New DEA Interim Policy on Multiple Prescriptions

In the November 16, 2004 edition of the Federal Register, the U.S. Drug Enforcement Administration published an "Interim Policy Statement" entitled *Dispensing of Controlled Substances for the Treatment of Pain.* http://www.deadiversion.usdoj.gov/fed_regs/rules/2004/fr1116.htm

The stated purpose of the publication was to correct misstatements made in an August 2004 Frequently Asked Questions and Answers document that was posted on the DEA Office of Diversion Control web site. The statement is as follows:

> "Refills of schedule II prescriptions--The August 2004 FAQ stated: "Schedule II prescriptions may not be refilled; *however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different dates*." (Italics added.) The first part of this sentence is correct, as the CSA expressly states: "No prescription for a controlled substance in schedule II may be refilled."21 U.S.C. 829(a)". However, the second part of the sentence (italicized above) is incorrect. For a physician to prepare multiple prescriptions 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 one of the fundamental purposes of section 829(a). Indeed, as the factors quoted above from the Rosen case indicate, writing multiple prescriptions on the same day with instructions to fill on different dates is a recurring tactic among physicians who seek to avoid detection when dispensing controlled substances for unlawful (nonmedical) purposes. It is worth noting here that the DEA regulations setting forth the requirements for the issuance of a controlled substance prescription are set forth in 21 CFR 1306.01-1306.27."

Further noted in the document is the following.

Nature of This Document and the August 2004 FAQ under the Administrative Procedure Act

> "This document is a statement of policy within the meaning of the Administrative Procedure Act (APA). It is termed an "interim" statement to indicate that a more complete statement on the subject will subsequently be issued by the agency. (Given the misstatements in the August 2004 FAQ, and the significant questions DEA has received following the withdrawal of that document, an immediate preliminary explanation is warranted.) The APA expressly requires agencies to make available to the public and publish in the Federal Register statements of general policy and interpretations formulated and adopted by the agency. 5 U.S.C. 552(a)(1)(D). Further, the APA contemplates that agencies shall issue policy statements without engaging in the notice-and-comment proceedings that are required for legislative rules. 5 U.S.C. 553(b)(A). **This is because policy statements, unlike legislative rules, are not binding. Consistent with these APA principles, this document does not create any new substantive requirements or change the rights and duties of any member of the public; nor is DEA applying the CSA or DEA regulations in a new manner as a result of this document.** Rather, this document provides the public with DEA's policy for ensuring that the law administered by the agency relating to the subject matter of this document is faithfully executed."
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> "It also bears emphasis that the August 2004 FAQ was not an official statement of the agency. As indicated above, the APA requires publication in the Federal Register of agency policy statements or interpretations of the law administered by the agency. The August 2004 FAQ was not published by the agency in the Federal Register and did not constitute an authoritative or official statement of the agency."

This is intended to be a restatement of the published DEA policy and does not represent any rule or policy of the Tennessee Board of Pharmacy.

You may direct any comments on this matter to the DEA.

% Karen P. Tandy, Administrator
Drug Enforcement Administration
2401 Jefferson Davis Highway
Alexandria, VA 22301