may **not** prescribe controlled drugs in Schedules II-IV; they may prescribe only Schedule V or non-controlled medications that are authorized by the supervising physician and set forth within the written scope of practice guidelines (§40-97-965 and §40-97-970). Remember that a drug must be prescribed for a condition

within the practitioner's regular course of practice. Therefore, it would be inappropriate for a veterinarian to prescribe a drug for a human, a dentist to write a prescription for a condition not relating to the oral cavity and adjacent tissues, or a podiatrist to prescribe a medication for a condition not manifested in the foot. Prescriptions from out-of-state providers may be recognized in South Carolina if that practitioner ordinarily would be entitled to issue prescriptions under SC law (§61-4-114; please see §114 of Regulation 61-4 for other requirements regarding out-of-state prescriptions). Ultimately, the pharmacist who fills the prescription has a corresponding responsibility to ensure that the order is appropriate, and he or she must exercise sound professional judgment in making these decisions.

Pharmacy Care = Quality Commitment

By Jennifer Baker, PharmD, Manager of Professional Affairs, South Carolina Pharmacy Association

There are so many good reasons to be concerned with the quality of our professional work. When we took the pharmacist's oath we swore to assure optimal drug therapy outcomes for our patients and maintain competency. We also stated we would embrace change in our profession to improve patient care. We are seeing a shift in the focus of pharmacy and health care (especially with the ever-morphing Medicare Prescription Drug, Improvement, and Modernization Act of 2003) to outcomes – providing therapeutically effective care in the most cost-effective way.

Concerns of reimbursement aside, this is a tremendous opportunity for pharmacists; we are finally being recognized as health care providers. We can use, and hopefully profit from, our professional judgment. We do not want to set ourselves back to the days of lick, stick, pour, and count. It is our duty to show we deserve this recognition as part of the health care team. With this duty and fight to maintain our overdue recognition comes the responsibility of providing quality pharmacy care and continuous improvement efforts to reduce errors.

In addition to quality assessment simply being our duty, there is also a demand from our patients. The 1999 Institute of Medicine report, *To Err is Human: Building a Safer Health System*, and the follow up report in 2001, *Crossing the Quality Chasm*, received national attention and have motivated the health care industry to take the quality initiative to heart.

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DEA Amends Rule for Reports of Theft or Significant Loss of Controlled Substances

Drug Enforcement Administration's (DEA) amended regulations regarding reports by registrants of theft or significant loss of controlled substances became effective September 12, 2005. Changes were made to the regulations, found in Title 21 of the Code of Federal Regulations, Part 1300 to 1399, due to confusion as to what constitutes a significant loss and when and how initial notice of a theft or loss should be provided to DEA. Specifically, DEA made changes in order to clarify the exact meaning of the phrases "upon discovery" and "significant loss."

Regarding the timing of initial theft or loss reports, DEA inserted the word "immediately" before the phrase "upon discovery." While DEA Form 106 is not immediately necessary if the registrant needs time to investigate the facts surrounding a theft or significant loss, he or she should provide, in writing, initial notification of the event. This notification may be a short statement provided by fax. DEA notes that faxing is not the only method a registrant may use, but that the notification should be in writing. If the investigation of a theft or significant loss lasts longer than two months, registrants should provide updates to DEA.

To help registrants determine whether or not a loss is "significant," DEA has added to the rule a list of factors to be considered. DEA recognizes that no single objective standard can be applied to all registrants – what constitutes a significant loss for one registrant may be construed as comparatively insignificant for another. If a registrant is in doubt as to whether or not the loss is significant, DEA advises the registrant to err on the side of caution in alerting the appropriate law enforcement authorities.

Regarding "in-transit losses of controlled substance," DEA intends that all in-transit losses be reported, not just significant losses; therefore, the text is being amended to reflect this.

Changes to the regulations were reported in the August 12, 2005 edition of the *Federal Register*.

FDA Releases Update on Combating Counterfeit Drugs

Food and Drug Administration (FDA) recently released "Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update (Update)." This Update follows up on the agency's initial February 18, 2004 report addressing counterfeit drugs. Since the 2004 report, which identified measures that can be taken to better protect Americans from counterfeit drugs, FDA has worked with manufacturers, wholesale distributors, pharmacies, consumer groups, technology specialists, standard setting bodies, State and Federal agencies,

international governmental entities, and others to advance the measures outlined in the 2004 report such as the development and implementation of electronic product codes and radio frequency identification. In its 2005 Update, FDA notes that significant progress is being made in securing drug products and packaging, securing the movement of the product, enhancing regulatory oversight, increasing penalties for counterfeiters, heightened vigilance and awareness of counterfeits, and increasing international collaboration. However, more work needs to be done to further secure the United States' drug supply.

In 2004, FDA's Office of Criminal Investigations initiated 58 counterfeit drug cases, a significant increase over the 30 cases in 2003; however, the agency notes that this is likely due to increased vigilance. FDA also states that most of the suspect counterfeits discovered in 2004 were found in smaller quantities than those found in 2003.

The Update reviews steps taken and future actions required for track-and-trace technology, authentication technology, regulatory oversight and enforcement (electronic pedigree), state efforts, secure business practices, heightened vigilance and awareness, counterfeit alert network, and education. The full Update can be accessed at www.fda.gov/oc/initiatives/counterfeit/update2005.html.

"Fax noise" = Medication Errors in the making



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, Suite 810, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Most health care practitioners would agree that fax machines have facilitated communication of prescriptions. But there are inherent problems associated with this technology. In fact, an article in the *Journal of Managed Care Pharmacy* found that prescriptions received by fax required a greater number of clarification calls than those received by other methods of communication.¹ ISMP received a report from a long-term care facility about a patient who had been

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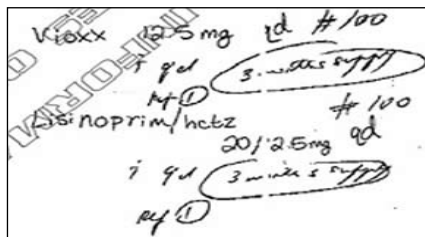
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receiving **Neurontin**[®] (gabapentin) 600 mg TID [three times a day]. However, an order had been faxed to the pharmacy to change the Neurontin dose to “**300 mg** 1 tab QID [four times a day].” The change was made and the new dose was sent to the facility. Later, when the pharmacist received the original order from the long-term care facility and compared it with the faxed copy, he realized that the physician had actually requested a change to “**800 mg** 1 tab QID.” The left side of the order had been cut off during the fax transmission, making the “8” look like a “3.” Fortunately, since the pharmacist had been sent the original order for comparison, he quickly realized the mistake. Unfortunately, not all pharmacies receive the original prescription for comparison purposes.

In another report received by ISMP, a faxed prescription was received at a pharmacy for what appeared to be **Monopril**[®] (fosinopril) **10 mg** #90 one tablet daily. Despite the fact that the fax machine created a definite vertical streak that ran between the drug name and the strength, the pharmacist felt confident in her interpretation of the prescription. Unfortunately, it was later discovered that the prescription was actually for **40 mg**. The streak had run through the “4” in 40 mg, making it look like 10 mg instead.

The following prescription (see image below) was faxed to a mail-order pharmacy. Look at the bottom order for “Lisinopril/hctz.” (Note: ISMP does not condone the use of the abbreviation “hctz.”) The pharmacist interpreted this order as “20/25 mg.” But what the prescriber had actually written was “20/12.5 mg.” A subtle vertical gap in the faxed copy (which can be seen “breaking” the circles around “3 months supply”) had obliterated the “1” in 12.5. In addition, the pharmacist reading the order had misinterpreted the decimal point as one of many stray marks on the faxed prescription.



Safe Practice Recommendations: “Fax noise” (the random marks and streaks on faxes) is an inherent problem with this form of communication, which may be more common in old or poorly maintained fax machines. Usually, fax noise is just an inconvenience. In the case of prescriptions, however, there is a very real chance that a patient could be harmed by misinterpretations caused by fax noise. To manage this risk, safeguards should be instilled into the fax process. Such safeguards include a careful review of all prescriptions received by fax for fax noise. If the transmission has fax noise in the area of the order, the prescriber should be contacted to confirm the prescription. Whenever pos-

sible, compare the faxed order against the original prescription. Prescribers should consider giving a copy of the prescription to the patient to present at the pharmacy for verification. To prevent confusion or duplication of the prescription at a different pharmacy, the copy could be stamped with a statement such as “Verification Copy ONLY” to indicate that the prescription was already faxed to a particular pharmacy. Maintenance should be regularly scheduled for fax machines on both the sending and receiving end. If maintenance fails to improve fax quality, the machine should be replaced.

¹ Feifer RA et al. Mail-order prescriptions requiring clarification contact with the prescriber: prevalence, reasons, and implications. *JMCP* 2003;9:346-352.

December 2005 FPGEE Date and Locations Announced

On December 3, 2005, NABP will again administer a paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination[®] (FPGEE[®]). The examination is being offered at three United States locations: Northlake (Chicago area), IL; New York, NY; and San Francisco, CA. Candidates who have been accepted to sit for the December 3, 2005 administration were mailed their admission tickets in early fall.

To prepare for the December examination, candidates may take the Pre-FPGEE[®], a Web-based practice examination for the FPGEE. The practice examination is accessible at www.nabp.net and www.pre-fpgee.com.

For more information on the FPGEE, visit NABP’s Web site at www.nabp.net.

2006 Survey of Pharmacy Law

NABP’s 2006 *Survey of Pharmacy Law* CD-ROM will be available in late November 2005. New topics include the number of wholesale drug distributors and laws and/or regulations concerning the sales of over-the-counter pseudoephedrine, and information concerning emergency contraception.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. Most charts specify terms that can be used when conducting searches on NABP’s NABPLAW[®] Online state pharmacy law and rules database. The *Survey* can be obtained for \$20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. If you do not have Web access or would like more information on the *Survey*, please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

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Patients and a sense of duty are propelling us to improve our systems. In addition, most payer contracts, including Medicare Part D, require that all health care entities, down to the level of the practitioner, have a continuous quality improvement process in place that can be audited. Regardless of the motivation, it is clear that the focuses on reduction of medical errors and implementation of continuous quality improvement processes are at the forefront of today's health care agenda.

For pharmacy, the obvious focus will be on improving the medication fill process, workflow, and patient education components of our practice to ensure quality health outcomes and reductions of medication errors. This focus is vital as we will be adjusting to an increase in the number of prescriptions filled due to the implementation of Medicare Part D. It is a well recognized fact that if you cannot measure it, you cannot manage it; so the question for most of us is "How do I do that?"

Fortunately, South Carolina Pharmacy Association (SCPhA) has a simple answer to that vexing question. We recognize the need for a pharmacy to have a simple, effective program that is appropriately priced. SCPhA has partnered with the nation's state pharmacy associations to purchase a dynamic, turnkey, continuous quality improvement tool called the Pharmacy Quality Commitment®.

The Pharmacy Quality Commitment is a two-part program that will allow you to measure and appropriately manage your practice to improve quality. The first component is the Sentinel® program that contains policy and procedure templates, workflow schemes, and best practice standards to implement your quality assessment process. The sample workflows and best practices are meant to be flexible so that they are easily adapted to your practice site.

The second and most important component of the Pharmacy Quality Commitment is the Quality Manager®, which is an online, voluntary, self-reporting process that allows you to measure and manage your process. The data and the reports generated from that data is only available to the pharmacy owner and/or manager and should be used to evaluate trends, educate staff, and adjust workflow to avoid repeating errors. You will be able to compare your information with national data to identify trends. This report-

ing system is not for placing blame – it is an evaluation of the process. It should be noted that it is equally important to report "near misses" as well as errors that actually reach the patient. The "near misses" provide the necessary information to effectively manage staff and workflow for effective error reduction. If your pharmacy commits to reporting, you will be able to identify common errors down to the day of the week and time of day.

A quality assessment program has to be realistic in its objectives. It is impossible to **eliminate** prescription errors; the only way to achieve that would be the removal of medications from the health system. The most effective program focuses on risk **management** and evaluating the pharmacy's process to reduce errors, **not** placing blame on an individual. Once a quality assessment tool is decided upon, commitment to the program is vital to improving workflow and conditions.

We are all human and no one is perfect. However, this never gives us the right to be negligent. It is our responsibility to correct controllable conditions and processes that result in errors. In response to duty, demand, and law, I hope that you will see the wisdom of proactively implementing a quality assurance process. There is a saying that says "The only real mistake is the one from which we learn nothing."

Please visit the Pharmacy Quality Commitment® Web site at www.pqc.net or contact the South Carolina Pharmacy Association with questions at 1-800/532-4033.

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