

## USE OF BUPRENORPHINE IN TREATMENT OF OPIOID DEPENDENCE

On Oct. 17, 2000, Congress passed the Drug Addiction Treatment Act (DATA), which permits qualified physicians to treat narcotic dependence with Schedule III-V controlled substances that have been approved by the Food and Drug Administration for that indication. At present, Subutex® (buprenorphine sublingual tablets) and Suboxone® (buprenorphine and naloxone sublingual tablets) are the only medications approved for such use. (1) With the passage of this law, patients can be treated for narcotic dependence in an office setting, rather than in a hospital or through a methadone clinic.

Qualified physicians, as defined in the act, are issued a waiver authorizing them to conduct maintenance and detoxification treatment without registering as a Narcotic Treatment Program. DATA-waived physicians may treat up to 30 patients initially. After at least one year, they may submit for a second waiver to increase the limit up to 100 patients. The DEA will issue a registration certificate with a unique identifier beginning with an "X." Physicians must write their "X" number on all prescriptions for Suboxone and Subutex. (1)

There are a number of ways to verify that a physician has a valid waiver for prescribing buprenorphine, for example:

- Check that the physician's prescribing number begins with "X." Physicians are required to include their "X" identifying number and their DEA registration number on all prescriptions for Suboxone® and Subutex® written for treatment of opioid dependence.
- Check the Substance Abuse and Mental Health Services (SAMHSA) physician locator at [http://buprenorphine.samhsa.gov/bwns\\_locator/index.html](http://buprenorphine.samhsa.gov/bwns_locator/index.html) . This Web site lists some of the physicians in each state that have DATA 2000 waivers. Some physicians elect not to be listed on this site.
- Call SAMHSA at (866) 287-2728 to verify a physician has a valid DATA 2000 waiver.

- Call the physician directly and ask to have the DEA registration certificate containing the "X" identifier faxed to you. (2)

Subutex® and Suboxone® have received FDA approval only for the treatment of opioid addiction. However, once approved, a drug product may be prescribed by a licensed physician for any use that, based on the physician's professional opinion, is deemed to be appropriate. Off-label use is not illegal, but it means that the data to support that use has not been independently reviewed by the FDA.

Physicians and other practitioners who are authorized to prescribe Schedule III controlled narcotic medications under federal and state laws are eligible and the unique identifier under the Drug Addiction Treatment Act is not required. (3)

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of sound professional practice. The practitioner is responsible for the proper prescribing and dispensing of controlled substances. However, a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order for controlled substances that purports to be a valid prescription, but is not issued in the usual course of professional treatment, or for legitimate and authorized research, is not a valid prescription. (4)

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### Other News:

- [Disciplinary Actions](#)
- [PA Becomes Smoke-Free](#)
- [2009 Novel Influenza A \(H1N1\)](#), information from the PA Department of Health
- [CHIP](#), health insurance for Pennsylvania children and teens

Since pharmacists dispensing controlled substances have a responsibility to ensure that these medications are being used for a legitimate medical purpose, it is important to have an understanding of the requirements for prescribing and dispensing buprenorphine.

References:

- (1) [www.deadiversion.usdoj.gov/pubs/docs/index.html](http://www.deadiversion.usdoj.gov/pubs/docs/index.html)
- (2) [www.suboxone.com/hcp/pharmacists/pharmacists\\_faqs.aspx#30](http://www.suboxone.com/hcp/pharmacists/pharmacists_faqs.aspx#30)
- (3) <http://buprenorphine.samhsa.gov/faq.html#A21>
- (4) DEA Pharmacists Manual (April 2004)

## PENNSYLVANIA DEPARTMENT OF HEALTH

Pennsylvania is home to 12 million people. Many more visit the state each year, and each of them — resident and visitor alike — can benefit from the Pennsylvania Department of Health's many health and promotional programs.

The Pennsylvania Department of Health's mission is to promote healthy lifestyles, prevent injury and disease, and to assure the safe delivery of quality health care for all commonwealth citizens. The mission has been adapted to meet the needs and demands of the dynamic nature of public health, but one thing has not changed — the commitment, dedication and professionalism of Department of Health staff to provide top-quality programs and services that benefit the health, safety and well-being of all Pennsylvanians.

In an effort to keep Pennsylvania pharmacists informed regarding various issues, the Department of Health has a Web site that is an invaluable informational resource: the Pennsylvania Public Health Information Clearinghouse. It contains hundreds of articles related to substance abuse and many other health related publications.

The Web site's address is [www.padohric.org](http://www.padohric.org). Articles or pamphlets can be ordered by calling the PA Department of Health at 1-877-PAHEALTH and select Option 9.

In addition to the resources listed in the attachment, the Pennsylvania Department of Environmental Protection produces a pamphlet called: "Disposal Tips for Home Health Care Wastes." This addresses the disposal of needles and other sharp instruments.

### LINKS OF INTEREST

[Controlled Substance, Drug, Device and Cosmetic Act](#)

[Controlled Substance, Drug, Device and Cosmetic Regulations](#)

[Generic Drug Substitution/Equivalency Laws](#)

[Narrow Therapeutic Index Info](#)

[Controlled Substances Information - the DEA Pharmacist's Manual](#)

### Governor's Newsletter

[Sign up now](#) to receive the weekly e-newsletter from Governor Rendell on important issues facing Pennsylvania.

- Learn more about how stimulus money will help PA residents and businesses, [www.recovery.pa.gov](http://www.recovery.pa.gov).
- [Here to Help](#) State programs to help in these tough times