



December 17, 2004

Michelle Leonhart
Deputy Administrator
Drug Enforcement Administration
2401 Jefferson Davis Highway
Alexandria, VA 22301

Re: Frequently Asked Questions (FAQs) and Interim Policy Statement (IPS)

Dear Ms Leonhart:



The Liaison Committee on Pain and Addiction (LCPA), representing the American Academy of Pain Medicine (AAPM), the American Pain Society (APS), and the American Society of Addiction Medicine (ASAM) wishes to voice its concern with the unilateral withdrawal of DEA's support of "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel" (FAQ), which was published on the Office of Diversion Control Web site in August 2004 and received favorably by the health care community with an excellent review in the Journal of the American Medical Association (JAMA) and newspapers across the country. The LCPA was surprised that DEA withdrew support of the FAQ without discussion with or prior notification of the principal work group and reviewers who participated closely with the DEA in developing this two-year project.

The DEA shares interests with the pain treatment community – the assurance of access to controlled substances by those with a legitimate need, and the prevention of access by all others. Despite these common goals, a climate of fear and mistrust has existed that impeded patient care. At times patients were allowed to suffer because physicians had unrealistic fears of sanctions for legitimate prescribing. Over the course of the last 5 years, the DEA has partnered with the pain community at numerous conferences and task force meetings in an effort to clarify the obligations of prescribing physicians both to patients and to community safety. Clarification of regulations has assisted physicians in treating the underserved population of people in pain while meeting regulatory requirements that protect the public health. The FAQ was a valuable continuation and expansion of that process.



The interim policy statement on "Dispensing of Controlled Substances for the Treatment of Pain" published in the Federal Register of November 16, 2004 (IPS) is an unfortunate step backwards, largely because of the tone in which it is written, which promotes a return to an adversarial relationship between registrants and the DEA. It is striking that the IPS took factual issue with only one statement (that permitting "Do not fill until" orders on prescriptions), yet failed to affirm any of the remaining 29 statements in the FAQ.

Liaison Committee on Pain and Addiction

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The LCPA would like to address each of the perceived misstatements in the August 2004 FAQ as laid out in the Interim Policy Statement (IPS) in the Federal Register, Vol. 69, No. 220 titled "Dispensing of Controlled Substances for the Treatment of Pain," its stated purpose was to explain how some of the statements in FAQ were erroneous. It appears to committee members that some of the "erroneous" statements were taken out of context, and that the IPS clarifications are not consistent with published material and existing federal regulations.

The LCPA agrees with the statement in the IPS that "...chronic pain is a serious problem for many Americans. It is crucial that physicians who are engaged in legitimate pain treatments not be discouraged from providing proper medication to patients as medically justified." Yet, the IPS's explanation of FAQ misstatements will undoubtedly have the exact opposite effect on any practitioner reading them.

The first explanation dealt with *commencement of investigations*. The IPS says that the following statement in the August 2004 FAQ was erroneous: "The number of patients in a practice who receive opioids, the number of tablets prescribed for each patient, and the duration of therapy with these drugs do not, by themselves, indicate a problem, and they should not be used as the sole basis for an investigation by regulators or law enforcement." According to the IPS, "in fact, each of the foregoing factors---though not determinative---may indeed be indicative of diversion." It goes on to quote a longstanding legal principal that the government can investigate merely on suspicion that the law is being violated or even just because it wants assurance that it is not. It follows that with the statement that "it would be incorrect to suggest that DEA must meet some arbitrary standard or threshold evidentiary requirement to commence an investigation of a possible violation of the Controlled Substances Act (CSA)."

The IPS has taken this "erroneous" statement out of context. This statement was the first part of an answer to the following question: "Do the number of patients who receive opioids, the number of tablets prescribed for each patient, or the duration of therapy with these drugs by themselves indicate abuse or diversion?" The answer to this FAQ was making the point that a specialist who treats pain patients would by definition have a large number of patients in the practice who receive opioids; might have to prescribe a "large" amount of medication for those patients with severe, chronic pain; and would see patients for a long time since the patients have chronic pain. This would be normal and within the accepted standard of care; therefore, these factors should not be used as the *sole* [italics added] basis for an investigation. The second part of the answer, which the IPS ignores, says: "However, these factors, combined with others, may indicate that prescriptions are being issued or dispensed for other than legitimate medical purposes or not in the course of professional practice."

It was not the purpose of FAQ to suggest that the DEA meet some arbitrary standard to commence an investigation, but to reassure physicians who prescribe CS that the mere fact of prescribing opioids would not subject them to indiscriminate investigation by the DEA. Yet, reading that the government can investigate merely on suspicion that the law is being violated will send chills down the spine of practitioners who are treating patients with CS and certainly will contribute to the undertreatment or non-treatment of moderate to severe chronic pain. Is this the intent of the DEA? It certainly is not consistent with the IPS statement that "chronic pain is a serious problem for many Americans. It is

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crucial that physicians who are engaged in legitimate pain treatment not be discouraged from providing proper medication to patients as medically justified. DEA recognizes that the overwhelming majority of physicians dispense controlled substances lawfully for legitimate medical reasons, including the treatment of pain."

The second explanation of a FAQ misstatement in the IPS dealt with *refills of schedule II prescriptions*. The IPS takes issue with the FAQ statement: "*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.*" However, this practice has been endorsed by the DEA in official correspondence dated January 31, 2003 and published in a peer-reviewed journal (HA Heit, E Covington, PA Good: Dear DEA. *Pain Medicine*. 2004; 5(3):303-08). Pain Medicine specialists use the "Do Not Fill" method of prescribing in several situations. Some insurance companies and local authorities set a coverage limit of a 30-day supply of medication. If a patient is stable and does not need to be seen that often, giving the patient two prescriptions dated on the same day, but with one bearing a "Do Not Fill" date, is a way to comply with the requirement and to control costs by preventing the necessity of another office visit. In addition, for clinical reasons, some patients may require smaller quantities of medications provided at more frequent intervals, for example every two weeks, while seeing the patient that often is not necessary. Finally, some states set dose unit limits that require patients on even low to moderate doses of some medications to receive two or more prescriptions to receive a months supply of medication.

The third misstatement addressed in the IPS is *reselling of controlled substances*. In this section, the IPS criticized the FAQ for understating the degree of caution a physician must exercise to minimize the likelihood of diversion when dispensing a controlled substance to a known or suspected addict. Yet, the FAQ was clear in stating that physicians must be on the lookout for "red flags" that would indicate abuse or diversion and listed things to be aware of. Moreover, the FAQ states clearly that, "incontrovertible evidence of criminal activity, such as diversion, is grounds for termination of the doctor-patient relationship." But at the same time, a physician must recognize that federal regulations do not preclude the treatment of pain with opioids in a patient with the disease of addiction.

The IPS also states that the "August 2004 FAQ incorrectly minimized the potential significance of a family member or friend expressing concern to the physician that the patient may be abusing the pain medication." In answering a question on what kinds of problems a patient might encounter when obtaining opioids prescriptions, in having them filled, or in taking them properly, the FAQ said: "Family and friends, or health care providers who are not directly involved in the therapy, may express concerns about the use of opioids. These concerns may result from a poor understanding of the role of this therapy in pain management or from an unfounded fear of addiction; they may be exacerbated by widespread, sometimes inaccurate, media coverage about abuse of opioid pain medicine." There is nothing in this statement that would imply that a physician should ignore a family member or friend who expresses concern about a patient. The DEA also makes no mention of privacy policies to which physicians must adhere. However, we concur it is reasonable to articulate the fact that concerns expressed by family and friends may in fact be based on observations of misuse of medications and should be carefully assessed.

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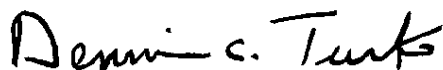
It is the hope of the LCPA and the organizations it represents that DEA will work to restore a spirit of cooperation and communication between the healthcare community and the DEA. We ask that the DEA publicly reaffirm its commitment the goal of achieving a better balance in addressing the treatment of pain while preventing abuse and diversion. The LCPA urges the DEA to consult with either the original group that worked on FAQ for two years or other experts in the field of pain management and addiction medicine before addressing the issue of dispensing controlled substances in another Federal Register document. It is our hope that the interim policy statement will be followed by a more lasting one that not only addresses the specific issues detailed herein, but also affirms the necessity of a DEA/registrant alliance for optimal public health and safety.

We look forward to hearing from you.

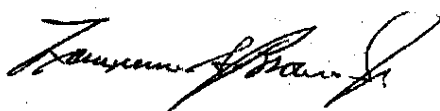
Sincerely,



Samuel J. Hassenbusch, MD PhD
AAPM President



Dennis C. Turk, PhD
APS President



Lawrence Brown, MD
ASAM President

cc: Karen P. Tandy, DEA Administrator
William Walker, DEA Deputy Assistant Administrator

Liaison Committee on Pain and Addiction (LCPA) Representatives
Seddon Savage, MS MD FASAM (Chair) - APS; Edward C. Covington, MD - AAPM;
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