

291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

AUTHORITY: Secs. 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 371); 21 U.S.C. 823; secs. 301(d), 548, 1976 of the Public Health Service Act (42 U.S.C. 241(d), 290ee-3, 300y-11); 42 U.S.C. 257a.

§ 291.501 Narcotic drugs in the maintenance treatment of narcotic addicts.

(a) The Food and Drug Administration, the National Institute on Drug Abuse, and the Drug Enforcement Administration, Department of Justice, recognize that the use of narcotic drugs in the prolonged maintenance of narcotic dependence has been shown to be an effective part of a total treatment effort in the management and rehabilitation of selected narcotic addicts. It is also recognized that a number of dangers and possible abuses may arise from such efforts if professional services and controls are inadequately applied.

(b) Therefore, the Commissioner of Food and Drugs, the Director of the National Institute on Drug Abuse, and the Administrator of the Drug Enforcement Administration, Department of Justice, agree that interested professionals, municipalities, and organizations should be allowed to use narcotic drugs in the medical treatment of narcotic addiction within a framework of adequate controls designed to protect the individual patients and the community. Narcotic drugs that are to be used as part of the treatment of narcotic addiction must have an approved new drug application for such use. To facilitate this purpose, the Food and Drug Administration, the National Institute on Drug Abuse, and the Drug Enforcement Administration, Department of Justice, have jointly agreed upon acceptable conditions for the use of narcotic drugs in a treatment program, which are set forth in § 291.505. In addition, such other provisions of the Federal narcotic laws and regulations as are applicable must also be observed.

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(a) *Definitions.* As used in this part:

(1) *Detoxification treatment* means the dispensing of a narcotic drug in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period. There are two types of detoxification treatment: short-term detoxification treatment and long-term detoxification treatment.

(i) *Short-term detoxification treatment* is for a period not in excess of 30 days.

(ii) *Long-term detoxification treatment* is for a period more than 30 days but not in excess of 180 days.

(2) *Maintenance treatment* means the dispensing of a narcotic drug, at relatively stable dosage levels, in the treatment of an individual for dependence on heroin or other morphine-like drug. There are two types of maintenance treatment: comprehensive maintenance treatment and interim maintenance treatment.

(i) *Comprehensive maintenance treatment* is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

(ii) *Interim maintenance treatment* is maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to comprehensive maintenance treatment.

(3) A *medical director* is a physician, licensed to practice medicine in the jurisdiction in which the program is located, who assumes responsibility for the administration of all medical services performed by the narcotic treatment program including ensuring that the program is in compliance with all Federal, State, and local laws and regulations regarding the medical treatment of narcotic addiction with a narcotic drug.