



The following letter was sent to Dr. Howard Heit by **Patricia M. Good** Chief Liaison and Policy Section, Office of Diversion Control an official of the U.S., DEA and therefore should be considered an Official clarification of federal policy.

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Dear Dr. Heit:

This is in response to your correspondence dated October 14, 2003, in which you requested the Drug Enforcement Administration (DEA) to respond to the following questions:

***Can a clinician prescribe off-label use of buprenorphine with or without naloxone (Suboxone®/Subutex®) for the treatment of pain? If a clinician uses buprenorphine (Suboxone®/Subutex®) for the treatment of pain, does the prescriber have to have a DEA registration or does he or she need the special waiver that is required to prescribe buprenorphine for addiction?***

The buprenorphine products Suboxone® and Subutex® are the two Schedule III narcotic medications currently approved for the treatment of opioid dependence under the federal Drug Addiction Treatment Act of 2000 (DATA). The off-label use of the sublingual formulations of buprenorphine (Suboxone®/Subutex®) for the treatment of pain is not prohibited under DEA requirements. However, off-label use does pose a dilemma for pharmacists. Currently, there is no requirement under the DATA for a qualified practitioner to put the Unique Identification Number (UIN) on a prescription for Suboxone® or Subutex® for maintenance or detoxification treatment.

On June 24, 2003, the DEA published a Notice of Proposed Rulemaking (NPRM) that will require qualified practitioners to include the UIN on all prescriptions written for either Suboxone® or Subutex® for narcotic addiction treatment. This requirement will be the only way to determine whether a prescription for Suboxone® or Subutex® was written for maintenance or detoxification treatment or some other condition. Buprenex®, a Schedule III, injectable formation of buprenorphine, is approved and marketed in the United States as an analgesic and is widely used in the treatment of pain.

If a physician prescribes, dispenses or administers buprenorphine (Suboxone®/Subutex®) for the treatment of pain or for any other reason, a DEA registration is required because both products are Schedule III controlled substances. The DATA waiver specifically authorizes qualified practitioners to treat narcotic dependent patients, using FDA approved Schedule III-V narcotic controlled substances for maintenance and detoxification. The DATA waives the requirement for obtaining a separate DEA registration as a narcotic treatment program for physicians using the approved drugs for maintenance and detoxification; however, it does not apply to physicians using Suboxone® or Subutex® for

the treatment of pain. A physician using Suboxone® or Subutex® for the treatment of pain would be required to register with DEA as practitioner with Schedule III privileges.

The Narcotic Addict Treatment Act of 1974 and the DATA amend the Controlled Substances Act (CSA) to allow for the use of opioid drugs to treat addiction either through maintenance or detoxification under specific criteria. Schedule II opioids approved for addiction treatment are limited to methadone and LAAM, and may only be administered and dispensed (not prescribed) by DEA registered Narcotic Treatment Programs. Schedules III through V opioids specifically approved by the Food and Drug Administration for use in addiction treatment maybe prescribed, administered and dispensed by certified practitioners who have obtained the appropriate waivers from the Center for Substance Abuse Treatment.

The above legal allowances were established to allow for the treatment of addiction with opioid controlled substances. These limitations and requirements in no way impact the ability of a practitioner to utilize opioids for the treatment of pain when acting in the usual course of medical practice. Consequently, when it is necessary to discontinue a pain patient's opioid therapy by tapering or weaning doses, there are no restrictions with respect to the drugs that may be used. This is not considered "detoxification" as it is applied to addiction treatment.

I hope this information is of assistance to you in your continued efforts to promote the effective and responsible treatment of pain. If I can of further assistance, please do not hesitate to contact me....

Sincerely,

**Patricia M. Good**

Chief Liaison and Policy Section  
Office of Diversion Control Drug Enforcement Administration  
U.S. Department of Justice