

## Healthcare professionals and the DEA: Restoring the balance

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We in the pain community were afraid that, as Yogi Berra once said, it would be “*déjà vu* all over again” when, on September 6, 2006, the Drug Enforcement Administration (DEA) announced from its office in Arlington, Virginia, its proposed regulations on the issuance of multiple prescriptions for Schedule II controlled substances<sup>1</sup> (CSs) and their policy for dispensing CSs for the treatment of pain.<sup>2</sup> But my colleagues and I were pleased when we could say, “Not this time, Yogi!”

The DEA proposes to amend its regulations to allow practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same Schedule II CS; such multiple prescriptions allow a patient to receive up to a 90-day supply of the CS. This will allow the return of the “Do Not Fill Until \_\_\_\_\_” prescription. This proposal, along with the clarification of the DEA’s policy on dispensing CSs for the treatment of pain, reopens the dialogue between the DEA and healthcare professionals, a move that is to the benefit of prescribers, patients, and society as a whole. In my opinion, it also reflects recognition that the DEA and healthcare professionals who are treating pain have the shared goal of “balance”—to ensure that those who need Schedule II CSs for pain or other medical conditions receive them, while preventing misuse and diversion.<sup>3</sup>

The DEA announced the following:

1. The refilling of a prescription for a CS listed in Schedule II is prohibited. This is not a change from existing regulation (21 CFR 1306.2).
2. An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to 90 days’ worth of a Schedule II CS, provided the following conditions are met:
  - a. The individual practitioner properly determines that there is a legitimate medical purpose for the patient to be prescribed that CS, and the individual practitioner is acting in the usual course of professional practice. This is not a change from existing regulation (21 CFR 1306.04).

- b. The individual practitioner writes instructions on each prescription (other than the first prescription) regarding whether he or she intends for that prescription to be filled immediately or indicating the earliest date on which a pharmacy may fill the prescription.

- c. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.

- d. The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws.

- e. The individual practitioner complies fully with all other applicable requirements under the act and these regulations, as well as any additional requirements under state law.

3. This new policy shall not be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II CSs. Rather, individual practitioners must determine on their own, based on sound medical judgment and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see the patient when doing so.

4. When a prescription has been prepared with instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.

Based on these new regulations, it appears to me that the DEA has listened to the medical community and addressed many of our concerns.

A prescriber, if he or she deems it appropriate, can now write any number of sequential prescriptions providing up to a 90-day supply. All of the prescriptions must be dated, usually in the upper right corner, on the date of issue. "Do Not Fill Until \_\_\_\_\_" must be written on all prescriptions that are to be filled after the date of the first prescription. (All prescriptions for CSs shall be dated as of, and signed on, the date when issued. One must *never* postdate a prescription [21 CFR 1306.05]).

The return of the "Do Not Fill Until \_\_\_\_\_" prescription allows stable patients to be evaluated and prescribed their CSs at intervals that are determined by the patients' individual treatment plans. The stable patient is happy because he or she does not have to bear the unnecessary cost of frequent office visits, the insurance company is happy because it is receiving a co-payment for each prescription (usually a 30-day supply), and the prescriber is happy because he or she has fewer administrative tasks and more open slots to see patients—a win-win for everyone.

Being able to use a "Do Not Fill Until \_\_\_\_\_" format also allows a prescriber who is seeing a new patient or a patient with a comorbid condition (or conditions) to make the clinical decision to see the patient every two weeks but prescribe one week's worth of a CS at a time.

I believe the DEA has recognized that allowing a prescriber to have more control over the amount and interval of a prescription for a Schedule II medication may lead to less abuse and diversion of CSs, a goal shared by the medical community and the DEA.

The DEA's policy for dispensing CSs for the treatment of pain states that the DEA's charge is to enforce existing

regulations and to clarify existing regulations upon request.<sup>2</sup> The DEA does not want to write or endorse guidelines, or to be perceived as practicing medicine. Therefore, it is the prescriber's responsibility to know and follow all federal regulations for prescribing a CS. However, it is the DEA's responsibility to ensure that all DEA agents, from the national to the local level, be knowledgeable about the agency's regulations, enforce the regulations, and follow the policies as written. If all parties accept their responsibilities, the result should be less-fearful healthcare professionals who are able to appropriately prescribe CSs, as well as reduced suffering and increased productivity for millions of patients who do not currently have access to pain management.

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## REFERENCES

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2. Drug Enforcement Administration: Dispensing controlled substances for the treatment of pain: Notice. Issuance of multiple prescriptions for Schedule II controlled substances: Proposed rule. *Fed Regist.* 2006; 71(172): 52715-52723. Available at [www.dea diversion.usdoj.gov/fed\\_regs/notices/2006/fr09062.htm](http://www.dea diversion.usdoj.gov/fed_regs/notices/2006/fr09062.htm). Accessed October 19, 2006.
3. Joranson DE, Gilson AM, Ryan KM, et al.: *Achieving Balance in State Pain Policy: A Guide to Evaluation*. Madison, WI: University of Wisconsin Comprehensive Cancer Center, 2000.