

prescribe Schedule III, IV, and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment, then he or she would have to comply with the proposed regulations.

**What Additional Requirements Would Apply When a "Qualifying Physician" Writes a Prescription for Schedule III, IV, and V Narcotic (Opioid) Drugs Approved by FDA Specifically for Maintenance or Detoxification Treatment?**

Proposed changes to § 1306.05(a) require the practitioner to include on the prescription the identification number (issued under proposed § 1301.27(d)) or written notice that the practitioner is acting under the good faith exception of proposed § 1301.27(e). These prescriptions would be subject to all of the existing requirements of Part 1306 that apply to prescriptions for controlled drugs. To be valid, a prescription must be written for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice (§ 1306.04(a)). The prescription must be dated and signed on the day issued, must contain 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 (§ 1306.05(a)).

Under current law practitioners are not normally required to keep records of prescriptions issued. However, DEA regulations (§ 1304.03(c)) do require records to be kept by practitioners prescribing controlled drugs listed in any schedule for maintenance or detoxification treatment of an individual.

For conformity §§ 1306.04, Purpose of issue of prescription, and 1306.07, Administering or dispensing of narcotic (opioid) controlled drugs, would also be amended by this NPRM. Section 1306.04(c) currently prohibits the issuance of prescriptions for narcotic (opioid) drugs listed in any schedule for "detoxification treatment" or "maintenance treatment." Under this NPRM, the prohibition against prescriptions in § 1306.04(c) would be amended to permit prescriptions for Schedule III, IV, and V narcotic (opioid) controlled drugs approved by FDA specifically for maintenance or detoxification treatment by practitioners who are in compliance with proposed § 1301.27.

Section 1306.07(a) currently permits the administering and dispensing (but not prescribing) of narcotic (opioid) drugs for detoxification or maintenance

treatment only by practitioners who are separately registered as a Narcotic Treatment Program. This proposed rule would add paragraph (d) to § 1306.07 to permit a practitioner to administer or dispense (including prescribe) any Schedule III, IV, or V narcotic (opioid) controlled drug approved by FDA specifically for use in maintenance or detoxification treatment if the practitioner is in compliance with proposed § 1301.27. This NPRM would also revise § 1306.07(a) to improve the clarity of the language, but not to change the drug of the paragraph.

**Could a Practitioner Authorize Refills of Prescriptions for Schedule III, IV, or V Narcotic (Opioid) Drugs Approved by FDA Specifically for Use in Maintenance or Detoxification Treatment?**

DEA regulations allow practitioners to authorize refills for Schedule III, IV, or V controlled drug prescriptions. Prescriptions for Schedule III, IV and V controlled drugs are subject to the requirements in §§ 1306.22 and 1306.23, regarding the refilling and partial filling of prescriptions. In addition, practitioners prescribing Schedule III, IV, or V narcotic (opioid) drugs for use in maintenance or detoxification treatment would be subject to all relevant state and federal requirements that apply to prescriptions for controlled drugs.

**Under Current Regulations, What Other Requirements Would Apply When a Practitioner Administers or Dispenses Schedule III, IV, or V Narcotic (Opioid) Drugs Approved by FDA Specifically for Maintenance or Detoxification Treatment?**

Practitioners who administer or dispense (other than by prescription) Schedule III, IV, or V narcotic (opioid) drugs approved by FDA specifically for maintenance or detoxification treatment must maintain records and provide security for the controlled drugs in their possession. Records required to be maintained include inventories, records of receipt, reports of theft or loss, destruction of controlled drugs, and records of dispensation. These records must be maintained for two years.

The regulations also require practitioners to safeguard controlled drugs (§ 1301.75(b)). The Schedule III, IV, or V narcotic (opioid) controlled drugs approved by FDA specifically for maintenance or detoxification treatment must be stored in a securely locked, substantially constructed cabinet.

Current regulations on prescribing permit the use of a written prescription signed by a practitioner. Current

regulations also permit a practitioner, or the practitioner's agent, to transmit a facsimile of a written signed prescription to a pharmacy (§ 1306.21). In addition, a practitioner may telephone the pharmacy with an oral prescription. The pharmacist must immediately reduce the oral prescription to writing, including all information required in § 1306.05, except for the signature of the practitioner (§ 1306.21(a)).

**Regulatory Certifications**

*Regulatory Flexibility Act*

The Deputy Assistant Administrator, Office of Diversion Control, has reviewed this proposed regulation and hereby certifies that it has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) and that it will not have a significant economic impact on a substantial number of small entities. This proposed rulemaking would permit practitioners to prescribe Schedule III, IV and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment without being separately registered with DEA as a NTP. Although virtually all entities affected would be small, the cost of determining eligibility and applying for a waiver is negligible.

*Executive Order 12866*

The Deputy Assistant Administrator further certifies that this proposed rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant rulemaking action. Therefore, this action has not been reviewed by the Office of Management and Budget. As noted above, this proposed rulemaking would permit practitioners to prescribe Schedule III, IV and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment without being separately registered with DEA as a NTP.

*Executive Order 12988*

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

*Executive Order 13132*

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have Federalism implications warranting the application of Executive Order 13132.