

TEMPORARY REGULATION*Article 22– Dishonorable Conduct**

K.A.R. 100-22-8a. Phosphatidylcholine and sodium deoxycholate. (a) As used in this regulation, the following terms shall have the meanings specified in this subsection.

(1) “Adverse event” means any unfavorable medical occurrence experienced by a patient that reasonably could be related to the administration of PCDC.

(2) “Compounding” means combining component drug ingredients by or upon the order of a physician for the purpose of creating a drug tailored to the specialized needs of an individual patient.

(3) “Designated physician” means a physician who is professionally competent to compound or order the compounding of PCDC and who agrees to be available on the premises during the administration of PCDC whenever the physician who compounded or ordered the compounding of PCDC is not present.

(4) “Institutional review board” and “IRB” mean a board or committee designated by a public or private entity or agency to review biomedical research and to ensure protection of the rights and welfare of patients.

(5) “PCDC” means phosphatidylcholine and sodium deoxycholate prepared for administration individually or in combination.

(6) “Physician” means a person licensed in this state to practice medicine and surgery or osteopathic medicine and surgery.

(b) Except as specified in subsections (c) and (d), a physician shall not administer or authorize another person to administer PCDC by injection to a human being.

(c) This regulation shall not prohibit the administration of PCDC to a research subject during clinical research of PCDC as an investigational new drug.

(d) This regulation shall not prohibit a physician from compounding PCDC or from preparing a written prescription order directing a lawfully operating pharmacy to compound PCDC for a specific patient if all of the following conditions are met:

(1) The physician has notified the board in writing of the intent to compound or order the compounding of PCDC in the scope of the physician’s practice and agrees to meet the requirements stated in subsection (e).

(2) The physician has a physician-patient relationship with the specific patient.

(3) The patient has given the physician written informed consent for the administration of PCDC that includes, at a minimum, all of the following:

(A) The patient acknowledges that PCDC is a drug and that neither the state of Kansas nor any federal agency has approved PCDC as a drug.

(B) The patient has been informed that a preponderance of competent medical literature regarding clinical research establishing whether PCDC is safe and effective has not been published.

(C) The patient has been informed that the clinical data will be submitted to an IRB for peer review.

(D) The patient has been given a description of the known and potential side effects of PCDC.

(4) Before compounding or writing an order to compound PCDC, the physician personally performs a physical examination of the patient, records the patient's medical history in the patient record, performs or orders relevant laboratory tests as indicated, and, based upon the examination, history, and test results, determines that PCDC is indicated for the patient.

(5) The physician or designated physician supervises and is personally present on the premises when the PCDC is administered.

(6) The patient record identifies each ingredient, the amount of each ingredient, and the amount of the preparation compounded by the physician, or the order to compound PCDC identifies each ingredient, the amount of each ingredient, and the amount of the preparation to be dispensed.

(e) Each physician who compounds or writes an order to compound PCDC shall meet each of the following requirements:

(1) Before compounding or writing an order to compound PCDC, the physician shall establish a written procedure that identifies each of the following:

(A) A general plan of care applicable to all patients, including indications and contraindications for administering PCDC to patients;

(B) each designated physician;

(C) each person who may administer PCDC upon the order of the physician; and

(D) each location within this state at which PCDC will be administered based upon the order of the physician.

(2)(A) A physician who has compounded or ordered PCDC to be compounded for a patient under a medical regimen that has not been completed on or before the effective date of this regulation shall, before administering or authorizing the administration of PCDC, submit a copy of the written procedure and informed consent form to the board and shall, within 60 days following the effective date of this regulation, submit evidence that an IRB has approved the written procedure and the informed consent form that the physician uses.

(B) Each physician not described in paragraph (e)(2)(A) shall obtain approval of the written procedure and informed consent form by an IRB and submit evidence of that approval and a copy of the written procedure and informed consent form to the board, before compounding or writing an order to compound PCDC.

(3) The physician shall report each adverse event resulting in medical intervention to the IRB and to the board within 24 hours of receiving notice of the adverse event. The physician shall report all other adverse events observed by or reported to the physician and all clinical results for each patient to the IRB at least monthly.

(4) At least monthly, the physician shall prepare or obtain from the compounding pharmacy and shall forward to the IRB the following information:

(A) Verification that the preparation is sterile;

(B) a description of the quantity and strength of all ingredients used as components of the preparation;

(C) documentation of adequate mixing to ensure homogeneity of the preparation; and

(D) verification of the clarity, completeness, or pH of the solution.

(f) Each departure from this regulation shall constitute prima facie evidence of dishonorable conduct. (Authorized by K.S.A. 65-2865; implementing K.S.A. 65-2836; effective, T-100-12-10-07, December 10, 2007.)

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