

U. S. Department of Justice Drug Enforcement Administration 8701 Morrissette Drive Springfield, Virginia 22152

www.dea.gov

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Dear Practitioner,

The Drug Enforcement Administration (DEA), Office of Diversion Control, calls your attention to the existing federal regulations that define a practitioner's responsibilities when issuing oral prescriptions for schedule II controlled substances in emergency situations.

Federal regulations require prescriptions for schedule II controlled substances to be made in writing and to be signed by a DEA registered practitioner. If the prescribing practitioner determines that the situation is an emergency, however, a pharmacist may dispense a schedule II substance after receiving oral authorization from the DEA registered practitioner, as long as the prescription also meets additional requirements discussed below. 21 C.F.R. § 1306.11(d).

If a DEA registered practitioner authorizes an emergency oral prescription for a schedule II controlled substance, the practitioner must provide the pharmacist with a written prescription soon after issuing the oral prescription. The federal regulations at 21 C.F.R. § 1306.11(d)(4) state:

Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 1306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner. [emphasis added]

Pharmacists also have an obligation to obtain a written prescription from the practitioner that authorized the emergency oral prescription. If the pharmacist does not receive the written prescription within the specified timeframe, the pharmacist must inform the local DEA office of the prescribing practitioner's failure to comply. If the pharmacy does not notify the DEA of the failure, the pharmacy will lose its authority to dispense schedule II controlled substances in emergencies based on oral prescriptions.

DEA also reminds you that prescribing practitioners have responsibility for the proper prescribing of controlled substances. 21 C.F.R. § 1306.04. This responsibility applies to the issuance of emergency oral prescriptions as well as, to written prescriptions. In addition, DEA reminds you that a practitioner may authorize an oral prescription for a schedule II controlled substance only if he/she determines (1) that immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user, (2) that no appropriate alternative treatment is available, including administration of a drug which is not a schedule II controlled substance, and (3) that it is not reasonably possible for the prescriber to provide a written prescription to the person dispensing the substance, prior to dispensing. 21 C.F.R. § 290.10. For such dispensing, the prescribing practitioner may only authorize an amount of the drug adequate to treat the patient during the emergency period. 21 C.F.R. § 1306.11(d)(1).

I am hopeful that this letter clarifies the prescribing practitioner's responsibility to provide a written prescription following the issuance of an emergency oral prescription. Additional information concerning the DEA Diversion Control Program can be found at <u>www.DEAdiversion.usdoj.gov</u>. If you have additional questions, please contact the Liaison and Policy Section at (202) 307-7297.

Sincerely,

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Joseph T. Rannazzisi Deputy Assistant Administrator Office of Diversion Control