



State of New Jersey
Department of Human Services
Division of Medical Assistance & Health Services
New Jersey Drug Utilization Review Board

BULLETIN

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TO: Physicians, Advanced Practice Nurses, Clinics, Federally Qualified Health Centers- **For Action**
Providers of Pharmaceutical Services, Health Maintenance Organizations – **For Information Only**

SUBJECT: Clinical News from the New Jersey Drug Utilization Review Board (DURB)

PURPOSE: To provide practitioners useful clinical information that may be helpful to the prescribing of prescription drugs

BACKGROUND: The DURB serves as an advisory board to the New Jersey Department of Human Services and the New Jersey Department of Health and Senior Services. The Board's responsibilities include recommending clinical standards based, in part, on the evaluation of prescription drug use by participants in the State's prescription drug programs. The Board is also responsible for disseminating information that the Board has determined would encourage appropriate drug utilization.

ACTION: Attached please find more information pertaining to **Suboxone[®]/Subutex[®] Prescribing**. The Board welcomes your comments regarding this bulletin. Send comments to www.state.nj.us/humanservices/dmahs/durb.html. The Subject should read, "DURB Comments."

RETAIN THIS BULLETIN FOR FUTURE REFERENCE



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Buprenorphine/Naloxone for Opioid Dependence

More people die in New Jersey every year from unintentional drug overdoses than from either automobile accidents or homicides. Many of these individuals are addicted to either illicit or prescription medications, primarily opioids. Until recently, treatment options for these individuals, before they overdose, were extremely limited. Historically methadone maintenance has been the only treatment option. Methadone treatment of opioid abuse is restricted to treatment programs with special licensure. There are strict laws and regulations that need to be followed in order to supply methadone for opioid addiction. As a result, there are not enough methadone programs (34 centers in the State of New Jersey) and patients may not have adequate access to opioid detoxification programs.

Suboxone® (buprenorphine and Naloxone) and Subutex® were FDA approved in October 2002 as alternatives to methadone for providing opioid detoxification by independent practitioners in their office setting. Although there is a fair number of New Jersey physicians currently prescribing these drugs (under 400), there is still a large number who are unaware of the possibility of using them in their practices. This informational package provides information about the drugs and to encourage their greater utilization in treating opioid-addicted individuals in the office setting.

How does the patient benefit?

As office-based treatment, Suboxone® is more convenient than going to a methadone treatment clinic.

- Daily physician or clinic visits are not required.
 - Unlike methadone treatment which requires a daily visit to the methadone program, Suboxone® treatment is more flexible and mimics the management of any chronic disease.
 - Treatment consists of three phases:
 1. **Induction** - The patient is switched from the current opioid that they are abusing to Suboxone®
 2. **Stabilization** - The Suboxone® dose is adjusted once a week to determine which dose best suppresses the patient's withdrawal symptoms
 3. **Maintenance** – Maintenance therapy will be provided once the patient's dose is stabilized. Patient will be medically monitored. Length of time of the maintenance phase is patient specific
- Less interference with patient daily activities:
 - Ability to work a normal schedule.
 - Ability to travel for work or pleasure without interfering with the treatment plan.
 - Office based prescribing of Suboxone® may benefit a patient who geographically does not have easy access to methadone clinics
- Suboxone® treatment protects patient confidentiality by providing healthcare in a private office setting. Patient can schedule an appointment with the prescribing physician and be seen routinely as for any other health problem.
- There is no stigma of going to an inpatient addiction facility. Instead, patients receive a prescription and fill it at the local pharmacy, like any other medical condition.
- There is limited data regarding the safety of these drugs when compared to methadone; however, that which does exist suggests that these agents have a better track record of safety in all treatment groups, including pregnancy.

As a physician, what can you do?

- Patients feel more comfortable seeking treatment from their primary physician. Knowing the patient's history, the physician can better understand the patient's needs. Allowing physicians to prescribe Suboxone® to their patients may build a better foundation for a patient-physician relationship. This foundation may in fact help increase patient compliance and therefore allow better outcomes with opioid detoxification.
- Physicians are the frontline of the long battle and are the key to providing these patients access to much needed treatment.
- Often patients take multiple drugs and other substances, both prescription and over the counter. There are numerous potential adverse drug interactions particularly with methadone. Opening the possibility to treat drug addiction in the office setting, the physician can help decrease the chances for serious interactions and side effects.
- By playing an active role in prescribing Suboxone® in their offices, physicians can help contain healthcare costs, decrease mortality and morbidity as well as help decrease other diseases associated with opioid addiction. Such diseases are HIV, TB and hepatitis B and C.

Prescribing of Suboxone® may be underutilized for several reasons. These reasons include:

1. perceived difficulties in obtaining the required training
2. regulations limiting the number of patients being treated in a practice
3. not being aware of the benefits vs. methadone treatment

Information about the specific medications:

Buprenorphine is a partial opioid agonist. It is similar to other opioids such as morphine, codeine, and heroin and therefore can produce typical opioid agonist effects and side effects. However, it produces less euphoric effects and therefore may be easier to stop taking. Its effects are less than those of full agonists.

Naloxone is an opioid antagonist. If Suboxone® is injected, Naloxone will block the effects of buprenorphine and lead to withdrawal symptoms in a person with an opioid addiction.

How Supplied:

Both Suboxone® and Subutex® are supplied as 2 and 8 mg tablets for sublingual use. Suboxone® tablets contain 0.5 and 2 mg of Naloxone.

How to gain approval to prescribe Suboxone®/Subutex®:

The Drug Addiction Treatment Act of 2000 (DATA 2000) enables qualifying physicians to receive a waiver from the special registration requirements in the Controlled Substance Act (CSA) for the provision of medication-assisted opioid therapy. This waiver allows physicians to practice medication-assisted opioid addiction therapy with Schedule III, IV, or V narcotic medications specifically approved by the Food and Drug Administration (FDA). This includes Suboxone® tablets (buprenorphine hydrochloride and Naloxone hydrochloride) and Subutex® (buprenorphine hydrochloride). Unlike methadone, Suboxone® and Subutex® may be prescribed in an office setting and can be filled at a retail pharmacy. Suboxone® and Subutex® tablets are currently approved by the FDA for the treatment of opioid addiction only. Buprenorphine injection has been used for the management of pain in other settings for years.

To prescribe Suboxone, ® a physician must train and hold **one** of the following:

- Completion of no less than 8 hours of authorized training on therapy or management of opioid dependence patients.
 - Training covers topics such as: how to diagnose a patient suffering from opioid addiction, how to medically monitor patients receiving Suboxone®
 - Training is offered by The Substance Abuse and Mental Health Services Administration (SAMHSA) whose website and telephone is www.buprenorphine.samhsa.gov and 866-BUP-CSAT (287-2728), respectively.

Or

Opt-In™, Opioid-Dependence Physicians Training, which can be easily accessed by logging onto DocOptIn.com or by simply calling 1-888-DOC-OPT-IN (888-362-6784).

- Subspecialty board certification in addiction psychiatry from American Board of Medical Specialists or Board certification in Addiction Medicine from American Osteopathic Association or an addiction certification from American Society of Addiction Medicine
- Participation as an investigator in 1 or more clinical trials leading to the approval of Suboxone®
- Training or other such experience as determined by the physician's state medical licensing board
- Training or other such experience as determined by the United States Secretary of Health and Human Services.

In addition to the above:

- To be a “qualifying physician” the practitioner must submit to the Secretary of HHS notification of the practitioner’s intent to begin dispensing the drugs approved by FDA specifically for maintenance or detoxification. Notification must contain the following:
 - The practitioner is registered with DEA as an individual practitioner.
 - The practitioner is a “qualifying physician” if he/she is licensed under State law and has specific medical certification, training, or experience in maintenance or detoxification treatment as specified in CSA.
 - With respect to patients to whom the practitioner will provide such drugs or combination of drugs, the practitioner may refer the patients for appropriate counseling and other appropriate ancillary services.
 - Total number of patients the practitioner may treat at any one time will not exceed 30 unless, not sooner than one year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of HHS of the need and intent of the practitioner to treat up to 100 patients.
 - Notification must be in writing and must state the name and DEA registration number of the practitioner.
 - If the practitioner is a member of a group practice, the notification must state the names of the other practitioners in the practice and identify the registrations issued for the other practitioners.

Suboxone Contact Information

Telephone: 1-888-DOC-OPT-IN (888-362-6784)

Websites:

1. Suboxone® .com
2. <http://www.buprenorphine.samhsa.gov>
3. DocOptIn.com
4. Physician Clinical Support System (PCSS)
www.asam.org/conf/BupMentoring/PCSS.htm
5. American Academy of Addiction Psychiatry (AAAP)
www.aaap.org/contact.htm
6. American Osteopathic Academy of Addiction Medicine (AOAAM)
www.aoaam.org
7. American Psychiatric Association (APA)
www.psych.org
8. American Society of Addiction Medicine (ASAM)
www.asam.org

For more information on regulatory requirements, contact SAMHSA at: 1-877-SAMHSA-7 (1-877-726-4727) or visit their website at:

http://buprenorphine.samhsa.gov/waiver_qualifications.html

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