

practitioners dispensing or prescribing 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 (see also proposed amendments to §§ 1306.04(c) and 1306.07). This NPRM would allow “qualifying physicians,” whether they are already registered as NTPs or not, to dispense and prescribe Schedule III, IV, and V narcotic (opioid) controlled drugs or combinations of controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment. (On October 8, 2002, FDA approved two products containing buprenorphine, subutex and suboxone, Schedule III controlled drugs, for use in maintenance and detoxification treatment.) Under this proposed rule, practitioners permitted to dispense and prescribe Schedule III, IV, and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment would not be required to have separate DEA registrations as NTPs. DEA is taking this proposed action in conjunction with the Department of Health and Human Services’ (HHS) adoption of the concept of Office-Based Opioid Treatment. Proponents believe that the changes proposed here would provide greater access to narcotic (opioid) addiction treatment, and permit expanded treatment services. This action also responds to the recent amendment to the Controlled Substances Act by the Drug Addiction Treatment Act of 2000. This proposed rule would not affect the existing prohibition against prescribing any Schedule II narcotic (opioid) controlled drugs for maintenance or detoxification treatment.

The proposed rule would:

(1) Permit qualifying physicians to dispense and prescribe Schedule III, IV, and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment;

(2) Permit opioid dependent patients to have one-on-one consultations with a practitioner in a private practice setting;

(3) Permit pharmacies to fill prescriptions for Schedule III, IV, and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment; and

(4) Permit practitioners to offer maintenance and detoxification treatment in their private practices without having a second registration as a NTP.

This proposed rule would apply to individual practitioners working in

traditional NTPs or any other practice setting.

#### **What Is the Legal Basis for Providing Maintenance or Detoxification Treatment?**

Congress passed the Harrison Narcotic Act of 1914 to fulfill U.S. obligations to uphold the international Opium Convention signed at the Hague in 1912. The Act was the first comprehensive federal legislation to place controls on licit pharmaceuticals and allowed practitioners to prescribe narcotics (opioids) only for legitimate medical purposes in the course of their professional practice. It did not permit the prescribing of narcotics (opioids) simply to support or maintain an addiction.

During the late 1960s and the early 1970s, drug substitution therapy for addiction treatment using methadone was introduced as a medical modality and was considered “research,” that is, still outside the scope of “medical treatment.” At that time, medical and legal standards governing the use of methadone in addiction treatment programs did not exist. In effect, there were no clear means for differentiating legitimate treatment efforts using the drug as part of a comprehensive program of treatment services from bogus clinics or unethical practitioners distributing methadone to addicts under the guise of treatment. As a result the diversion of methadone was occurring on a large-scale basis.

In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act (Pub. L. 91–513), which consolidated existing Federal drug control statutes, and created new laws regarding activities pertaining to controlled drugs. Title II of this legislation, also known as the Controlled Substances Act, regulates the manufacture and distribution of controlled drugs. However, the issues of maintenance treatment and detoxification treatment were not addressed.

In the mid-1970s, methadone maintenance treatment became the subject of intense policy debate, and Congress passed the Narcotic Addict Treatment Act of 1974. This amendment to the Controlled Substances Act required practitioners who wished to conduct maintenance/detoxification treatment to obtain separate registration as NTPs. To be registered as NTPs, practitioners must comply with DEA requirements for secure drug storage and record keeping; must be qualified under the treatment standards established by the Department of Health and Human Services (HHS); and must

comply with standards established by HHS (after consultation with DEA) regarding quantities of narcotic (opioid) drugs for unsupervised take-home use by persons undergoing addiction treatment (21 U.S.C. 823(g)). Since the mid-1970s, products containing methadone and, by the 1990’s products containing levo-alpha-acetyl-methadol (LAAM), which are Schedule II controlled substances, have been approved by FDA specifically for use in maintenance or detoxification treatment. (On October 8, 2002, FDA approved buprenorphine products, Schedule III controlled drugs, for use in maintenance and detoxification treatment.)

The Narcotic Addict Treatment Act allows practitioners to dispense narcotic (opioid) drugs for maintenance or detoxification treatment. Under this legislation the term dispense means to deliver a controlled drug to an ultimate user under a lawful order of a practitioner, including the prescribing and administering of a controlled drug. However, as drug replacement therapy was considered research at that time, and to ensure public health and safety, practitioners were restricted to administering and dispensing (other than by prescription) controlled drugs for maintenance or detoxification treatment. After passage of the Narcotic Addict Treatment Act, such drug replacement therapy was no longer considered research.

Today treatment experts view addiction as a medical condition, which should be treated as a chronic disease, and believe that drug replacement therapy is a viable form of medical treatment for opioid dependent individuals. On October 17, 2000, Congress passed DATA, amending the Controlled Substances Act to establish “waiver authority for physicians who dispense or prescribe certain narcotic (opioid) drugs for maintenance treatment or detoxification treatment” (Pub. L. 106–310, title XXXV; 116 Stat. 1222). When the DATA bill was introduced in the United States Senate, it was described as follows:

The goal of the DATA provisions is simple but it is important: The DATA bill attempts to make drug treatment more available and more effective to those who need it. This legislation focuses on increasing the availability and effectiveness of drug treatment. The purpose of the Drug Addiction Treatment Act is to allow qualified physicians, as determined by the Department of Health and Human Services, to prescribe schedule III, IV and V anti-addiction medications in physicians’ offices without an additional Drug Enforcement Administration, DEA, registration if certain conditions are met.