



## PIC QUESTION OF THE WEEK: 11/09/09

Q: What are the general requirements for prescribing and dispensing buprenorphine in Pennsylvania?

A: Subutex® (buprenorphine) and Suboxone® (buprenorphine/naloxone) are indicated for the management of opioid dependence. The parenteral form of buprenorphine is labeled for the treatment of moderate – severe pain. Physicians desiring to treat patients with opioid dependence on an outpatient basis must meet specific qualifications outlined in the Drug Addiction Treatment Act (DATA) of 2000. Specific criteria for prescribing are detailed on the Suboxone® website at [www.suboxone.com](http://www.suboxone.com). In addition, physicians must have the ability to provide or refer patients for necessary ancillary services such as psychosocial therapy. Initially, the individual physician or group is limited to treating a maximum of thirty patients. After one year, they may obtain a special waiver from the Drug Enforcement Administration (DEA) to treat up to 100 patients. Prior to passage of the DATA of 2000, it was illegal for physicians to prescribe any narcotic drugs to treat opioid dependence (other than through a registered methadone maintenance clinic). Prior to prescribing Subutex® or Suboxone®, the physician must also notify the Center for Substance Abuse Treatment (CSAT), a unit of the Substance Abuse and Mental Health Services Administration (SAMHSA) of the Department of Health and Human Services (DHHS). The CSAT then notifies the DEA that the requesting physician is qualified as required by the DATA. This review process may take up to 45 days. The DEA then issues the physician a *unique identification number* that begins with an “X”. If the physician must treat a patient prior to receiving the registration number, they are required to notify the CSAT and DEA of their intention. Physicians must include their unique “X” identifier along with their standard DEA number on all prescriptions for Subutex® and Suboxone® when written for treatment of *opioid dependence*. Pharmacists must ensure that the physician is registered to prescribe Subutex® or Suboxone®. If the unique “X” identification number is not included on the prescription, the pharmacist must contact the physician and confirm that the CSAT has been notified prior to prescribing these drugs. When in doubt, call SAMHSA at 1-866-287-2728 to determine whether the physician has a valid DATA 2000 waiver. Physicians and other practitioners authorized to prescribe Schedule III controlled narcotic medications may prescribe buprenorphine for pain and are *encouraged, but not required*, to include a statement on the prescription stating *for pain control*. In this case, the “X” identification number is not required. The standard prescription is typically written for a 30-day supply; however, limits are restricted to the same prescribing regulations as that of other Schedule III substances. The physician and pharmacist bear equal and corresponding legal responsibility for the prescribing and dispensing of Subutex® and Suboxone®.

### References

- Pennsylvania State Board of Pharmacy Newsletter. Use of buprenorphine in treatment of opioid dependence. [http://www.dos.state.pa.us/bpoa/lib/bpoa/20/phabd/02\\_june\\_09\\_pharmacy.pdf](http://www.dos.state.pa.us/bpoa/lib/bpoa/20/phabd/02_june_09_pharmacy.pdf) (Accessed November 3, 2009)
- CSAT Buprenorphine Information Center. Frequently asked questions about buprenorphine and the drug addiction treatment act of 2000 (DATA 2000). <http://buprenorphine.samhsa.gov/faq.html#21> (Accessed November 3, 2009)

Photo by: Peasap: used under Creative Commons License; <http://www.flickr.com/photos/peasap/2081514907/> (Accessed November 3, 2009)

Lauren N. Lettrich and Kyle B. Zaffino, Pharm.D. Candidates and David N. Ombengi, Pharm.D.

**The PIC Question of the Week is a publication of the Pharmaceutical Information Center, Mylan School of Pharmacy, Duquesne University, Pittsburgh, PA 15282 (412.396.4600).**