MEDICAL UNIVERSITY OF SOUTH CAROLINA
OFFICE OF THE PRESIDENT
POLICY MEMORANDUM

		MEMORANDUM ID:	AA-2006-001-CONTROLLED SUBSTANCES
TITLE:	OUTPATIENT PRESCRIBING OF CONTROLLED SUBSTANCES		
ORIGINATOR	JOHN R. RAYMOND, M.D.		
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I. RATIONALE

Policies Governing the Outpatient Prescribing of Controlled Substances:

Prescribing and dispensing of controlled substances is a common practice at MUSC and its affiliates and their use is directed at both the long- and short-term control of the signs and symptoms of a variety of disorders in the ambulatory population. Most notable in this process is the prescribing of narcotic analgesics for post-operative pain, relief of the pain of a terminal illness (e.g., hospice patients), or other chronic pain syndromes in the ambulatory population.

Given the number and diversity of practitioners (dentists, physicians, nurse practitioners, and physician assistants) having prescribing privileges for controlled substances in a widely distributed system of clinical sites, it is imperative for the institution to assure that such prescribing is done in a uniform and consistent method that assures compliance with State and Federal laws.

In order to assure that the prescribing of controlled substances is limited to legitimate medical use by patients receiving health care services from duly licensed practitioners in its various clinical sites, MUSC has undertaken to create the following comprehensive policy, which will govern the outpatient prescribing of controlled substances.

II. COMPLIANCE WITH FEDERAL AND STATE LAWS

State and Federal Laws:

The laws relating to the prescribing and dispensing of controlled substances in South Carolina are detailed in *The Code of Laws of South Carolina, 1976, Title 44, Chapter 53.* Enforcement of these laws is under the jurisdiction of the S.C. Department of Health and Environmental Control (DHEC). These state laws very closely follow the federal Controlled Substances Act, Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970. The U.S. Drug Enforcement Administration (DEA) is responsible for enforcement of these laws at a national level, but also has jurisdiction at the state level.

Registration of Institutions and Practitioners:

According to §44-53-290, any duly licensed health care practitioner who wishes to engage in the provision of controlled substances to patients must obtain a registration issued by the DEA and DHEC in accordance with their rules and regulations. Similarly, a separate registration is required at each principal place of business or professional practice where the aforementioned practitioner cares for patients. Any practitioner who provides narcotic drugs to individuals for maintenance treatment or detoxification treatment must obtain yet a separate registration on an annual basis.

Being the "principal place of business" and "professional practice", the Medical University of South Carolina (MUSC), and its affiliated clinical sites (the Medical University Hospital Authority, University Medical Associates, and Carolina Family Care), maintain the appropriate controlled substance registrations that are separate and distinct from those of the individual prescribers who practice in the various patient care areas on and off of the campus.

Prescriber-Patient Relationship:

§44-53-360 states that controlled substances in any schedule may be provided to a patient only for medical purposes and that Schedule II narcotics may not be provided to maintain the addiction of a narcotic dependent person outside of a facility or program approved for the care of such dependent individuals.

This same statute prohibits any practitioner from providing "any controlled substances to any person outside of a bona fide physician-patient relationship".
§508.2 and §514.2 of Chapter 61 of the Code of Laws of South Carolina, 1976 define the conditions for such a relationship prior to the issuance of a prescription for a controlled substance in schedules II, III, IV, or V. Such a relationship must include, but not be limited to "a sufficient knowledge of the medical need of the patient for such a [schedule II, III, IV, or V] controlled substance, determination of the benefit to risk ratio of the use of such substance, good faith determination of the identity and address of the patient, a determination of the physical condition of the patient, and such practitioner shall be in personal attendance of the patient at the time of issuance of the prescription."

Notwithstanding the requirement for a valid practitioner-patient relationship to exist at the time a controlled substance is prescribed, §514.2 allows that "In the event of a bona fide emergency situation, where great detriment to the health or safety of a patient may be involved, a practitioner may administer, dispense or prescribe limited amounts of controlled substances to any person, notwithstanding the provisions of this Section, until such time as another objective practitioner can be contacted."

Regarding the requirement for the "personal attendance of the patient at the time of issuance of the prescription", the DEA has provided further explanation in a document entitled "Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances" (Docket No. DEA-271N, dated August 28, 2005). With concern for the addictive nature of these agents and, therefore, their potential for abuse and diversion, "Physicians must use the utmost care in determining whether their patients for whom they are prescribing schedule II controlled substances should be seen in person each time a prescription is issued or whether seeing the patient in person at somewhat less frequent intervals is consistent with sound medical practice and appropriate safeguards against diversion and misuse." This document goes on to state: "in those instances where the physician (who regularly sees a patient) issues a prescription for a schedule II controlled substance for a legitimate medical purpose without seeing the patient in person, the physician may mail the prescription to the patient or pharmacy."

The S.C. Board of Medical Examiners has also issued "Guidelines for the Use of Controlled Substances for the Treatment of Pain" and includes in Section II, paragraph 1 (Evaluation of the Patient) the following: "A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coesixting diseases or conditions, the effect of the pain on the physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance."

Prescriptions:

§44-53-395 renders it unlawful for "(1.) any practitioner to issue any prescription document signed in blank; (2.) any person other than the practitioner registered with the Department [DHEC] under this article to possess a blank prescription not completed and signed by the practitioner whose name appears printed thereon; (3.) any person to withhold the information from a practitioner that such a person is obtaining controlled substances of like therapeutic use in a concurrent time period from another practitioner" (see also "Doctor Shopping", below).

Documentation in the Patient Record:

Although not specifically referenced in any DEA or DHEC regulations, the S.C. Board of Medical Examiners has issued a document entitled "Guidelines for the Use of Controlled Substances for the Treatment of Pain" which addresses the need to document all patient-related activities in the medical record. Pursuant to Section II, paragraph 6 (Medical Records) of these Guidelines: "The physician should keep accurate and complete records to include, when indicated (1) the medical history and physical examination; (2) diagnostic, therapeutic and laboratory results; (3) evaluations and consultations; (4) treatment objectives; (5) discussion of risks and benefits; (6) treatments; (7) medications (including date, type, dosage and quantity prescribed); (8) instructions and agreements; and (9) periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review."

"Doctor-Shopping":

§44-53-40 prohibits any person from obtaining or attempting to obtain any controlled substance by "(a.) fraud, deceit, misrepresentation, or subterfuge; (b.) the forgery or alteration of a prescription; (c.) the falsification in any manner of any record of sale required by law; (d.) the use of a false name or the giving of a false address; (e.) the concealment of a material fact; or, (f.) falsely assuming the title of or representing himself to be a person authorized by the laws of this State to possess such drugs, pharmaceutical preparations, chemicals, chemical compounds, or devices".

III. UNIVERSITY PRESCRIBING POLICY AND PROCEDURES

NOTE: THE FOLLOWING SHALL APPLY TO ALL CONTROLLED SUBSTANCES (SCHEDULES II THROUGH V).

Prescribing After Hours:

The prescribing of controlled substances for outpatients after normal clinic hours (to include weekends and holidays) will be permitted only in the following situations:

Principal Prescriber: (i.e. primary provider, practitioner-of-record) – may issue a prescription without benefit of the patient's presence or the patient's medical record. However, documentation of such prescribing activity must be noted in the medical record on the next business day.

Secondary Prescriber: (i.e. on-call or "covering" practitioner) - in the absence of a bona fide emergency, the practitioner may issue a prescription only following a review of the patient's medical record and documentation of such prescribing activity at the time of prescribing. Should a bona fide emergency exist, the secondary prescriber may issue a prescription, without benefit of the medical record, for a limited amount of controlled substance until the patient can be seen by a practitioner. Such prescribing activity must be noted in the medical record on the next business day.

Prescriptions:

Pursuant to Federal and State laws on the subject, practitioners may not issue a blank prescription that has been pre-signed to any individual with the intent of the recipient completing that prescription. Likewise, practitioners duly licensed to prescribe controlled substances may not issue signed prescriptions on behalf of patients of practitioners not licensed to prescribe controlled substances (such prescribing would also violate the requirements of the prescriber-patient relationship).

Prescription Quantity:
In order to comply with this policy and assure that patients receive relief of symptoms during those times when outpatient clinics are closed and/or the principal prescriber cannot be reached, practitioners are encouraged to provide a sufficient quantity of doses for weekend and holiday periods.

Documentation in Patient Record:

Pursuant to the Guidelines issued by the S.C. Board of Medical Examiners, all practitioners who prescribe narcotic analgesics for outpatient therapy shall keep accurate and complete records to include the elements cited in Section II. of this policy document. The record should be updated at the time the patient is seen by the prescriber. The only exception to this relates to prescriptions for additional narcotic analgesics provided after normal clinic hours by the original prescriber of record. In this situation the medical record should be updated on the next business day.

Hospice Patients:

With regard to the prescribing of narcotic analgesics for hospice patients, the following exceptions to State and Federal regulations exist:

- Schedule II prescriptions may be faxed by a physician to a pharmacy. Such prescriptions must indicate "hospice patient" or "terminally ill patient" on the face of the prescription. Schedule III, IV, and V prescriptions may not be faxed to a pharmacy.
- A pharmacist may fill a schedule II prescription for less than the prescribed quantity; hospice payments are for two weeks only.
- More than one prescription for the same schedule drug can be written at the same time. However, they must bear the same date and are valid for only 60 days.

Prescribing and Patient Safety:

1) The name of the patient on the prescription should be as complete as possible.
   a. Nicknames may be added, but the legal name is important for medication profile completeness.
   b. Include the date of birth of the patient so that the pharmacist is alerted to a prescription for an infant, a child, an adolescent, an adult, or a geriatric individual.
2) Medication orders on outpatient prescriptions should include:
   a. The name of the medication:

i. Generic is preferred with the brand name in parenthesis.

b. The dose of the medication should be in metric units (mg, micrograms, etc).
   i. Avoid the use of prescribing the dose by volume because different concentrations may be available. If the volume is an important part of the patient's medication education, then the use of "mL" rather than "cc" is the preferred abbreviation.
   ii. Avoid the use of prescribing by container (one bottle, one box, etc).

c. The directions for use should be specific.
   i. The use of "As directed" or "As needed" is vague and can lead to toxicity. These should be avoided.
   ii. All PRN orders should include an indication to avoid over-dosing and decrease the potential for toxicity.

d. The total quantity needed can be delineated two ways:
   i. The prescriber specifies the exact amount of tablets, capsules, etc. However, when writing numbers, it is best to both write the number and spell out the number as a tamper-proofing mechanism. For example, spell out "thirty" in addition to writing "30."
   ii. The pharmacist calculates the amount needed when the prescriber specified the duration of therapy (i.e., thirty day supply, ten day supply). This is beneficial when an elixir, suspension, or other liquid medication is prescribed and the prescriber is unsure about the concentrations available.

e. The number of refills should be completed on all prescriptions. Tamper-proofing methods may include:
   i. When there are no refills, do not leave this section blank. It is best to write "No refills" or use "NR" rather than writing "0."
   ii. Spelling out the number. For example writing "five" instead of "5."
   iii. Circling the number of refills

Ordering and Security of Prescription Blanks:

In order to assure that prescription blanks issued by prescribers practicing in the MUSC system, will be available only to authorized personnel, this policy also addresses the creation of a process for the ordering, receiving, and secured storage of prescription blanks available from MUSC Printing Services. The procedures detailed below shall apply to all prescription blanks utilized by practitioners in the MUSC system. Basically, the process will identify personnel authorized to order prescription blanks; limit ordering to specified order forms; provide internal validation of authorized signatures; and provide detailed identification of personnel receiving printed prescription blanks.

University-Approved Prescription Blanks:

The only prescription blanks approved for use in the MUSC system shall be those obtained through MUSC Printing Services. This shall include the standard, two-part NCR forms (#500426) and single page forms (#410151). Additionally, all prescriber-personalized blanks as well as Department, Center, or Institute prescription blanks must be procured from MUSC Printing Services. Although the identity of the prescriber may be printed on the prescription blanks, medical license numbers and/or DEA numbers will not be printed on any university-approved prescription blanks.

Ordering – Required Forms:

Orders for prescription blanks shall be placed by utilizing the standard Intra Institutional Transfer (IIT) form. Only the IIT may be used for this purpose. The completed form may be faxed, mailed or hand delivered to MUSC Printing Services. Credit card orders will not be accepted.

Ordering – Authorized Personnel:

MUSC Printing Services will be provided with a list of personnel authorized to order prescription blanks within the MUSC system. This list will be updated at least annually, on or about July 1, or more frequently as personnel changes occur. The responsibility for identifying authorized personnel for this list shall fall to the appropriate hospital administrator, dean, or department chair in each unit where prescriptions are issued to patients i.e., in-patient and ambulatory care settings. Only these designated personnel will be authorized to sign an IIT for prescription blanks.

Upon receipt of an IIT, Printing Services personnel will validate the signature as being an individual authorized to order. Should the validity of a signature be in question, processing of the order will be delayed until clarification, to the satisfaction of Printing Services personnel, is achieved.

Delivery and Security:

MUSC Printing Services will deliver a prescription order to the unit address on the IIT. Personnel receiving the order will be required to both sign and print their name and indicate their position on the delivery form. Personnel receiving a prescription order will assure that they are stored in a secure area and notify the appropriate administrator (i.e., the person placing the order) that the order has been received.

IV. ACCESS:

Academic Affairs Policy AA-2006-01 will be available from the Office of the Vice President for Academic Affairs & Provost. It will be distributed digitally and by hardcopy to all units reporting to the Provost, and be maintained on the Office of Academic Affairs website www.musc.edu/Academic/. The Vice President for Academic Affairs & Provost, or a designee, will be responsible for monitoring and maintaining the policy. This policy will be reviewed for revision every three years. This memorandum is a public document and has no restriction on its distribution.