Overview of DEA Policy Statements

This section covers key DEA policy statements concerning the use of controlled substances to treat pain, including:

1. **Interim Policy Statement**. Published in the Federal Register in November 2004. This document replaced a document called Prescription Pain Medications: Frequently Asked Questions and Answers (the FAQ).

2. **Clarification Statement**. Published in the Federal Register in August 2005. This document "clarifies" the Interim Policy Statement and certain issues regarding Schedule II drugs.

3. Final Policy Statement. Published in the Federal Register in September 2006. This document is the final effort by DEA and closes out the Interim Policy Statement.

4. Proposed Rule Regarding Issuance of Multiple Prescriptions for Schedule II Controlled Substances. Published in the Federal Register in September 2006. This document is the DEA's effort to describe the method by which it will allow practitioners to use so-called "Do Not Fill Before" prescriptions for Schedule II controlled substances.

5. Final Rule Regarding Issuance of Multiple Prescriptions for Schedule II Controlled Substances. Published in the Federal Register in October 2007.

Use Table 2 as you read this section. You will find additional useful information by reviewing the series of letters and comments about DEA's retraction of the FAQ and its decision to issue the Interim Policy Statement and Clarification Statement on the University of Wisconsin Pain & Policy Studies Group's website at http://www.medsch.edu.painpolicy.org.

Introduction to Federal Policy:

Federal policy statements on the use of controlled substances to treat pain are relatively new—since 2004. And, prior to DEA's publication of the Interim Policy Statement (November 2004), DEA had been working with the pain management community to develop policy-type materials on the use of controlled substances to treat pain. The best example of DEA's work with the medical Community was the document called Prescription Pain Medications: Frequently Asked Questions and Answers (the FAQ). Unfortunately, DEA retracted the FAQ before many pain Practitioners had the opportunity to review the document. As of February 2006, it appears that DEA has taken steps to further insulate itself from the medical community. Consequently, pain practitioners must now wait for DEA's forthcoming (and rather unilateral) publication – a final policy statement on the use of controlled substances to treat pain. We discuss the current federal policy statements below.

The Interim Policy Statement (IPS):

In November 2004, following the publication and retraction of the FAQ, DEA published an Interim Policy Statement (IPS) on dispensing controlled substances to treat pain. The IPS contains DEA's "official position" on the CSA and legal boundaries on the use of controlled substances for the treatment of pain. The IPS is published in the federal register, making it an official government document. The IPS contains several key points illustrating DEA's concerns over the use of controlled substances to treat pain. I discuss these points below. Remember, because the IPS is an official statement of the DEA, the agency will use it when performing agency functions relating to registrants and prescribed controlled substances.

The IPS and the DEA's Ability to Commence Investigations:

DEA first used the IPS to remind registrants that DEA may initiate an investigation of a registrant at any time and for any reason without jumping through any "hoops". This is not a new concept as DEA, much like most state licensing boards, has the ability (and the responsibility) to investigate allegations that a registrant has failed to follow the federal law relating to controlled

substances – from both an administrative and a criminal perspective. DEA's responsibility here is analogous to a state medical licensing board's responsibility to investigate allegations that a licensee has practiced medicine in a manner inconsistent with state minimum standards, etc.

DEA claimed "the FAQ erroneously stated '[t]he 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.'" DEA cites several factors from a federal criminal case, *United States v. Rosen*, and notes that these factors, while not necessarily determinative may indeed be indicative of diversion. The *Rosen* factors include physicians who: (1) prescribe inordinately large quantities of controlled substances, (2) issue large numbers of prescriptions, (3) fail to perform physical examinations, (4) warn the patient to fill prescriptions at different drug stores, (5) issue prescriptions to a patient known to be diverting the drugs to others, (6) prescribe controlled drugs at intervals inconsistent with legitimate medical treatment, (7) use street slang rather than medical terminology to refer to the drugs they prescribe, (8) prescribe despite a lack of logical relationship between the drugs prescribed and the accepted treatment for the patient's condition, and (9) prescribe more than one prescription on occasions in order to spread out prescriptions.

DEA also used the IPS to reiterate a "longstanding legal principle - that the Government 'can investigate merely on suspicion that the law is being violated, or even just because it wants assurances that it is not.'" Thus, DEA believes "the FAQ incorrectly suggested DEA must meet some arbitrary standard or threshold evidentiary requirement to commence an investigation of a possible violation of the Controlled Substances Act."

The IPS and "Trouble Signs" in a Practice

DEA claims "FAQ erroneously stated '[t]he 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.'" It is DEA's position that these factors while not "necessarily determinative" "may indeed be indicative of diversion." In support for its position, DEA cites a federal case called *United States v. Rosen*, pointing out that the *Rosen* court summarized "certain recurring concomitance of condemned behavior: (1) an inordinately large quantity of controlled substances was prescribed; (2) large numbers of prescriptions were issued; (3) no physical examination was given; (4) the physician warned the patient to fill prescriptions at different drug stores; (5) the physician issued prescriptions to a patient known to be delivering the drugs to others; (6) the physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment; (7) the physician involved used street slang rather than medical terminology for the drugs prescribed; (8) there was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing; (9) *The physician wrote more than one prescription on occasions in order to spread them out*." Note, the ninth example in *Rosen* is the phrase DEA relies upon to prohibit DNF prescriptions, as discussed below.

The IPS and "Do Not Fill" Prescriptions

DEA used the IPS to prohibit the use of "Do Not Fill" prescriptions (DNF). The FAQ contained the following statement about DNF prescriptions: "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." According to the DEA, "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.'" However, DEA used the IPS to say the CSA does not allow for the activity described in the italicized portion of the FAQ language above. Instead, in the IPS, DEA said that physicians who "prepare multiple prescriptions on the same day with instructions to fill on different dates" are essentially "writing a prescription authorizing refills of a schedule II controlled substance, [and doing so] conflicts with one of the fundamental purposes of section 829(a)."

To support its position, DEA refers to factors quoted in a federal criminal case, *United States v. Rosen*, and comments that "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 (non-medical) purposes." DEA's reference to *Rosen* is weak because *Rosen* involved "postdated prescriptions" rather than DNF prescriptions. A post-dated prescription is one that is not dated and signed on the date the prescription is issued to the patient. Conversely, DNF prescriptions are properly dated and signed on the date issued to the patient, but contain an instruction to the dispensing pharmacist to fill the prescription on or after a specific date. In many ways, DEA's position against DNF prescriptions is one that may actually promote abuse and diversion rather than minimize it. Hopefully, DEA will realize these important distinctions and reconsider its position on DNF prescriptions prior to issuing a final policy statement on the use of controlled substances for the treatment of pain.

The IPS and the Registrant's Responsibility to "Minimize the Potential for Abuse and Diversion"

DEA cited a third problem with the FAQ, claiming that the FAQ [allegedly] understates "the degree of caution that a **physician must exercise to minimize the likelihood of diversion when dispensing controlled substances to known or suspected addicts."** DEA used the IPS to explain that **registrants have "a responsibility to exercise a much greater degree of oversight to prevent diversion in the case of a known or suspected addict than in the case of a patient for whom there are no indicators of drug abuse." Thus, DEA believes physicians must "engage in additional monitoring of the patient's use of narcotics" when the physician "is aware that the patient is a drug addict and/or has resold prescription narcotics." DEA also believes the federal law prohibits physicians from "dispensing controlled substances with the knowledge that they will be used for a non-medical purpose or that they will be resold by the patient."** DEA leaves the method of monitoring to the individual clinician and the states. The IPS contains a discussion of monitoring examples.

The IPS and the DEA Registrant's Responsibility to "Seriously Consider" any "Sincerely Expressed Concerns" By Family Members about a Patient

DEA's fourth criticism of the FAQ is that it "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 this regard, the FAQ states: "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 medications." DEA believes that "family members are not always determinative of whether the patient is engaged in drug abuse," but thinks "the above-quoted [FAQ] statement is incorrect to the extent it implies that physicians may simply disregard such concerns expressed to them by family members or friends."

While "a family member or friend might be aware of information that the physician does not possess regarding a patient's drug abuse." DEA also believes "(1) the addictive and sometimes deadly nature of prescription narcotic abuse, (2) the tremendous volume of such drug abuse in the United States, and (3) the propensity of many drug addicts to attempt to deceive physicians in order to obtain controlled substances for the purpose of abuse," requires physicians to "seriously consider any sincerely expressed concerns about drug abuse conveyed by family members and friends." Unfortunately, DEA did not explain in the IPS its expectations regarding "sincerely consider" or "sincerely expressed concerns." Consequently, if a family member or friend contacts you about a patient's behavior regarding controlled substances, document the contact and do something that shows you addressed the matter with the patient. While it is not necessary to discuss the third-party contact with the patient, it is necessary to take steps to minimize the potential for abuse and diversion of the controlled substances you prescribe using follow-up visits, laboratory testing, psychological and substance abuse counseling, changes in the treatment plan, consultations, and referrals, to ensure the patient continues to benefit from the medications prescribed.

The August 2005 Clarification Statement

Following its publication of the IPS and its solicitation of comments regarding the IPS, in August 2005, the DEA issued a document called a Clarification of Existing Requirements under the CSA on the Use of Schedule II Controlled Substances (the Clarification Statement). DEA issued the Clarification Statement to respond to some of the comments made by the public about the IPS. In particular, DEA received many comments from patients who have been using schedule II controlled substances for several years and routinely saw this physician once every three months. DEA said that some of the individuals commenting on the IPS "were under the mistaken impression that, because of the [IPS], they now must begin seeing their physician every month." In response to these comments, DEA states: "the IPS did not state that 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." Significantly, however, DEA clearly states: "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."

DEA recognizes that "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." Thus, DEA expects physicians to: "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." DEA also expects physicians to "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."

What does this mean to your practice? If you regularly see a patient and issue him/her a prescription for a schedule II controlled substance (for a legitimate medical purpose and without seeing the patient in person), DEA believes it is proper for you to "mail the prescription to the patient or pharmacy." The Clarification Statement also notes that 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]." DEA therefore believes the CSA allows registrants to fax a schedule II prescription to facilitate processing to the patient, "but only if the pharmacy receives the original written, signed prescription prior to dispensing the drug to the patient [and only if state law permits]."

Neither the CSA nor the CFR contain "a 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 and you must follow them as well, "so long as the state requirements do not conflict with or contravene the Federal requirements." Again, DEA expects its registrants to issue controlled substance prescriptions for a legitimate medical purpose in the usual course of professional practice. And, "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."

DEA and a Final Policy Statement

DEA issued its Final Policy statement in September 2006. This document contains a reiteration of prior statements. However, it does go further.