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Establishment of Physician-Patient Relationship as Prerequisite to Prescribing Drugs

Approved by the [South Carolina Board of Medical Examiners] at its November 5, 2012 meeting and Revised at its meeting on February 5, 2013

Service Area: Medical

Subject: Establishment of Physician-Patient Relationship as Prerequisite to Prescribing Drugs

In accordance with S.C. Code Ann. § 40-47-113 of the 1976 Code of Laws of South Carolina, as amended, the South Carolina Board of Medical Examiners has adopted the following statement as guidance for physicians in the practice of medicine under the South Carolina Medical Practice Act and the Principles of Medical Ethics as adopted by the Board.

Establishment of Physician-Patient Relationship as Prerequisite to Prescribing Drugs

S.C. Code of Laws Section 40-47-113 (1976, as amended), provides:

(A) It is unprofessional conduct for a licensee initially to prescribe drugs to an individual without first establishing a proper physician-patient relationship. A proper relationship, at a minimum, requires that the licensee make an informed medical judgment based on the circumstances of the situation and on the licensee's training and experience and that the licensee: (1) personally perform and document an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan; (2) discuss with the patient the diagnosis and the evidence for it, and the risks and benefits of various treatment options; and (3) ensure the availability of the licensee or coverage for the patient for appropriate follow-up care.

(B) Notwithstanding subsection (A), a licensee may prescribe for a patient whom the licensee has not personally examined under certain circumstances including, but not limited to, writing admission orders for a newly hospitalized patient, prescribing for a patient of another licensee for whom the prescriber is taking call, prescribing for a patient examined by a licensed advanced practice registered nurse, a physician assistant, or other physician extender authorized by law and supervised by the physician, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment.

(C) Prescribing drugs to individuals the licensee has never personally examined based solely on answers to a set of questions is unprofessional.

With regard to the exceptions set forth in S.C. Code Ann. § 40-47-113 (B), the South Carolina Board of Medical Examiners has adopted the definition of "on-call" as the temporary assumption of responsibility for an established doctor-patient relationship. An "on-call" physician is a South Carolina licensed physician who is available to physically attend, if necessary, to urgent and follow up care needs of a patient for whom he has temporarily assumed responsibility with the acknowledgment of the patient's primary provider of care.

A physician who prescribes drugs to an individual he has never personally examined and for whom he has not assumed responsibility with the acknowledgment of the patient's primary provider of care has engaged in unprofessional conduct **unless** he is writing admission orders for a newly hospitalized patient, prescribing for a patient examined by a licensed advanced practice registered nurse, a physician assistant, or other physician extender authorized by law and supervised by the physician, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment.

Specifically, a physician who prescribes drugs for an individual with whom he has only had telephonic and/or electronic communication and for whom he has not assumed responsibility with the acknowledgment of the patient's primary provider of care has engaged in unprofessional conduct **unless** he is writing admission orders for a newly hospitalized patient, prescribing for a patient examined by a licensed advanced practice registered nurse, a physician assistant, or other physician extender authorized by law and supervised by the physician, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment.

Pharmacy Technician Renewals

The 2015 renewal notices were mailed to pharmacy technicians on or about April 15. You will be mailed a renewal notice

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FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes 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, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

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with a **user ID** and a **password** to allow you to access the online renewal website. **If you are a state-certified pharmacy technician, you must mail a copy of your current national certificate (from the Pharmacy Technician Certification Board) to the South Carolina Department of Labor, Licensing & Regulation – Board of Pharmacy.**

If you choose not to renew online, you may download the renewal application and renew by mailing the completed form and proper fees to the Board office. **Applications need to be received in the Board office by June 1, 2015. Pharmacy technicians who do not renew prior to June 30, 2015, will be assessed penalties and cannot work as pharmacy technicians until a 2015-2016 registration is in hand or disciplinary action may result.** If you do not renew online, please document the date the application is mailed. **The Board recommends the paper renewal be sent via certified mail with a return receipt requested.**

Facility Permit Renewals

The permit renewal notices and forms were mailed out in mid-April 2015 to the last known address on file in the Board office. If you are a permit holder and have not received your permit renewal application, contact the Board office immediately. The renewal notice you receive will contain a **user ID** and **password** to allow you access to the online renewal website.

If you choose not to renew your permit online, you may download a renewal form from the Board's website. Mail the completed form, along with proper fees, to the Board at PO Box 11927, Columbia, SC 29211. All applications must be received at the Board's office prior to June 1, 2015, or a $50 late fee will be assessed. After June 30, 2015, the facility permit will lapse.

Upon application for reinstatement, the facility will be assessed a penalty of $10 a day until the permit is reinstated, plus the $50 late fee and a new application fee. Depending upon the circumstances, the facility, the pharmacist-in-charge, and/or the pharmacists who practice in the pharmacy may be charged with violations of the practice act for operating without a permit pursuant to South Carolina Code Annotated §40-43-83, resulting in discipline.

Update on PA Prescriptive Authority for Schedule II Drugs

[28] PA PRESCRIBING QUESTION ADVISORY OPINION - The Board of Medical Examiners (BME) does not interpret the language of the PA act as amended to impose an obligation upon the pharmacy in question to verify compliance with §40-47-965. Licensees under the BME, supervising physicians and physician assistants are expected to comply with the medical practice act and are subject to discipline if they do not. Pharmacies may choose to implement their own verification procedures for prescriptions in accordance with the requirements of the Pharmacy Practice Act.

S.C. Code Ann. §40-47-965(6) was amended to allow physician assistants (PAs) to authorize prescriptions for an orally administered Schedule II controlled substance (CS) as defined in the federal Controlled Substances Act pursuant to the following requirements:

(a) the authorization to prescribe is expressly approved by the supervising physician as set forth in the physician assistant's written scope of practice guidelines;
(b) the physician assistant has directly evaluated the patient;
(c) the authority to prescribe is limited to an initial prescription and must not exceed a seventy-two hour supply;
(d) any subsequent prescription authorization must be in consultation with and upon patient examination and evaluation by the supervising physician, and must be documented in the patient's chart; and
(e) any prescription for continuing drug therapy must include consultation with the supervising physician and must be documented in the patient's chart.

The PA must have a valid Drug Enforcement Administration (DEA) registration and must prescribe in accordance with DEA rules. Schedule II CS can be prescribed if set forth in the written scope of practice guidelines. Prescriptions must meet all other state and federal laws.

The *South Carolina Board of Pharmacy News* is published by the South Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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