
COMMENTARY

Is the DEA's New "Prescription Series" Regulation Balanced?

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ABSTRACT. To address the dual public health imperatives of enhanced pain management and decreased abuse and diversion of prescription medications, the U.S. Drug Enforcement Administration (DEA) recently adopted regulations to allow practitioners to issue multiple prescriptions for a Schedule II controlled substance on the same day, to be dispensed sequentially. Public feedback suggested there was concern that practitioners could interpret the initially proposed language as limiting the quantity of prescribed medication and establishing an ambiguous practice standard. The DEA later explicitly confirmed that they did not intend to impose undue limits on practice. Rather, if implemented appropriately, the new regulation can be considered an important mechanism to control medication diversion while maintaining access for legitimate medical purposes and patient care.

KEYWORDS. Drug Enforcement Administration, DEA, controlled substances, prescriptions, prescription series, diversion, balance, drug regulation

On December 19, 2007, the U.S. Drug Enforcement Administration (DEA) affected an amendment to the Code of Federal Regulations (CFR), which allows practitioners to issue multiple prescriptions for a Schedule II controlled substance, each issued on the same date and dispensed sequentially (a "prescription series"). (See box for Final Rule.)¹ The CFR amendment was first proposed on September 6, 2006,² along with a policy statement explain-

ing the DEA's rationale for introducing the federal policy change.³ The Final Rule, which differs slightly from the rule proposed over a year ago, results from the DEA's Solicitation of Comments about dispensing controlled substances for pain management,^{4,5} and is an effort to reassure health care practitioners that it is lawful to provide a prescription series for Schedule II medications to individual patients during a single office visit.³

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In response to the proposed rule, the Pain & Policy Studies Group (PPSG) issued a commentary outlining the DEA's history of inconsistent interpretations of the legality of a prescription series and expressing concern that practitioners could misinterpret the requirements without further DEA clarification. Specifically, we asked two key questions:

- (1) Does the phrase “a total of up to a 90-day supply” mean that, for the first time, the federal government is limiting the quantity of a Schedule II controlled substance that can be prescribed?
- (2) Is a new prescribing standard established by requiring a practitioner to issue a prescription series after determining that it “does not create an undue risk of diversion or abuse”?⁶

These questions are based on the principle that controlled substances regulations must strike an appropriate balance between medicine and law enforcement, and be unambiguous so that health care practitioners can understand and adhere to them, so that patients are not denied access to Schedule II opioid analgesics when needed to relieve chronic severe pain.⁷

During the rule development process, it is evident that the DEA listens and responds positively to comments from the health care community. In fact, the DEA received 264 comments regarding its proposed prescription series rule (88% of comments supported the rule), and attempted to address the broad themes inherent in all the comments.¹ In its notice of final rulemaking, the DEA directly addressed commenters' questions, including those of the PPSG, offering clarifications to the requirements and implications of this new rule.

First, the DEA confirmed that allowing a 90-day prescription series does not alter the fact that the federal Controlled Substances Act (CSA) and the CFR do not limit the quantity or number of days for which a single prescription for a Schedule II controlled substance can be written.

“The [Final] rule in no way changes longstanding federal law governing the issuance of prescription for controlled substances. . . the CSA and DEA regulations contain no specific limit on the number of days worth of a schedule II controlled sub-

stance that a physician may authorize per prescription” (pp. 64923–64924).¹

Second, the DEA verified that the “undue risk of diversion or abuse” language in no way establishes an additional practice standard to which health care professionals must conform.

“Under this Final Rule, practitioners who prescribe controlled substances are subject to the same standard in preventing diversion as they always have been under the CSA and DEA regulations. Section 1306.12(b)(iii) of this Final Rule is intended to make clear that a practitioner may not simply comply with the other requirements of this Final Rule while turning a blind eye to circumstances that might be indicative of diversion. Thus, section 1306.12(b)(iii) merely underscores that the longstanding requirement of providing effective controls against diversion remains in effective when issuing multiple schedule II prescriptions in accordance with this Final Rule” (p. 64926).¹

CONCLUSION

It is clear that the DEA's Final Rule aims to affirm a practitioner's legal authority to issue a prescription series for a Schedule II controlled substance, with the intent to allow (and even enhance) continued patient access to medications to treat chronic pain while decreasing the potential for abuse and diversion.¹

Federal regulations continue to prohibit refills of Schedule II controlled substances, and establish no new standards relating to the quantity or duration of a Schedule II prescription or for controlling medication abuse or diversion. The PPSG considers the Final Rule to be balanced,⁷ and an important step to improve the regulatory environment for both diversion control and pain management and palliative care. The DEA also recognizes the need for balance:

“. . . DEA, through its enforcement of the CSA and its implementing regulations, must prevent the diversion and abuse of controlled substances while ensuring that there is an adequate supply for legitimate medical purposes. DEA supports the intent

of this Final Rule to address patients' needs for schedule II controlled substances while preventing the diversion of those substances" (p. 64929).¹

This new rule should mark the beginning of a rededication to education for law enforcement, health care regulators, and practitioners. It is important for the DEA to renew its commitment to disseminate information about federal controlled substances regulations, along with examples of practical application, to field agents, state and local law enforcement, and medical and pharmacy practitioners throughout the United States. It is equally important for such information to be addressed in professional and continuing education for health care practitioners.

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