

## A summary of current Drug Enforcement Administration positions and resulting federal legal and regulatory “standards”

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This article contains a quick summary of the Drug Enforcement Administration’s (DEA) current position on using controlled substances to treat pain. My discussion covers three key sources:

1. The Code of Federal Regulations section 1306.04 pertaining to valid prescriptions;
2. *The Interim Policy Statement on Dispensing Controlled Substances for the Treatment of Pain*, published by the DEA in the *Federal Register* on November 16, 2004; and
3. The *Clarification Statement on the Controlled Substances Act and the Use of Schedule II Controlled Substances for the Treatment of Pain*, published by the DEA in the *Federal Register* on August 23, 2005.

In a “back to school” sense, I recommend that you cut out Figure 1, laminate it, and keep it as a quick reference card. The DEA is in the process of drafting a final policy statement on the dispensing of controlled substances for the treatment of pain, but the agency has not said when it will publish this final policy statement. Use our website, [www.legalsideofpain.com](http://www.legalsideofpain.com), to stay current on DEA releases. As you read this article, realize that I share your frustration about the lack of clear boundaries and the inconsistency between regulatory and health plan approaches to prescribing controlled substances to treat pain. I, and many others, continue to work for balance and clarity on your behalf.

### 21 CFR §1306.04—PURPOSE OF ISSUE OF PRESCRIPTION

When you receive a federal drug registration number, the DEA expects you to follow federal controlled substances laws, regulations, and policies. Citing federal law, the DEA expects its registrants to administer, dispense, and prescribe controlled substances for **a legitimate medical purpose while acting in the usual course of**

**professional practice.**<sup>1</sup> These two concepts, often viewed formally as a single standard, are well established in federal law. The Code of Federal Regulations (CFR), which explains most of the Controlled Substances Act (CSA) of 1970, contains the “legitimate medical purpose” standard.

In relevant part, 21 CFR §1306.04, entitled *Purpose of Issue of Prescription*, states:

(a) A prescription for a controlled substance to be effective **must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.** The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, **but a corresponding responsibility rests with the pharmacist who fills the prescription.** An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.<sup>2</sup>

A related CFR provision is 21 CFR §1306.05, entitled *Manner of Issuance of Prescriptions*, states:

**All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued<sup>3</sup> and shall** bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not

permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. **A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.**<sup>4</sup>

**Many states adopt the federal “legitimate medical purpose” standard and incorporate it into state licensing board regulations.** Make sure that you know your state’s position on what constitutes “legitimate medical purpose within the usual course of professional practice” and that you read all applicable state laws, regulations, and guidelines on controlled substance prescribing and pain management. Use our website, [www.legalside-offpain.com](http://www.legalside-offpain.com), to locate these materials.

#### THE DEA’S INTERIM POLICY STATEMENT

In November 2004, following the publication and retraction of a document called *Prescription Pain Medications: Frequently Asked Questions* (the FAQ), the DEA published an *Interim Policy Statement* (IPS) on dispensing controlled substances to treat pain.<sup>5</sup> In part, the DEA published the IPS to explain what the agency characterizes as “misstatements” in the FAQ. The IPS covers, among other things, four key areas of the DEA’s concern about the use of controlled substances to treat pain. The DEA published the IPS in the *Federal Register*, meaning that it is the agency’s official statement on matters related to the CSA. Also, it means that the DEA will use the IPS when it performs agency functions relating to registrants and prescribed controlled substances. The DEA acknowledges that both chronic pain and the abuse and diversion of controlled substances to treat it are large problems in the United States.

#### THE IPS AND THE DEA’S ABILITY TO COMMENCE INVESTIGATIONS

The DEA contends the FAQ contains language that suggests the “DEA must meet some arbitrary standard or threshold evidentiary requirement to commence an investigation of a possible violation of the Controlled Substances Act.”<sup>6</sup> Federal law does not require the DEA to meet any such standard. It is 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.’”<sup>7</sup>

Thus, the DEA first uses the IPS to remind registrants

that it may initiate an investigation of a registrant at any time and for any reason without jumping through any “hoops.”<sup>8</sup>

In the IPS, the DEA states 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.’”<sup>9</sup> The DEA acknowledges that these factors, while not “necessarily determinative,” “*may indeed be indicative of diversion.*”<sup>10</sup> The DEA cites a federal case called *United States v Rosen*<sup>11</sup> in support of its arguments and highlights several factors cited by the *Rosen* court regarding “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.**<sup>12</sup>

Under the CSA, the DEA has both the ability and the responsibility to investigate allegations that a registrant has failed to follow the federal law relating to controlled substances. The DEA uses both its administrative and criminal investigative authorities to fulfill its mission. In many ways, the DEA’s responsibility to investigate violations of the CSA 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 standards.



## Key DEA Expectations for Registrants who Prescribe Controlled Substances to Treat Pain (February 2006)

### Code of Federal Regulations

21 CFR § 1306.04 (purpose of issue of a prescription)

To be valid, a prescription must be issued for a legitimate medical purpose by a provider acting in the usual course of professional practice.

NOTE: There are several more federal regulations relating to controlled substance prescribing. Physicians should read all of these materials, including 21 CFR § 1306.05, which requires prescriptions to be dated as of, and signed on, the date when issued.

### Interim Policy Statement

Federal Register, Vol. 69, No. 220 [pages 67170-67172], Nov. 16, 2004

Responsibility to Minimize the Potential for Abuse and Diversion of Controlled Substances

Seriously Consider and Sincerely Expressed Concerns Made by Family Members or Friends about a Patient's Potential Abuse of Controlled Substances.

NOTE: The IPS also contains a prohibition against the use of "Do Not Fill" prescriptions. Physicians should consider the IPS and the below-described Clarification Statement when deciding how to issue prescriptions. This is a changing area of law, so use [www.legalsideofpain.com](http://www.legalsideofpain.com) to stay updated.

### Clarification Statement

Federal Register, Vol. 70, No. 165 [50408-50409], Aug. 26, 2005

Reiterates Legitimate Medical Purpose & Usual Course of Professional Practice

Patients do not have to "see" their physicians every 30 days to get prescriptions for controlled substances. HOWEVER, physicians should consider whether a patient should be seen more or less frequently based on each patient's individual circumstances.

Mailing and faxing of Schedule II controlled substance prescriptions *may* be an option for some physicians, depending on state law.

There is NO federal quantity limit for the dosage quantity in Schedule II controlled substance prescriptions. HOWEVER, there may be state law quantity limits. Likewise, health plans may have quantity limits (some less; some more).

Legitimate Medical Purpose

Usual Course of Professional Practice

Minimize the Potential for Abuse and Diversion

Seriously Consider Sincerely Expressed Concerns about a Patient's Potential Abuse or Diversion

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

Using what you know about each patient, determine whether you should see them less or more frequently relative to their use of controlled substances, especially those in Schedule II.

Check state laws and licensing board requirements regarding the faxing and mailing of Schedule II prescriptions, and regarding the quantity of dosage units for Schedule II prescriptions and the life of these prescriptions.

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Figure 1. DEA expectations.

### THE IPS AND "DO NOT FILL" PRESCRIPTIONS

The DEA's second problem with the FAQ concerns the following language:

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.*<sup>15</sup>

The DEA states in the IPS that "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.'<sup>14</sup> However, the DEA contends that the CSA does not allow for the activity described in the italicized portion of the FAQ language above.<sup>15</sup> Instead, **the DEA uses the IPS to take the position that physicians who "prepare multiple prescriptions on the same day with instructions to fill on different dates"<sup>16</sup> 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)."**<sup>17</sup>

The DEA supports its argument by discussing factors quoted in *United States v Rosen*,<sup>18</sup> 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 (nonmedical) purposes."<sup>19</sup> The DEA's reliance on *Rosen* is flawed because the facts in *Rosen* involve "postdated" prescriptions (dated improperly) rather than "do not fill" prescriptions (dated properly but containing instructions to the dispensing pharmacist about the dispensing period).<sup>20</sup> Thus, the DEA's position against "do not fill" prescriptions is one that requires additional analysis and may actually promote abuse and diversion rather than minimize it.<sup>21</sup>

## THE IPS, RESELLING OF MEDICATIONS, AND THE REGISTRANT'S RESPONSIBILITY TO "MINIMIZE THE POTENTIAL FOR ABUSE AND DIVERSION"

The DEA cites a third problem with the FAQ, claiming that the FAQ [allegedly] understated "the degree of caution that a physician must exercise to minimize the likelihood of diversion when dispensing controlled substances to known or suspected addicts."<sup>22</sup> The DEA states the "FAQ listed a number of behaviors, or 'red flags,' that are 'probable indicators of abuse, addiction, or diversion,'" including the sale of medications. The FAQ "suggested that certain steps be taken to deal with such indicators, including 'appropriate management' and possible referral to an addiction specialist. However, the FAQ also stated that these behaviors (including reselling medications) 'should not be taken to mean that a patient does not have pain or that opioid therapy is contraindicated.'" Regarding the phrase "appropriate management," the FAQ stated: "management may or may not include continuation of therapy, depending on the circumstances." Thus, according to the FAQ, "if continued opioid therapy makes medical sense, then the therapy may be continued, even if drug abuse has occurred. The DEA recommends that physicians engage in "additional monitoring and oversight of patients who have experienced such an episode." The DEA retracted its support on several of these FAQ statements, as discussed below.

The DEA confirms that "the behaviors listed in the August 2004 FAQ as 'red flags'" are indeed indicators of possible diversion, . . . but the FAQ understated the degree of caution that a physician must exercise to minimize the likelihood of diversion when dispensing controlled substances to known or suspected addicts." If a physician is aware that a patient is a drug addict, has resold prescription narcotics, or both, it is not merely "recommended" that the physician engage in additional monitoring of the patient's use of narcotics.

The DEA uses 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."**<sup>23</sup> Thus, the DEA believes that physicians *must* "engage in addition 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."<sup>24</sup> The DEA also believes the federal law prohibits physicians from "dispensing controlled substances [to any patient] with the knowledge that they will be used for a non-medical purpose or that they will be resold by the patient."<sup>25</sup> The DEA leaves the method of monitoring to the individual clinician and the states. The IPS contains a discussion of monitoring examples.<sup>26</sup>

## THE IPS AND THE DEA REGISTRANT'S RESPONSIBILITY TO "SERIOUSLY CONSIDER" ANY "SINCERELY EXPRESSED CONCERNS" BY FAMILY MEMBERS ABOUT A PATIENT

The 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."<sup>27</sup> 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.<sup>28</sup>

The 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."<sup>29</sup>

Because "a family member or friend might be aware of information that the physician does not possess regarding a patient's drug abuse,"<sup>30</sup> the 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,<sup>31</sup>

**requires physicians to "seriously consider any sincerely expressed concerns about drug abuse conveyed by family members and friends."**<sup>32</sup>

Unfortunately, the DEA did not explain in the IPS its interpretation of "sincerely consider" or "sincerely expressed concerns." Consequently, when 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. In all cases, your response should include monitoring measures that minimize the potential for abuse and diversion of the controlled substances you prescribe. Often you can meet this DEA standard through focused follow-up visits, laboratory testing, psychological and substance abuse counseling, changes in the treatment plan, consultations, and referrals.



## THE DEA'S CLARIFICATION STATEMENT

In August 2005, the DEA used its authority to *clarify* its position on the CSA in a document called *Clarification of Existing Requirements under the Controlled Substances Act for Prescribing Schedule II Controlled Substances*.<sup>33</sup> The DEA once again pronounced its belief that the CSA of 1970 and federal regulations on controlled substances prohibit the use of “do not fill” prescriptions.<sup>34</sup> However, the DEA acknowledged that since its release in November 2004, many people wrongly interpreted the *Interim Policy Statement* as a federal law requiring clinicians to see patients using schedule II medications every thirty days. Because of the confusion, and the many letters sent to the DEA following the *Interim Policy Statement*, the DEA chose to address this point in the *Clarification Statement*, stating the *Interim Policy Statement* [and federal law] does not require patients to see their physicians every thirty days to get their prescriptions for schedule II controlled substances.<sup>35</sup>

Nonetheless, the DEA expects its registrants to **“consider whether a patient should be seen more or less frequently depending on their individual circumstances.”**<sup>36</sup> This comment by the DEA **implies that registrants have a burden to balance what they know about a patient and his/her history (medical, substance abuse, and behavioral) during the course of the physician-patient relationship when deciding how frequently to see a patient who requires schedule II medications.** Generally, the more risks a patient presents, the more frequently you should see them personally and the more monitoring measures you should consider.

The DEA also points out in the *Clarification Statement*:

**. . . 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.**<sup>37</sup>

The 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.”<sup>38</sup> Thus, the 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.**<sup>39</sup>

The 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.”<sup>40</sup>

Assuming the DEA is correct<sup>41</sup> when it says “do not fill” prescriptions are illegal under federal law, what other options do you have for getting patients their schedule II medications? The DEA uses the *Clarification Statement* to point out that a clinician who regularly sees a patient and issues him/her a prescription for a schedule II controlled substance for a legitimate medical purpose and without seeing the patient in person may **“mail the prescription to the patient or pharmacy.”**<sup>42</sup> Of course, your ability to mail prescriptions is further subject to state law and some states disallow mailing, whereas others impose a “patient permission” requirement. In addition, mailing has its own problems—like ensuring receipt by the patient, which may entail the added cost of certified or registered mail.

The DEA uses the *Clarification Statement* to confirm yet another alternative to getting patients their schedule II medication—faxing the prescription:

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].<sup>43</sup>

Remember, however, your ability to fax schedule II prescriptions is further subject to state law. Make sure that you understand your state’s position on this matter before you use the faxing alternative.

As a final point, the DEA uses the *Clarification Statement* to explain the **federal law does not contain dosage limits for schedule II prescriptions.**<sup>44</sup> However, some states do impose dosage limits on the amount of a schedule II controlled substance that clinicians may prescribe.<sup>45</sup> Find out your state’s position, and factor it into your daily prescribing practices. Many states require clinicians to “control the drug supply,” especially to patients with a substance abuse history or other indications of abuse potential. Thus, **increasing the number of dosage units may not be the right answer because it may actually encourage abuse and diversion in certain patient populations.**

The DEA expects its registrants to issue a controlled substance prescription **for a legitimate medical purpose in the usual course of professional practice. "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."**<sup>46</sup>

## THE DEA AND A FINAL POLICY STATEMENT

The DEA will issue a final policy statement on the use of controlled substances for the treatment of pain, and every physician who prescribes controlled substances should find a good source to help them stay current on these matters. In all cases, physicians and physician extenders must make every effort to stay current with existing federal and state legal and regulatory materials and must be prepared to reevaluate their practices for compliance purposes.

**This is a Legal Side of Pain educational tool:** I intend for this article to serve as an educational tool for pain management practitioners, and I do not intend for it to serve as specific legal advice. If you need help on legal questions, contact me at 865-560-1945 or [jbolen@legalsideofpain.com](mailto:jbolen@legalsideofpain.com).

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## NOTES

1. 21 CFR 1306.04 - Prescriptions.
2. 21 CFR 1306.04.
3. This language relates to current issues surrounding the legality of "Do Not Fill" prescriptions. Federal case law tells us that those who "post date" prescriptions (do not date and sign prescriptions on the date issued) violate federal law. Do Not Fill prescriptions, however, are dated properly but contain instructions to the dispensing pharmacist about the timing of dispensation. The DEA claims Do Not Fill prescriptions are the same as postdated prescriptions. The case law suggests otherwise. For more on this issue, see Bolen J: Commentary. DEA and Schedule II "Do Not Fill Prescriptions" - Disappointing Enforcement Activity. *Pain Medicine*. 2006; 7(1): 80-85.
4. 21 CFR 1306.05.
5. US Drug Enforcement Administration, Interim Policy Statement on Dispensing Controlled Substances for the Treatment of Pain, November 16, 2004, as published in the Federal Register: Volume 60, Number 220, Pages 67170-67172. Available at <http://waisaccess.gpo.gov> (DOCID:fr16no04-82). Accessed January 10, 2006. Although the DEA used the term "dispensing" in the IPS, the DEA will apply its interpretation to other conduct, including administering and prescribing controlled substances to treat pain.
6. Interim Policy Statement, see note 5 above.
7. United States v. Morton Salt Co., 338 US 632, 642-643 (1950). Despite the DEA's ability to initiate investigations without satisfying any initial burdens, the DEA may not continue investigations or charge individuals without meeting basic criteria.
8. Interim Policy Statement, see note 5 above.
9. Interim Policy Statement, see note 5 above.
10. Interim Policy Statement, see note 5 above.

11. United States v. Rosen, 582 F.2d 1032, 1035-36 (5th Cir. 1978).
12. Rosen, 582 F.2d at 1035-1036 (internal cases citations omitted). Point 9 is the one the DEA relies on to claim that Do Not Fill prescriptions are improper. You can read more about this debate in Bolen, J. Commentary. DEA and Schedule II "Do Not Fill Prescriptions" - Disappointing Enforcement Activity. *Pain Medicine*. 2006; 7(1): 80-85.
13. To find the FAQ, conduct an Internet search using the following terms: DEA, FAQ, Prescription Pain Medications. The DEA retracted the FAQ from its website on or about October 6, 2004. Thus, there is no formal citation to the document available.
14. Interim Policy Statement, see note 5 above. See also 21 U.S.C. § 829(a).
15. Interim Policy Statement, see note 5 above.
16. Interim Policy Statement, see note 5 above.
17. Interim Policy Statement, see note 5 above.
18. Rosen, 582 F.2d 1032, 1035-1036.
19. Rosen, 582 F.2d 1032, 1035-1036.
20. Bolen J: Commentary, DEA and Schedule II "Do Not Fill Prescriptions" - Disappointing Enforcement Activity. *Pain Medicine*. 2006; 7(1): 80-85.
21. Bolen J: Commentary, DEA and Schedule II "Do Not Fill Prescriptions" - Disappointing Enforcement Activity. *Pain Medicine*. 2006; 7(1): 80-85.
22. Interim Policy Statement, see note 5 above.
23. Interim Policy Statement, see note 5 above.
24. Interim Policy Statement, see note 5 above.
25. Interim Policy Statement, see note 5 above.
26. Interim Policy Statement, see note 5 above.
27. Interim Policy Statement, see note 5 above.
28. Interim Policy Statement, see note 5 above.
29. Interim Policy Statement, see note 5 above.
30. Interim Policy Statement, see note 5 above.
31. Interim Policy Statement, see note 5 above.
32. Interim Policy Statement, see note 5 above.
33. US Drug Enforcement Administration, Clarification of Existing Requirements Under the Controlled Substances Act for Prescribing Schedule II Controlled Substances, August 26, 2005, as published in the *Federal Register*. 2005; 70(165): 50408-50409. Available at <http://wais.access.gpo.gov> (DOCID:fr26au05-139). Accessed January 10, 2006.
34. For a complete discussion of the DEA's position on "Do Not Fill" prescriptions and case law surrounding this issue, see Bolen J: Commentary, DEA and Schedule II "Do Not Fill Prescriptions" - Disappointing Enforcement Activity. *Pain Medicine*. 2006; 7(1): 80-85.
35. The exact language from the Clarification Statement is as follows: "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." Clarification Statement, see note 8 above.
36. Clarification Statement, see note 33 above.
37. Clarification Statement, see note 33 above.
38. Clarification Statement, see note 33 above.
39. Clarification Statement, see note 33 above.
40. Clarification Statement, see note 33 above.
41. I am not convinced the DEA is correct in its claim that "Do Not Fill" prescriptions are improper under federal law. For more information on this topic, see Bolen J: Commentary, DEA and Schedule II "Do Not Fill Prescriptions" - Disappointing Enforcement Activity. *Pain Medicine*. 2006; 7(1): 80-85.
42. Clarification Statement, see note 33 above.
43. Clarification Statement, see note 33 above.
44. Clarification Statement, see note 33 above.
45. Clarification Statement, see note 33 above.
46. Clarification Statement, see note 33 above.