



November 6, 2006

Deputy Administrator
Drug Enforcement Administration
Washington, DC 20537
Via email to dea.diversion.policy@usdoj.gov

Attention: DEA Federal Representative/ODL

Re: Docket No. DEA -287N

We are responding on behalf of the Alliance of State Pain Initiatives, formerly the American Alliance of Cancer Pain Initiatives, to the request for written comments on proposed rule 21 CFR Part 1306. We welcome the Drug Enforcement Administration's (DEA) effort to address the concerns of advocates for pain management by proposing a rule that allows for the practice of issuing multiple prescriptions for Schedule II controlled substances with instructions to fill at later dates.

The Alliance of State Pain Initiatives is a national network of health care professionals and patient advocates dedicated to improving the management of pain. Our organization has been involved in many collaborative efforts with the DEA, state regulators and law enforcement officials to promote balance in the laws and regulations that govern the use of controlled substances for the treatment of pain, including the issuance of the joint statement, *Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act*, with the DEA in 2001. We are committed to assuring that persons have access to the drugs that are essential for controlling their pain while minimizing the diversion and abuse of these medications.

First, we agree that it would be beneficial to allow health care professionals to issue multiple prescriptions in order to provide appropriate care for persons with chronic pain; however, we have the following concerns with certain provisions in the proposed rule.

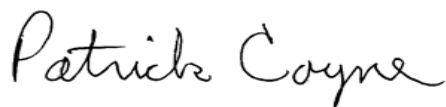
- We do not support the inclusion of a specific limitation (90-day supply) on the total amount of schedule II controlled substances that practitioners are allowed to prescribe when issuing multiple prescriptions. We feel that such limits unduly restrict clinical judgment and intrude upon the patient-physician relationship. The DEA may be correct in stating that the most common practice used among physicians who write multiple prescriptions has been to give the patient three prescriptions, each for a thirty-day supply, but there are circumstances in which it is medically appropriate for a longer time frame. For example, many persons with chronic pain may live part of the year in locations far from their health care provider. Under the proposed rule, will these persons be required to visit their doctors' offices at least every three months? Our preference is a federal rule that provides the individual practitioner the discretion to issue multiple prescriptions in a time frame based upon on the practitioner's medical judgment and relationship with the patient.

- We believe that section 21 CFR Sec.1306.12 (b)(1)(iii) of the rule that requires practitioners to conclude that issuing multiple prescriptions does not create an “undue risk” of diversion and abuse is unnecessary. The mere practice of issuing multiple prescriptions minimizes diversion and abuse because it provides the practitioner with greater control and oversight. Yet, this provision implies that this practice could contribute to diversion or abuse. Practitioners who prescribe controlled substances, regardless of whether they issue multiple prescriptions, are already obligated to minimize the risk that the drugs will be diverted and abused. We feel that state professional regulatory boards, and not the Drug Enforcement Administration, should judge the validity of a practitioner’s prescribing practices and determine if sufficient safeguards were taken to minimize diversion or abuse.
- We recommend that the language, “in accordance with established medical standards”, contained in paragraph (b)(2) of the proposed rule be eliminated. We are not aware of any standards that a practitioner could use to determine whether it is appropriate to issue multiple prescriptions.

Finally, it is important that the implementation of the new rule does not reinforce the misperception that there is a federal limit on the amount of controlled substances that may be dispensed with a single prescription. Indeed, several news reports on the proposed rule misinterpreted the DEA’s action as increasing the amount allowed for a schedule II controlled substance from a 30-day supply to a 90-day supply. It is vitally important that the adoption of the rule be accompanied by an explanation that the proposed rule does not prohibit a practitioner from prescribing more than a 30-day supply of a schedule II controlled substance from a *single* prescription provided it is done for a legitimate medical purpose and in conformance with state law. A clear explanation of existing law and the impact of the rule change must be communicated to health care professionals, state Attorneys General, drug control officials, and professional licensing and regulatory boards.

We appreciate the DEA’s consideration of our comments, and welcome the opportunity to renew our dialog and work together to promote effective pain relief nationwide.

Sincerely,



Patrick Coyne, RN, MSN
Chairperson, Advisory Council
Alliance of State Pain Initiatives



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