APPENDIX B

Administrative Bulletin

Division of Mental Health and Addiction Services

4-2007

Subject: BUPRENORPHINE GUIDELINES

I. Background

The FDA approved the use of Buprenorphine, in the form of **Suboxone and Subutex**, for the treatment of opiate dependence on October 8, 2002 for **medical maintenance and medically supervised withdrawal**. Buprenorphine is a partial agonist that is available for use solely by certified physicians in addiction medicine and those who have satisfied qualifications set-forth by and under the provisions of the Drug Addiction Treatment Act of 2000 (DATA 2000). **Qualified physicians may prescribe to 100 patients at one time.**

While there are some current federal guidelines for use and the practice of opiate treatment, the State of New Jersey's Division of Mental Health and Addiction Services (DMHAS) seeks to provide modified details and guidelines for the use and practice in New Jersey. These guidelines are meant to enhance the existing federal guidelines.

A. Rationale for Buprenorphine Treatment

Patients are reporting for opiate treatment at increasingly higher rates than ever before. The opiate drugs are heroin, illegal methadone, hydrocodone, and oxycodone. The rates of addiction to prescription medication are also increasing at an alarming rate from both licit and illicit use. Recent data has shown that two or more narcotic pain medications, oxycodone, hydrocodone, and codeine were ranked among the 10 most common drugs involved in drug abuse deaths (SAMHSA 2002). The prevalence of heroin addiction has also been on the rise and is the highest since the 1970s. The need for effective opiate treatment is unquestionable.

It has been long noted that opiate addicted patients who present for treatment often find it difficult to remain engaged in treatment, detoxification and primary counseling, because the withdrawal is very uncomfortable and the craving and compulsion to use is too great to overcome. In those situations where patients are able to make a reasonable start in their recoveries, they often relapse before they can become fully engaged in continuing and aftercare therapy. Use of Buprenorphine can significantly address both issues. The detoxification, when indicated, can be performed much smoother. The issue of craving can also be managed for longer periods of time until the patient can get his or her recovery network and program stabilized. Lastly, for those individual patients who require long opiate medication therapy, Suboxone or Subutex can be safely utilized. Buprenorphine is approved by use for the treatment of opiate dependence only in the formulation as Suboxone or Subutex. **Injectable Buprenorphine is not approved for the treatment of opiate dependence.**

II. Services To Be Provided Post Detoxification

Buprenorphine therapy is an adjunct to the full treatment experience; not in lieu of a full treatment experience which includes stabilization (detoxification or maintenance), rehabilitation (counseling and education) and then follow-up (aftercare counseling and support groups). **All patients accepted into buprenorphine therapy must be referred to a DAS licensed substance use disorders treatment facility or individual therapists who are certified and/or licensed to provide substance abuse counseling. Such licensure and certification shall be current and not revoked or suspended.**

A. Primary and Aftercare Counseling

The primary counseling providers would need to accept buprenorphine therapy as an adjunct to addiction treatment, and not "contrary" to the previous concepts of total abstinence. Treatment professionals will need **initial and ongoing education** to effect this significant change in treatment philosophy. Those patients who are receiving therapy *should not be in segregated groups*. Currently those individuals in treatment with co-occurring disorders are not routinely segregated for primary and continuing care therapy, and those patients receiving Buprenorphine should not be segregated either. **Patients on Suboxone or Subutex should be permitted to participate in primary and aftercare substance abuse counseling.**

B. Patient Assessments/Screening Tools

All patients in all medical encounters should be screened for substance use disorders. Those patients who are presenting for substance use disorders treatment need to undergo a screening process to determine diagnosis, severity of illness, and the selection of an appropriate level of care for rehabilitation counseling. Providers should select a screening tool to utilize for each and every patient routinely (e.g. CAGE; COWS; CAGE-AID; and Narcotic Withdrawal Scale).

C. Complete History and Physical Examination

Each patient should undergo a complete history and physical examination. The history should include drug and alcohol use, psychiatric, past legal, medical, surgical, and family issues, and previous substance use disorders treatment. The physical examination should be complete and be specific for signs of addiction. Patient should also undergo a neurological and mental status examination. **All patients treated with Suboxone or Subutex should meet DMS-IV-TR criteria for opiate dependence or opiate abuse.**

D. Comprehensive Patient Management and Referrals

All patients should be referred for follow-up of other primary medical conditions not being addressed in opiate outpatient therapy by the provider. Additionally, all patients with **psychiatric diagnoses** should be under the care of a psychiatrist who is expert in managing patients with addictive disorders. Patients need appropriate referral for specialized care of non-addiction medical issues.

E. Detoxification

Subutex *is the formulation of choice for detoxification in the inpatient setting*. Subutex is Buprenorphine without Naloxone and is therefore less likely to induce a withdrawal syndrome in patients that are still under the influence of some opiate. ***Suboxone*** *is the formulation of choice for use in outpatient detoxification settings*. Suboxone is the Buprenorphine formulated with Naloxone which provides added protection and deterrence from using unauthorized opiates which is assumed to be a greater risk in the outpatient settings. Buprenorphine, when prescribed appropriately, is very effective in stabilizing opiate withdrawal symptoms without initiating or worsening withdrawal symptomatology in appropriately prepared patients.

Many patients who enter into treatment for opiate dependence are fearful that they will not receive the appropriate care and will be left to suffer moderate to severe withdrawal. Therefore, many patients who arrive have used an opiate just prior to their arrival. Use of Buprenorphine prematurely can induce withdrawal as it is also a partial agonist. **It is important to instruct the patients that they do not use any opiates at least twelve hours before they arrive.**

Detoxification is a two-step process; stabilization (the amelioration of signs and symptoms of withdrawal) followed by a **tapering** of the medication to zero. Patient selection for rapid detoxification is crucial. Some patients may require a slower detoxification occurring over a number of weeks and other patients may require maintenance therapy with Buprenorphine. *For those patients who cannot be stabilized and withdrawn from Buprenorphine on an inpatient basis, they can be managed by qualified providers, Addiction Medicine Physicians or Primary Care Physicians with the Buprenorphine Waivers*.

Once the patient has begun or completed detoxification, he or she is ready for primary substance abuse counseling.

F. Buprenorphine Maintenance

1. Adjunctive Therapy

Once detoxification or stabilization through the adjunctive use of Buprenorphine has occurred, **primary opiate addiction counseling** can commence without the distraction of opiate craving and withdrawal. The primary counseling should begin at the appropriate level of care as indicated by the use of some standardized criteria **(ASAM Patient Placement Criteria-2R). Primary counseling** can occur as **residential, intensive outpatient, traditional weekly individual or group therapy.** While the patient is engaged in primary substance abuse counseling treatment, his or her Buprenorphine can be managed by a certified physician provider. **Upon completion of primary treatment (counseling) and aftercare, the patient can continue under the care of a prescribing physician for continued use of the Buprenorphine, if indicated.**

If patients are stabilized with Subutex they should be switched over to Suboxone, which has less of an abuse potential and provides the added benefit of being a deterrent to illicit opiate use, during the time of primary treatment.

G. After Primary and Aftercare Treatment and Discharge Care

After patients have completed their primary and aftercare counseling, some patients will have been effectively withdrawn from their Buprenorphine therapy while others may be continuing on a maintenance regime. These patients will need to follow-up with a provider, their primary care physician, another provider with a waiver, or an Addiction Medicine Specialist, to prescribe the Buprenorphine. **These arrangements should be made prior to discharge from the counseling phase of treatment** so as not to interrupt the maintenance pharmacotherapy.

III. Treatment Protocols

All physicians are referred to the federal guidelines established through the Center for Substance Abuse Treatment (CSAT) for the minimum requirements. The New Jersey Guidelines are meant to enhance the guidelines put forth by CSAT.

A. 24-Hour Medical Care Availability

During the induction and stabilization phase of Buprenorphine therapy, medical care and consultation shall be available on a 24-hour basis. This care should be supervised by the waivered physician performing the induction.

IV. Special Populations

A. Buprenorphine and Pregnancy

Currently, *Methadone is still the pharmacotherapy of choice* for the treatment of opiate dependent pregnant patients. Patients should be offered referral to a Methadone provider for care. If the patient, however, refuses or has misgivings about Methadone, Buprenorphine has been used successfully. The FDA classifies Buprenorphine as a Category C drug. The risks of Category C drugs must be explained to the patient and thereafter can be used with **informed consent**. Buprenorphine use in pregnancy needs to be further evaluated by controlled studies. To date, the safety has been determined by case series reports. **The discussion**

and informed consent should be clearly documented in the patient's chart. Subutex is the formulation of choice.

B. Buprenorphine Maintenance and Pain Management

1. Acute Pain

Patients who are on Buprenorphine maintenance and who are experiencing *acute pain* should attempt to manage the pain with *non-narcotic medications* in combination with their prescribed Buprenorphine. Buprenorphine has analgesic properties and can be an effective analgesic. The dose of Buprenorphine can be increased to try to improve the analgesia, in conjunction with non-narcotic analgesics. **Patients for whom the pain is not relieved should undergo aggressive treatment with narcotic analgesics.** The Buprenorphine should be discontinued while the appropriate opiate analgesic is employed to address the acute pain. Once the acute pain has been successfully managed, the Buprenorphine should be restarted.

2. Chronic Pain

Opiate dependent patients with *chronic pain are usually not good candidates* for Buprenorphine therapy because of the analgesic "ceiling effect". These patients fair better with long acting narcotic analgesics. Methadone has proven to be an effective choice.

V. Clinical Guidelines References

For DETOXIFICATION see Clinical Guidelines CSAT TIP #40.

For INDUCTION see Clinical Guidelines CSAT TIP #40.

For MAINTENANCE THERAPY see Clinical Guidelines CSAT TIP #40.

For BUPRENORPHINE DISCONTINUATION see Clinical Guidelines CSAT TIP #40.

VI. Scope

Substance use disorders treatment providers or medical practitioners using Buprenorphine, in the form of Suboxone and Subutex, for the treatment of opiate dependence for medical maintenance and medically supervised withdrawal.