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Rules – 2005

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-271N]

Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Clarification.

SUMMARY: On January 18, 2005, DEA published in the Federal Register a solicitation of comments on the subject of dispensing controlled substances for the treatment of pain. Many of the comments that the agency received indicate that there is a need to issue a clarification regarding certain aspects of the prescription requirements for schedule II controlled substances. This document provides such clarification.

DATES: August 26, 2005.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; Telephone: (202) 307-7297.

SUPPLEMENTARY INFORMATION: On January 18, 2005, the Drug Enforcement Administration (DEA) published in the Federal Register a Solicitation of Comments on the subject of dispensing controlled substances for the treatment of pain. 70 FR 2883. Most of the comments that the agency received sought clarification on the legal requirements governing the prescribing of schedule II controlled substances by physicians in view of DEA's November 16, 2004, Interim Policy Statement. 69 FR 67170. Given these comments, DEA wishes to reiterate the following principles under the Controlled Substances Act (CSA) and DEA regulations.

1. As the Interim Policy Statement states, ``For a physician to prepare multiple prescriptions [for a schedule II controlled substance] on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II controlled substance." To do so conflicts with the provision of the CSA which provides: ``No prescription for a controlled substance in schedule II may be refilled."
2. Many of the comments that DEA received were from patients who said they have been receiving prescriptions for schedule II controlled substances for several years (for example, for the treatment of severe pain or attention deficit hyperactivity disorder) and have gotten into a routine of seeing their physician once every three months. Many such commenters were under the mistaken impression that, because of the Interim Policy Statement, they now must begin seeing their physician every month. DEA wishes to make clear that the Interim Policy did not state that such patients must visit their physician's office every month to pick up a new prescription. There is no such requirement in the CSA or DEA regulations. What is required, in each instance where a physician issues a prescription for any controlled substance, is that the physician properly determine there is a legitimate medical purpose for the patient to be prescribed that controlled substance and that the physician be acting in the usual course of professional practice. 21 CFR 1306.04(a); United States v. Moore, 423 U.S. 122 (1975).

At the same time, schedule II controlled substances, by definition, have the highest potential for abuse, and are the most likely to cause dependence, of all the controlled substances that have an approved medical use. 21 U.S.C. 812(b). Physicians must, therefore, 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. Physicians must also abide by any requirements imposed by their state medical boards with respect to proper prescribing practices and what constitutes a bona fide physician-patient relationship. 21 U.S.C. 823(f)(1), (4).

3. Under the circumstances described in paragraph 2, in those instances where the physician (who regularly sees a patient) issues a prescription for a

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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. In addition, as the DEA regulations state: ``A prescription for a schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted [elsewhere in this section of the regulations]." 21 CFR 1306.11(a). Thus, as this provision of the regulations provides, faxing may be used to facilitate the filling of a schedule II prescription, but only if the pharmacy receives the original written, signed prescription prior to dispensing the drug to the patient.

4. The CSA and DEA regulations contain no specific limit on the number of days worth of a schedule II controlled substance that a physician may authorize per prescription. Some states, however, do impose specific limits on the amount of a schedule II controlled substance that may be prescribed. Any limitations imposed by state law apply in addition to the corresponding requirements under Federal law, so long as the state requirements do not conflict with or contravene the Federal requirements. 21 U.S.C. 903. Again, the essential requirement under Federal law is that the prescription for a controlled substance be issued for a legitimate medical purpose in the usual course of professional practice. In addition, physicians and pharmacies have a duty as DEA registrants to ensure that their prescribing and dispensing of controlled substances occur in a manner consistent with effective controls against diversion and misuse, taking into account the nature of the drug being prescribed. 21 U.S.C. 823(f).

Finally, as stated in the Solicitation of Comments, once DEA has completed its review of the comments, the agency plans to issue a new Federal Register document, which will provide a recitation of the pertinent legal principles relating to the dispensing of controlled substances for the treatment of pain.

Dated: August 19, 2005.

Michele M. Leonhart,
Deputy Administrator.

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