

146 Cong. Rec. S9262 (daily ed. Sept. 26, 2000).

What Are the Conditions for Qualifying for the Proposed § 1301.27 Exemption From Separate Registration for Practitioners Dispensing or Prescribing Schedule III, IV, and V Narcotic Drugs Approved by FDA Specifically for Use in Maintenance or Detoxification Treatment?

There are two main sets of conditions involved in the proposed exemption: Conditions with respect to the practitioner and conditions with respect to the Schedule III, IV, or V narcotic (opioid) drugs approved by FDA specifically for use in maintenance or detoxification treatment. To qualify for the proposed exemption, a practitioner would have to submit notification to HHS stating his or her intent to dispense or prescribe narcotic (opioid) controlled drugs to opiate-dependent patients and certifying that all of following are true:

(1) The practitioner is a "qualifying physician." A practitioner is a "qualifying physician" if he or she is licensed under State law and has specific medical certification, training or experience in maintenance or detoxification treatment. The Secretary of HHS will establish criteria to be used for determining whether a practitioner is a "qualifying physician."

(2) The practitioner has the capacity to refer the patients, to whom the practitioner will provide specifically approved narcotic (opioid) drugs or combinations of narcotic (opioid) drugs, for appropriate counseling and other appropriate ancillary services.

(3) The total number of patients treated for opiate dependence by the practitioner who is not a member of a group practice will not exceed 30 at any one time, unless modified by regulation by the Secretary of HHS.

(4) If the practitioner is a member of a group practice, the total number of patients treated for opiate dependence by the group practice of which the practitioner is a member will not exceed 30 at any one time, unless modified by regulation by the Secretary of HHS.

Schedule III, IV and V narcotic (opioid) drugs to be dispensed or prescribed must meet the following two conditions:

(1) They must have been approved by FDA specifically for use in maintenance treatment or detoxification treatment.

(2) They cannot have been the subject of an adverse determination by HHS that their use requires additional standards respecting the qualifications of practitioners or the quantities of the drugs that may be provided for unsupervised use.

What Will Happen After the Practitioner Submits to HHS the Notification Under Proposed § 1301.27 of Intent To Dispense or Prescribe Narcotic Drugs?

When HHS receives a notification of intent to dispense or prescribe narcotic (opioid) controlled drugs for maintenance or detoxification treatment it will forward a copy of the notification to DEA. From the date HHS receives the notification it will have up to 45 days to review the practitioner's qualifications and make a determination whether the practitioner meets all of the requirements for the exemption. While HHS is conducting its determination, DEA will conduct its own review to determine if the practitioner has the appropriate DEA registration in accordance with 21 U.S.C. 823(a) and if there are any adverse determinations.

Once HHS has made its determination, it will send the findings to DEA. If DEA determines that the practitioner has the appropriate DEA registration in accordance with 21 U.S.C. 823(a) and if there are no adverse determinations, then DEA will issue the practitioner an identification number as soon as either of the following conditions occurs: (1) DEA receives the positive determination from HHS before the conclusion of the 45 day review period, or (2) the 45 day review period has concluded and no determination by HHS has been received. If HHS refuses to certify a practitioner or withdraws such certification once it is issued, then DEA will not issue the practitioner an identification number, or will withdraw the identification number if one has been issued. Under proposed § 1301.27(d) the practitioner would be required to include the identification number on all records when dispensing and on all prescriptions when prescribing Schedule III, IV or V narcotic (opioid) controlled drugs for use in maintenance or detoxification treatment.

Would Practitioners Have To Wait Until They Receive an Identification Number From DEA Before They Could Dispense or Prescribe Schedule III, IV or V Narcotic (Opioid) Drugs Approved by FDA Specifically for Use in Maintenance Treatment or Detoxification Treatment?

The practitioner would not have to wait if the practitioner was in compliance with proposed § 1301.27(e). As proposed, the practitioner could begin dispensing or prescribing during the 45-day review period if all of the following requirements are met:

(1) The practitioner has submitted, in good faith, a written notification under § 1301.27(b).

(2) The practitioner reasonably believes that the conditions specified in §§ 1301.27(b) and (c), regarding the practitioner and the narcotic (opioid) drugs, have been met.

(3) Prescribing or dispensing the narcotic (opioid) drugs would facilitate the treatment of an individual patient.

(4) The practitioner has notified both the Secretary of HHS and DEA of the intent to do so.

(5) The Secretary has not issued an order indicating that the registrant is not a qualified physician.

(6) The practitioner has the appropriate DEA registration under 21 CFR 1301.13.

The practitioner would be able to satisfy the fourth requirement by including within the notification required by proposed § 1301.27(b) a statement of his or her intent to immediately commence prescribing or dispensing. If HHS refuses to certify a practitioner or withdraws such certification once it is issued, then DEA will not issue the practitioner an identification number, or will withdraw the identification number if one has been issued.

What Happens if a Practitioner Dispenses or Prescribes Schedule III, IV, or V Narcotic (Opioid) Drugs in Violation of One of the Conditions in Proposed § 1301.27(b)?

If a practitioner dispenses or prescribes Schedule III, IV, or V narcotic (opioid) drugs in violation of any of the conditions specified in proposed § 1301.27(b), then DEA may revoke the practitioner's DEA registration in accordance with § 1301.36.

Due to the potential for diversion and in an effort to verify compliance with these regulations, DEA intends to conduct at least two regulatory investigations per field office per year of practitioners dispensing and prescribing to narcotic (opioid) dependent persons Schedule III, IV, and V narcotic (opioid) controlled drugs approved by the Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment.

Would the Proposed Requirements Be Applied Differently to Practitioners Working in Traditional NTPs as Opposed to Practitioners in Other Practice Settings?

The proposed regulation would affect practitioners working in traditional NTPs the same as any other practitioners. If a "qualifying physician" working in a NTP wants to dispense or