

Continuing Concerns About DEA’s “Prescription Series” Proposal

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To ensure that patients are not denied access to Schedule II opioid analgesics when needed for the relief of moderate to severe pain, controlled substances regulations must strike the right balance between the realms of medicine and law enforcement, and be unambiguous so that physicians and pharmacists can understand and adhere to them.¹

DEA’s proposal

On September 6, 2006, the U.S. Drug Enforcement Administration (DEA) proposed to amend the Code of Federal Regulations (CFR) to allow practitioners to issue multiple prescriptions of a Schedule II controlled substance, each issued on the same date and dispensed sequentially (a “prescription series”) (See Box for proposed rule).² The proposal follows a Solicitation of Comments about dispensing controlled substances for pain management.³ The DEA said it wanted to reassure healthcare professionals and patients that it was legal for practitioners to provide a prescription series to individual patients during a single office visit. Practitioners would be able to authorize up to a 90-day supply of a Schedule II medication in situations where he or she determined that a periodic review of treatment effectiveness was not required more frequently.

It is evident that the DEA listened to the healthcare community and responded positively by proposing a regulation that affirms a practitioner’s legal authority to issue a prescription series for a Schedule II controlled substance, with the intent to allow continued patient access to medications for chronic pain management while decreasing the potential for abuse and diversion.⁴ However, there remain several important questions that should be addressed before the DEA finalizes the rule, or in subsequent addenda to the DEA Practitioner and Pharmacist manuals.

Background on the proposed regulation

Federal regulations prohibit refills of Schedule II controlled substances; the option of issuing a prescription series for Schedule II controlled substances is not specifically authorized under the federal Controlled Substances Act (CSA), but neither is it prohibited. The DEA acknowledges that the CSA did not address this practice when it was adopted in 1970 because chronic pain was not a visible treatment priority at that time.² In the last 15 years, healthcare professionals began using a prescription series as a way to facilitate the management of chronic pain in stable patients while decreasing the potential for medication abuse and diversion. This approach appears to be consistent with the principle of Balance established by international and national drug regulatory and healthcare authorities – recognizing that patients who need controlled medications should receive them, and that reasonable control over abuse and diversion must be exercised but that control must not interfere in availability and access.^{1,5}

In 2003, the DEA Office of Diversion Control said that federal regulations did not prohibit a prescription series.⁶ But in 2004, the DEA temporarily changed its interpretation, questioning the legality of a prescription series as an illegal refill.⁷ Following receipt of many comments, the DEA has returned to its earlier interpretation, stating that it wants to reassure healthcare professionals and patients that a prescription series is legal.

Clinicians may not understand current regulations

We are concerned that incorrect knowledge about federal drug regulations among health professionals and the public could hamper accurate interpretation of the DEA prescription series proposal. Federal regulations do not and never have restricted the quantity or number of days of a controlled medication that can be prescribed using a single prescription. However, national news media reported that DEA's proposal would be an increase from a current "one-month supply" limitation.⁸ Furthermore, at the 2007 national conferences of the American Academy of Pain Medicine and the American Academy of Hospice and Palliative Medicine, the audiences were asked what federal DEA regulations say about the quantity of a Schedule II controlled substance prescription. The majority of both large audiences thought that there was a federal 30-day supply limit (Personal communication with David E. Joranson, March 14, 2007). Consequently, *many in the pain and palliative care fields may perceive, incorrectly, that DEA's proposal would increase the amount that can be prescribed.*

The questions

The aim of the proposed rule is to recognize the legality of a prescribing practice that has been gaining acceptance for the last decade. But several important questions remain about how the prescription series is to be implemented and whether it establishes new prescribing standards.

- Could the phrase "a total of up to a 90-day supply" be misinterpreted to mean that, for the first time, the federal government is limiting the quantity of a Schedule II controlled substance that can be prescribed? At the very least, the DEA should clarify that this is not their intent to regulate the quantity of a medical prescription, and that the 90-day language does not alter the fact that the CSA and CFR do not limit the quantity or number of days for which a single prescription for a Schedule II controlled substance can be written. (Prescription quantity is limited by the laws and regulations in a few states and by insurance policy.)
- What are the implications of the proposed requirement that, in issuing a prescription series, the practitioner must determine that it "does not create an undue risk of diversion or abuse?" An important element of the principle of Balance is that practitioners not contribute to diversion and abuse. But does this language establish an additional standard that practitioners should know about? What is that standard and are there steps a practitioner must take to determine there is no undue risk? What does "undue" mean? Is it a law enforcement standard, or is it a medical standard? What is a practitioner's liability if, after issuing a prescription series, abuse or diversion does occur? Are there implications for the pharmacist who dispenses a prescription series, given the

pharmacist's corresponding responsibility under federal regulations not to dispense under other than legitimate circumstances?

Conclusion

These are questions that the DEA should address in consultation with the pain medicine and palliative care community. When a balanced and unambiguous prescription series rule is adopted, it will be an important step to improve the regulatory environment for both pain management and diversion control. The next critically important step will be to disseminate the new policy along with examples of its practical application to field agents, state and local law enforcement, and to medical and pharmacy practitioners throughout the U.S.

References

- (1) Pain & Policy Studies Group. *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation (Third edition)*. Madison, WI: University of Wisconsin Paul P. Carbone Comprehensive Cancer Center; 2006.
- (2) Drug Enforcement Administration. Issuance of multiple prescriptions for Schedule II controlled substances. *Federal Register*. 2006;71(172):52724-52726.
- (3) Drug Enforcement Administration. Clarification of existing requirements under the Controlled Substances Act for prescribing Schedule II controlled substances. *Federal Register*. 2005;70(165):50408-50409.
- (4) Heit H. Healthcare professionals and the DEA: Restoring the balance. *Journal of Opioid Management*. 2006;2:310-311.
- (5) World Health Organization. *Achieving balance in national opioids control policy: Guidelines for assessment*. Geneva, Switzerland: World Health Organization; 2000.
- (6) Good, P. M. DEA policy concerning the legality of a practitioner issuing several Schedule II prescriptions on the same date for the same medication for a stable patient. Letter from Chief of the Liaison and Policy Section, DEA Office of Diversion Control to Dr. Howard Heit; January 31, 2003.
- (7) Drug Enforcement Administration. Dispensing of controlled substances for the treatment of pain. *Federal Register*. 2004;69(220):67170-67172.
- (8) Leinwand D. DEA to change rules on addictive prescriptions. *USA Today*. September 7, 2006.

Box:

SEC. 1306.12 REFILLING PRESCRIPTIONS; ISSUES OF MULTIPLE PRESCRIPTIONS

(A) THE REFILLING OF A PRESCRIPTION FOR A CONTROLLED SUBSTANCE LISTED IN SCHEDULE II IS PROHIBITED.

(B) (1) AN INDIVIDUAL PRACTITIONER MAY ISSUE MULTIPLE PRESCRIPTIONS AUTHORIZING THE PATIENT TO RECEIVE A TOTAL OF UP TO A 90-DAY SUPPLY OF A SCHEDULE II CONTROLLED SUBSTANCE PROVIDED THE FOLLOWING CONDITIONS ARE MET:

(I) THE INDIVIDUAL PRACTITIONER PROPERLY DETERMINES THERE IS A LEGITIMATE MEDICAL PURPOSE FOR THE PATIENT TO BE PRESCRIBED THAT CONTROLLED SUBSTANCE AND THE INDIVIDUAL PRACTITIONER IS ACTING IN THE USUAL COURSE OF PROFESSIONAL PRACTICE;

(II) THE INDIVIDUAL PRACTITIONER WRITES INSTRUCTIONS ON EACH PRESCRIPTION (OTHER THAN THE FIRST PRESCRIPTION, IF THE PRESCRIBING PRACTITIONER INTENDS FOR THAT PRESCRIPTION TO BE FILLED IMMEDIATELY) INDICATING THE EARLIEST DATE ON WHICH A PHARMACY MAY FILL THE PRESCRIPTION;

(III) THE INDIVIDUAL PRACTITIONER CONCLUDES THAT PROVIDING THE PATIENT WITH MULTIPLE PRESCRIPTIONS IN THIS MANNER DOES NOT CREATE AN UNDUE RISK OF DIVERSION OR ABUSE;

(IV) THE ISSUANCE OF MULTIPLE PRESCRIPTIONS AS DESCRIBED IN THIS SECTION IS PERMISSIBLE UNDER APPLICABLE STATE LAWS; AND

(V) THE INDIVIDUAL PRACTITIONER COMPLIES FULLY WITH ALL OTHER APPLICABLE REQUIREMENTS UNDER THE [CONTROLLED SUBSTANCES] ACT AND THESE REGULATIONS AS WELL AS ANY ADDITIONAL REQUIREMENTS UNDER STATE LAW.

(2) NOTHING IN THIS PARAGRAPH (B) SHALL 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 CONTROLLED SUBSTANCES. 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 THEIR PATIENTS WHEN DOING SO.

SECTION 1306.14 IS AMENDED BY ADDING A NEW PARAGRAPH (E) TO READ AS FOLLOWS:

(E) WHERE A PRESCRIPTION THAT HAS BEEN PREPARED IN ACCORDANCE WITH SEC. 1306.12(B) CONTAINS 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.