



Louisiana Board of Pharmacy

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May 1, 2009

Compliance Policy Guide – Buprenorphine in Treatment of Opiate Addiction

The U.S. Congress adopted the Children's Health Act of 2000 on October 17 of that year. Title XXXV of this law, entitled *Waiver Authority for Physicians Who Dispense or Prescribe Certain Narcotic Drugs for Maintenance Treatment or Detoxification Treatment*, is better known by the short title *Drug Addiction Treatment Act of 2000*, or *DATA*.

Buprenorphine Injection (Buprenex[®]) is an analgesic indicated for the relief of moderate to severe pain. Buprenorphine Tablets (Subutex[®]) and Buprenorphine/Naloxone Tablets (Suboxone[®]) are indicated in the treatment of opiate addiction. Buprenorphine is classified by the DEA in Schedule III.

DATA reduces some of the requirements on physicians prescribing narcotic drugs for the treatment of opiate addiction, and further, encourages the transition of the locale of treatment for opiate addicts from a narcotic maintenance clinic to the private physician's office and the patient's own pharmacy.

With respect to the prescribing of a Schedule III, IV, or V drug approved by the federal FDA for the treatment of opiate addiction (including buprenorphine), DATA requires the prescriber to obtain a Unique Identification Number (DATA 2000 waiver identification number, or "X" number) from the DEA. Pursuant to DEA rules effective 07-25-2005, physicians prescribing buprenorphine for opiate addiction shall include their "X" number on the prescription [21 CFR 1306.05(a)] The "X" number is not in lieu of the DEA registration number, but rather it is in addition to the DEA registration number. If the prescription is telephoned to the pharmacy, the pharmacist must have both numbers on the prescription record; the physician can provide the numbers or the pharmacist may have the numbers on file.

The federal government agency Substance Abuse and Mental Health Services Administration (SAMHSA) Buprenorphine Physician Locator website (http://www.buprenorphine.samhsa.gov/bwns_locator/index.html) lists the physicians in each state who have DATA 2000 waivers. [Note: approximately 165 from La. on this date] A physician listed on the site can be considered to have a valid DATA waiver. Note, however, that the site does not list every physician with a valid waiver, only those who agreed to be listed on the site. Physicians with valid waivers may choose not to be listed on the site.

A pharmacist desiring to verify that a physician who is not listed on the site still has a valid DATA 2000 waiver can contact SAMHSA by telephone at 1-866-BUP-CSAT (1.866.287.2728) or by email at info@buprenorphine.samhsa.gov. Pharmacists should convey their own DEA registration number with email requests.

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With respect to the dispensing of prescriptions for buprenorphine, the usual restrictions for Schedule III-V prescriptions are applicable: no maximum quantity in Louisiana, and not more than five refills of the original amount prescribed within the six month period following the date of issue.

Finally, please remember that drugs approved by the federal FDA may be used for purposes other than the approved indication. Such 'off-label' uses are not illegal. Therefore, a prescription for buprenorphine intended for use other than treatment of opiate addiction would not require the "X" number, just the DEA registration number. Similarly, a pharmacist should exercise caution in how they approach patients to fulfill their counseling responsibilities.

If you wish to obtain more information about the use of buprenorphine in the treatment of opiate addiction, we recommend the website maintained by SAMHSA: www.buprenorphine.samhsa.gov, in addition to your usual drug information reference materials.