



Board of Pharmacy

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Office
232 Capital Street
Charleston, West Virginia 25301

Memorandum

To: Pharmacist-in-charge
From: William T. Douglass, Jr., Executive Director *WTD*
Date: March 29, 2005
Re: CII refills; "Do not fill until..."

This is an updated memorandum with more clarification.

Please find enclosed an interim policy statement issued by the DEA on November 16, 2004 which clarifies a misstatements made in an August 2004 FAQ published on its Office of Diversion Control website.

The clarification states: "No prescription for a controlled substance in Schedule II may be refilled." 21 U.S.C. 829(a). "For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a Schedule II controlled substance. To do so conflicts with one of the fundamental purposes of section 829(a)."

Therefore, according to DEA officials **prescribers may no longer write multiple Schedule II prescriptions on the same day with instructions to fill at a later date and dispensers may no longer accept such prescriptions.** If a patient presents multiple scripts dated the same day, then the pharmacist would have the knowledge that this has been done and should inform the patient they cannot fill the subsequent scripts and the patient needs to contact their doctor to reissue a new script at a later date. If only one prescription is presented with a notation that it should not be filled until a later date and that is within 90 days of the date issued, then a pharmacist may fill the prescription.

This "clarification" by the DEA will actually cause a lot of confusion until prescribers are aware of the limitations. It will also create a hardship for some patients for whom such a mechanism of prescribing served their legitimate needs and posed no risk of diversion or abuse.

The information is being sent to the licensing boards of the prescribers so they can inform their licensees. Please inform all of your staff regarding this new interpretation of existing law. Although this is a federal regulation, it will be enforced by both federal and state enforcement personnel.

cc: West Virginia Board of Medicine
West Virginia Board of Osteopathy
West Virginia Board of Dental Examiners

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Memorandum

To: Pharmacist-in-charge
From: William T. Douglass, Jr., Executive Director *WTD*
Date: March 21, 2005
Re: CII refills; "Do not fill until..."

Please find enclosed an interim policy statement issued by the DEA on November 16, 2004 which clarifies a misstatements made in an August 2004 FAQ published on its Office of Diversion Control website.

The clarification states: "No prescription for a controlled substance in Schedule II may be refilled." 21 U.S.C. 829(a). "For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a Schedule II controlled substance. To do so conflicts with one of the fundamental purposes of section 829(a)."

According to DEA officials prescribers may no longer write Schedule II prescriptions with instructions to fill at a later date and dispensers may no longer accept such prescriptions.

This "clarification" will actually cause a lot of confusion until prescribers are aware of the limitations. It will also create a hardship for some patients for whom such a mechanism of prescribing served their legitimate needs and posed no risk of diversion or abuse.

The information is being sent to the licensing boards of the prescribers so they can inform their licensees. Please inform all of your staff regarding this new interpretation of existing law. Although this is a federal regulation, it will be enforced by both federal and state enforcement personnel.

cc: West Virginia Board of Medicine
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prescribed and treatment of the condition allegedly existing.

(9) The physician wrote more than one prescription on occasions in order to spread them out.

United States v. Rosen, 582 F.2d 1032, 1035-1036 (5th Cir. 1978) (citations omitted).

Moreover, 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." United States v. Morton Salt Co., 338 U.S. 632, 642-643 (1950). It would be incorrect to suggest that DEA must meet some arbitrary standard or threshold evidentiary requirement to commence an investigation of a possible violation of the **Controlled Substances Act (CSA)**.

Refills of schedule II prescriptions--The August 2004 FAQ stated: "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." (Italics added.) 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." 21 U.S.C. 829(a). However, the second part of the sentence (italicized above) is incorrect. For a physician to prepare multiple prescriptions on the same day with instructions to fill on different dates is tantamount to writing a prescription authorizing refills of a schedule II **controlled substance**. To do so conflicts with one of the fundamental purposes of section 829(a). Indeed, as the factors quoted above from the Rosen case indicate, 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. It is worth noting here that the DEA regulations setting forth the requirements for the issuance of a **controlled substance** prescription are set forth in 21 CFR 1306.01-1306.27.

Reselling of **controlled substances**--The August 2004 FAQ listed a number of behaviors, or "red flags," that are "probable indicators of abuse, addiction, or diversion." These behaviors include "selling medications." The document suggested that certain steps be taken to deal with such indicators, including "appropriate management" and possible referral to an addiction specialist. The document went on to state 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." The document also stated: "Management may or may not include continuation of therapy, depending on the circumstances." Finally, the document stated that "if continued opioid therapy makes medical sense, then the therapy may be continued, even if drug abuse has occurred. Additional monitoring and oversight of patients who have experienced such an episode is recommended." (Italics added.)

The behaviors listed in the August 2004 FAQ as "red flags" are indeed indicators of possible diversion. However, the August 2004 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 and/or has resold prescription narcotics, it is not merely "recommended" that the physician engage in additional monitoring of the patient's use of narcotics. Rather, as a DEA registrant, the physician has 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. Under no circumstances may a physician dispense **controlled substances** with the knowledge that they will be used for a nonmedical purpose or that they will be resold by the