



ASAM

American Society of Addiction Medicine

Public Policy Statement on Buprenorphine for Opioid Dependence and Withdrawal

Background:

Federal legislation has been passed that enables qualified physicians to prescribe Schedule III-IV medications approved by the federal Food and Drug Administration (FDA) for treatment of opioid dependence. The National Institute on Drug Abuse (NIDA), in collaboration with a pharmaceutical company, has developed buprenorphine for the treatment of opioid dependence, and a New Drug Application was submitted to and approved by the FDA for two formulations of sublingual buprenorphine tablets (one containing buprenorphine alone, and one containing buprenorphine in combination with naloxone). Buprenorphine is a partial opioid agonist and has clinical utility in the management of pain and in the treatment of heroin and prescription opioid dependence.

Like other opioids, buprenorphine can produce reinforcing effects. When used outside the confines of a physician-patient relationship, buprenorphine has the potential (akin to other opioid agonist therapies) to be diverted for unauthorized use. The formulation of buprenorphine in combination with naloxone is expected to have less potential for misuse, especially via intravenous routes of administration, and is generally the formulation preferred for unobserved maintenance or withdrawal therapy.

When used for the treatment of opioid dependence, and when prescribed by a physician for opioid withdrawal, buprenorphine has been shown to be a safe and effective treatment, although relapse to opioid use following withdrawal is common. In a sublingual form, buprenorphine has been shown to be an important therapeutic tool for addiction medicine specialists, when prescribed in a private physician's office or an addiction treatment facility. As a clinical tool, buprenorphine would have limited utility were the federal Drug Enforcement Administration (DEA) to classify it as a Schedule II medication or were it assigned solely to the regulatory structure for methadone.

Buprenorphine is a unique medication that has offered a unique and unprecedented opportunity for addiction medicine. Since its approval by the FDA in 2002, buprenorphine has led to expansion of the treatment system for opioid dependence. However, the Drug Addiction Treatment Act of 2000 and subsequent legislation have included caps on the number of patients who can be treated with buprenorphine, such as a 30-patient limit per registered practitioner.

Recommendations:

- 1. ASAM recommends that physicians appropriately trained and qualified in the treatment of opioid withdrawal and opioid dependence should be permitted to prescribe buprenorphine in the normal course of medical practice and in accordance with appropriate medical practice guidelines, and that federal controlled substance scheduling guidelines and other federal and state regulations should permit buprenorphine to be made available for physicians to prescribe for maintenance and withdrawal in opioid dependent patients.**
- 2. ASAM strongly opposes any action to restrict access to buprenorphine for the treatment of opioid addiction or withdrawal through either rescheduling under the U.S. Controlled Substances Act or international agreement under the umbrella of the World Health Organization. Either of these courses of action would unnecessarily and inappropriately reduce physicians' ability to use this medication to address the pressing public health problem of opioid addiction.**
- 3. Arbitrary caps on the number of patients who can be treated by a physician, the dosage of medication which is allowed, or the duration of treatment with buprenorphine, that are not supported by medical evidence, should not be imposed by law, regulation, or health insurance practices.**
- 4. Standards of professional practice should outline that psychosocial supports should be offered to patients receiving agonist medications for opioid dependence or undergoing detoxification from opioids.**

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