

November 3, 2006

Michele Leonhart
Deputy Administrator
DEA
Washington, D.C. 20537

Re: Comments re Docket No. DEA-287N

Dear Deputy Administrator Leonhart:

We the undersigned organizations submit the following comments in response to the Drug Enforcement Administration's September 6, 2006 call for public comment on its proposed rule to allow multiple Schedule II prescriptions. Our comments also pertain to the policy statement published in the Federal Register simultaneously with the proposed rule.

Comments to Docket No. DEA-287N

We would like to express our support of the proposed regulation as an important step to improve the regulatory environment for pain care in this country. We appreciate the D.E.A.'s recognition that the interpretation of the Controlled Substances Act in the Interim Policy Statement released in November 2004 would hamper good medical practice. The new rule permitting multiple prescriptions for Schedule II controlled substances will allow for more effective pain management by eliminating the medically unnecessary requirements of the Interim Policy, which placed burdens on patients, prescribers, and pharmacists.

We would also like to express specific concerns with the proposed rule.

- (1) We recommend that "90-day supply" be changed to, "An individual practitioner may issue multiple prescriptions at the same time, and each must bear the date that they were issued and signed, and the date on which they can be dispensed." This wording would avoid inevitable confusion about how to calculate the amount, and avoid the perception that the DEA, in the absence of such authority, has decided now to limit the quantity of prescriptions or the length of time for which they may be written.
- (2) In any event, we request clarification that this rule does not change the fact that federal law and regulations do not limit: a) the length of time for which an individual prescription may be written; or b) the total quantity, including number of dosages, that may be prescribed at one time. The DEA should make it clear, as stated in the Interim Policy Statement, that this determination falls under the reasonable medical judgment of the prescribing practitioner.
- (3) The final rule should clarify that it remains within the practitioner's reasonable medical judgment how often that practitioner must see the patient.

- (4) The final rule should clarify any implications for, or responsibilities of, the dispensing pharmacist.
- (5) The word “properly” should be eliminated from the phrase, “The individual practitioner properly determines there is a legitimate medical purpose....” It is difficult to conceive a legitimate medical purpose that would not also be proper.
- (6) The proposed rule requires that practitioners not “create an undue risk of diversion or abuse” in the issuance of multiple prescriptions. We are concerned about the meaning of the term “undue risk” and whether it imposes a new standard on practitioners. We are also uncertain of the need for the provision. One of the purposes or benefits of serial prescriptions is to *decrease* the potential for abuse or diversion by limiting the number of doses a patient will have in his or her possession at any given time.
- (7) Section 2 (b)(2) of the rule states, “...that individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is...” What “established medical standards” are being referred to?

Addressing the Pain Problem Requires Establishing a Shared Understanding and Partnership

An estimated 50 million Americans suffer with chronic pain. Far too many do not receive adequate pain care due, in part, to the persisting stigma surrounding pain medications and the perception that federal regulations impede practitioners from delivering the best possible care in a timely manner. For this reason, we call attention to and applaud the statement made by Administrator Tandy in the new Practitioner’s Manual which was released at the same time as the proposed rule and the policy statement, in which she, without reservation, reiterates that: “...*the D.E.A. remains committed to the 2001 Balanced Policy of promoting pain relief and preventing abuse of pain medication.*”

The under treatment of pain in this country represents a growing public health crisis. It is critical for the public and health care practitioners to understand and address this problem; it is equally important for regulators and law enforcement to comprehend its impact. The concept of balance helps define the appropriate roles and responsibilities of both healthcare practitioners and law enforcement officials when addressing pain management and the problems of drug diversion. The main role of practitioners is to treat pain, but they also must understand the laws governing their practice and avoid contributing to medication abuse and diversion. Similarly, the main role of law enforcement is to stop diversion but they should avoid interfering in legitimate medical practice and patient care. Thus, the concept of balance recognizes the strong common interest of healthcare and law enforcement to understand and avoid interfering with each others’ work to protect public health and safety.

We reaffirm our readiness and desire to work with the D.E.A. on an ongoing basis to address these and other issues affecting pain management and proper prescribing. In this regard, we are disappointed with the clear message given in the policy statement that the

D.E.A. is not prepared to form an advisory committee. As stated above, we believe it is essential to gain a mutual understanding for each other's concerns and obligations. By partnering on this issue, the D.E.A. can also avoid the frustration and, frankly, distrust which resulted from the unexpected withdrawal of the 2004 FAQ (developed jointly by D.E.A. and recognized experts in pain and addiction medicine). This included the withdrawal of some 10 years of authorization concerning the very multiple prescription process the present rule proposes to reinstate.

Again, we acknowledge the benefits of the proposed amendment and appreciate the agency's renewed commitment to balance enforcement policy with the provision of appropriate pain management. We urge the D.E.A. to establish a mechanism to engage in ongoing dialogue with the pain community. We must protect practitioners' ability to practice good medicine without undue restriction and uphold patients' rights to quality pain management.

We welcome the opportunity to further discuss the nature of pain care as well as enforcement efforts against diversion.

Signed,

Alliance of State Pain Initiatives
American Academy of Hospice and Palliative Medicine
American Academy of Pain Management
American Academy of Pain Medicine
American Cancer Society
American Chronic Pain Association
American Pain Foundation
American Society for Pain Management Nursing
Center for Practical Bioethics
Citizen Advocacy Center
Hospice and Palliative Nurses Association
Maryland Pain Initiative
National Pain Foundation
New Hampshire Pain Initiative
Pain and Policy Studies Group
National Chronic Pain Society
National Hospice and Palliative Care Organization