

U. S. Department of Justice

Drug Enforcement Administration 8701 Morrissette Drive Springfield, Virginia 22152

www.dea.gov

AUG 2 4 2011

Mr. Carmen Catizone, M.S., R.Ph., D.Ph. National Association of Boards of Pharmacy 1600 Feehanville Drive Mount Prospect, Illinois 60056

Dear Dr. Catizone:

This correspondence is in response to your letter dated July 26, 2011, to the Drug Enforcement Administration (DEA) seeking clarification on DEA's policy regarding information a pharmacist may provide when it is missing from a prescription for a schedule II controlled substance. Thank you for contacting DEA on this issue.

DEA is aware that pharmacists are sometimes presented with prescriptions for schedule II controlled substances that are missing information required for a valid prescription under state or federal law. In accordance with DEA regulations, pharmacists have a corresponding responsibility with practitioners for the proper prescribing and dispensing of controlled substances and must ensure that prescriptions for controlled substances conform in all essential respects to the law and regulations. 21 C.F.R. §§ 1306.04(a) and 1306.05(f). In particular, DEA regulations require that all prescriptions for controlled substances be dated as of, and signed on, the day when issued and bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner. 21 C.F.R. § 1306.05(a). Whether it is appropriate for a pharmacist to make changes to the prescription, such as adding the practitioner's DEA number to the prescription or correcting the patient's name or address, varies case-by-case based on the facts present. Consequently, DEA expects that when information is missing from or needs to be changed on a schedule II controlled substance prescription, pharmacists use their professional judgment and knowledge of state and federal laws and policies to decide whether it is appropriate to make changes to that prescription.

To this end, pharmacists and other practitioners must be mindful of what dispensing-related activities violate the Controlled Substance Act (CSA). For instance, it is unlawful to knowingly or intentionally furnish false or fraudulent material information in, or omit any material information from any application, report, record, or other document required to be made, kept, or filed under the CSA; to dispense a controlled substance in violation of 21 U.S.C. 829, which includes requirements for a schedule II controlled substance prescription; or to knowingly or intentionally use in the course of dispensing of a controlled substance a registration number that is fictitious, revoked, suspended, expired, or issued to another person. See e.g., 21 U.S.C. §§ 842(a)(1), (2), and (5), and 843(a)(2), (3), and (4)(A).

I would like to thank you again for your willingness to work with DEA and I look forward to our continued cooperation.

Sincerely,

(oseph T. Rannazzisi

Deputy Assistant Administrator

Office of Diversion Control