



Sep 1, 2000

Substance Abuse and Mental
Health Services Administration
Rockville MD 20857

Dear Colleague:

The purpose of this letter is to clarify the status of buprenorphine, a partial opioid agonist drug substance that is under investigation at selected sites for the treatment of opiate addiction. The Center for Substance Abuse Treatment (CSAT), the Food and Drug Administration (FDA), and the Drug Enforcement Administration (DEA) have all received several inquiries on this issue. Further, these agencies have received anecdotal reports that buprenorphine is being used in the treatment of opiate addiction. Buprenorphine is not currently approved or legally available for the treatment of opiate addiction in the United States, except when used under an Investigational New Drug (IND) Study.

In 1985, FDA approved a new drug application for Buprenex®, an injectable analgesic product containing buprenorphine as its active ingredient. At the same time and in association with FDA's approval of Buprenex®, DEA controlled buprenorphine as a narcotic in Schedule V of the Controlled Substance Act ("CSA," 21 U.S.C. § 811). From the questions received, there appears to be a misunderstanding that Buprenex® can be used in the treatment of opiate addiction as an "off label" use of an approved drug product. This is not accurate. Practitioners who dispense Buprenex® for the treatment of opiate addiction must comply with the Narcotic Addict Treatment Act (NATA) (21 U.S.C. 823(g)). Buprenex® may not be used for the treatment of opiate addiction unless and until it is approved for this use and there are standards in place to permit practitioners to be registered by DEA as required by NATA.

There has been considerable interest and activity in Congress on the issue of new medications for the treatment of opiate addiction. Measures have cleared both houses that, if passed and enacted into law, would provide waivers from the NATA requirements, discussed above, for certain narcotic drugs used in the treatment of opiate addiction if approved for that use by FDA. Buprenorphine has been discussed often within the context of these activities. As a result, some have mistakenly concluded that buprenorphine products are approved and available for use in the treatment of narcotic addiction.

There has also been rulemaking activity in this area. In May, the Department of Health and Human Services, which includes the Substance Abuse and Mental Health Services Administration and CSAT, published a Notice of Intent to allow for office-based treatment of opiate addiction using certain partial agonist medications. Please see the attached Notice for additional information. The purpose of this announcement was to notify affected parties of the agency's intent to propose new rules, which are subject to the notice and comment rulemaking process. As such, no regulations have been issued yet to permit the use of partial opioid agonist medications.

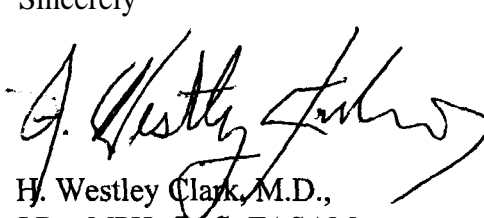
For the last several years, buprenorphine, in liquid and solid oral dosage form, has been under investigation for use in the treatment of opiate addiction. And, there are several multi-center clinical trials currently underway. Practitioners participating in these IND-sanctioned trials are entitled to conduct this research under the CSA and the Food, Drug, and Cosmetic Act without separate DEA registration. Practitioners interested in learning more about ongoing clinical trials with buprenorphine should contact the National Institute on Drug Abuse (NIDA), as noted below.

It is important to emphasize that at present there are no buprenorphine products approved and available for the treatment of opiate addiction. Buprenex® is not approved for the treatment of opiate addiction. Further, unlike methadone and ORLAAM, there are no treatment standards established by the Secretary of Health and Human Services to permit practitioners to be registered by DEA as required under the NATA. Therefore, buprenorphine products may not be used in the treatment of opiate addiction at this time.

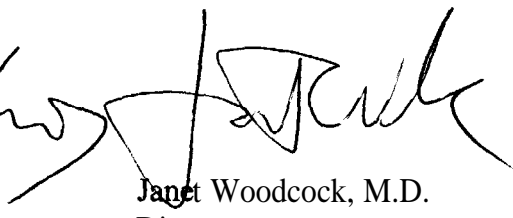
In closing, the undersigned would like to emphasize our shared goal to work together to expand patient access to safe and effective opiate addiction treatment.

For further information please contact Mr. Robert Lubran, Acting Director, Office of Pharmacological and Alternative Therapies, CSAT, at 301-443-0744. For further information about ongoing clinical trials with buprenorphine, contact Mr. Robert Walsh, Associate Chief, Regulatory Affairs Branch, Division of Treatment Research and Development, NIDA, at 301-443-5280.


Sincerely



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Enclosure:

LIBRARY OF CONGRESS**Copyright Office****37 CFR Part 201**

[Docket No. RM 99-7C]

Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies**AGENCY:** Copyright Office, Library of Congress.**ACTION:** Announcement of change in time a hearing will begin.

SUMMARY: The Copyright Office of the Library of Congress announces a change in the time of a public hearing on the possible exemptions to the prohibition against circumvention of technological measures that control access to copyrighted works to be held in Stanford, California on May 18, 2000. The date and location of the hearing remain unchanged

DATES: May 4, 2000.

FOR FURTHER INFORMATION CONTACT: Robert Kasunic, Senior Attorney, Office of the General Counsel, Copyright GC/I&R, P.O. Box 70400, Southwest Station, Washington, D.C. 20024. Telephone: (202) 707-8380. Telefax: (202) 707-8366.

SUPPLEMENTARY INFORMATION: The Copyright Office is conducting a rulemaking pursuant to 17 U.S.C. 1201(a)(1), which provides that the Librarian of Congress may exempt certain classes of works from the prohibition against circumventing a technological measure that controls access to a copyrighted work. On March 17, 2000 (65 FR 14505), the Office published a notice which announced that public hearings relative to the rulemaking would be held in Washington, DC on May 2-4, 2000, and in Stanford, California on May 18 and 19, 2000. A schedule for all of the hearings can be found on the office's website at www.loc.gov/copyright/1201/hearing.html. The Stanford hearings were scheduled to be held from 9:30 a.m. to 6:00 p.m. The hearing on May 18, 2000, is now scheduled to begin at 2:00 p.m. rather than 9:30 a.m.

Dated: May 1, 2000.

Marilyn J. Kretsinger,
Assistant General Counsel.

[FR Doc. 00-11151 Filed 5-3-00; 8:45 am]

BILLING CODE 1410-30-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Parts 141 and 142**

[FRL-6587-8]

RIN 2040-AA97

Ground Water Rule Public Meeting**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice of public meeting.

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) is holding a public meeting on May 18, 2000 in the EPA auditorium in Washington, DC. The meeting will provide a description and summary of the proposed Ground Water Rule (GWR) to be published in the **Federal Register** on May 10, 2000.

EPA is inviting all interested members of the public to attend the meeting. EPA is instituting an open door policy to allow any member of the public to attend the meeting for any length of time. Approximately 150 seats will be available for the public. Seats will be available on a first-come, first served basis.

DATES: The meeting will start at 2 PM on May 18, 2000 and will adjourn at 4:00 PM.

ADDRESSES: The meeting will be held in the EPA auditorium located at 401 M Street SW, Washington, DC 20460.

For information about the meeting, contact the Office of Ground Water and Drinking Water (MC 4607), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone (202) 260-3309. The GWR proposal, GWR fact sheet, and GWR draft implementation guidance may be obtained from www.epa.gov/safewater or by calling the Safe Drinking Water Hotline, telephone (800) 426-4791.

FOR FURTHER INFORMATION CONTACT: For general information, contact the Safe Drinking Water Hotline, telephone (800) 426-4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9 a.m. to 5:30 p.m. Eastern Time.

Dated: April 28, 2000.

Cynthia C. Dougherty,
Director, Office of Ground Water and Drinking Water.

[FR Doc. 00-11136 Filed 5-3-00; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Substance Abuse and Mental Health Services Administration****42 CFR Part 9****Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Conditions for the Use of Partial Agonists Treatment Medications in the Office-Based Treatment of Opiate Addiction****AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.**ACTION:** Notice of intent to issue regulations.

SUMMARY: The Secretary, Department of Health and Human Services, is announcing its intent to develop and issue regulations to address the use of approved partial agonist treatment medications in the "office-based" treatment of opiate addiction.

FOR FURTHER INFORMATION CONTACT: Nicholas Reuter, Center for Substance Abuse Treatment (CSAT), SAMHSA, 5600 Fishers Lane, Rockville, MD 20857, 301-443-0457.

SUPPLEMENTARY INFORMATION:**I. Background**

Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91-513) requires the Secretary of Health and Human Services (the Secretary) to determine the appropriate methods of professional practice for the medical treatment of narcotic addiction. In addition, the Narcotic Addict Treatment Act of 1974 (Pub. L. 93-281) amended the Controlled Substances Act (21 U.S.C. 823) to require that practitioners who wish to dispense narcotic drugs to individuals for the maintenance treatment or detoxification treatment of narcotic addiction must be registered annually with the Department of Justice, Drug Enforcement Administration (DEA). Registration depends, in part, upon a determination by the Secretary that the applicant is qualified, under treatment standards established by the Secretary, to provide such treatment. In addition, the applicant must comply with standards established by the Secretary (after consultation with DEA) respecting the quantities of narcotic drugs that may be provided for unsupervised use by individuals in such treatment. Finally, the applicant must comply with standards established by DEA respecting security of stocks of narcotic drugs used

for such treatment and maintenance of records on such drugs.

These statutory mandates have been reflected in treatment regulations that have been enforced by the Food and Drug Administration (FDA) since 1972. FDA has approved over 900 "narcotic treatment programs" under these regulations. Up until 1993, methadone was the only narcotic treatment medication approved for use under these regulations. In 1993, the regulations were revised to add regulatory standards for the use of levo-alpha-acetyl-methadol (LAAM), following review and approval of a New Drug Application (NDA) for this use by FDA.

FDA has received and is reviewing NDAs for two new narcotic treatment medications, buprenorphine and buprenorphine/naloxone (buprenorphine/nx). If approved, both products must be the subject of treatment standards.

The Secretary recognizes that partial or mixed agonist medications, are different than full agonists, such as methadone and LAAM. The Secretary has, therefore, determined that these differences warrant a different treatment standard model:

The Secretary notes that there are new medications under development for the treatment of opioid addiction. While still under investigation and review, it is conceivable that these new medications will present safety and effectiveness profiles that differ from the existing approved treatment medications, methadone and LAAM. A new medication, for example, could rely on weak or partial agonist properties or on mixed agonist-antagonist properties, with pharmacokinetic and pharmacodynamic properties that would minimize the risk of deliberate abuse through injection and, in turn, would minimize the overall risk of diversion. As such, it may be appropriate to tailor the Federal opioid treatment standards to the specific characteristics of these future medications. (See **Federal Register**, July 22, 1999, 64 FR 39810.)

Because of their special characteristics, partial agonist medications should be the subject of specific treatment standards. Indeed, partial agonist medications' pharmacological properties and safety profiles warrant a new paradigm in narcotic addiction treatment, office-based treatment. Therefore, the Department of Health and Human Services is announcing its intent to develop and issue a proposed rule that will address the use of partial agonist treatment medications in the office-based treatment of narcotic addiction.

II. Office-Based Treatment of Narcotic Addiction

The Department is preparing a proposed rule for publication in the near future that will address the use of approved narcotic partial agonist treatment drugs controlled in Schedules III-V, in office-based settings. The proposed rule will include standards and procedures for determining the training and experience necessary to safely and effectively treat opiate addicts with partial agonist treatment medications in an office-based setting. This may include limits on the number of patients that may be treated by any one office-based physician. In addition, the proposal will include standards that relate to medical and psychosocial services, including counseling, that should be available to patients that are determined to need them. The proposed rule will include standards respecting the quantities of medications that may be prescribed, dispensed or administered to patients for unsupervised use.

In anticipation of the availability of partial agonist treatment medications, a Subcommittee on Buprenorphine was formed as part of SAMHSA's Center for Substance Abuse Treatment (CSAT) National Advisory Council. The Subcommittee considered the available research base on buprenorphine, office-based settings, and Federal oversight during two public meetings. The full CSAT National Advisory Council, after deliberation, adopted the Subcommittee's findings and recommendations which were subsequently conveyed to CSAT by the Council on June 11, 1999, in the form of a comprehensive report. The report may be obtained by notifying the CSAT contact listed above. The report is also available at the SAMHSA website (www.samhsa.gov).

SAMHSA believes that a key feature of office-based treatment will be the ability of the office-based physician to prescribe partial agonist treatment medications to patients in treatment. Without the ability to prescribe, office-based physicians would have to store and dispense medications directly to patients. These practices could be expensive and impractical for the patient and office-based physician. Current regulations enforced by the Drug Enforcement Administration (21 CFR 1306.07(a)) prohibit prescriptions for narcotics drugs used in the treatment of narcotic addiction. However, DEA is preparing a separate proposed rule to rescind this prohibition as it pertains to narcotic treatment drugs controlled in Schedules III-V.

III. References

1. Using Buprenorphine for Office-Based Treatment of Opiate Addiction, Recommendations to the Center for Substance Abuse Treatment.

Dated: December 29, 1999.

Nelba Chavez,

Administrator, Substance Abuse and Mental Health Services Administration.

Dated: March 30, 1999.

Donna E. Shalala,

Secretary, Health and Human Services.

[FR Doc. 00-10969 Filed 5-3-00; 8:45 am]

BILLING CODE 4162-20-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 00-44; FCC 00-93]

Extension of the Filing Requirement for Children's Television Programming Reports (FCC Form 398)

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The document proposes to amend the FCC's rules to continue indefinitely the requirement that commercial broadcast television licensees file with the Commission, on an annual basis, their quarterly Children's Television Programming Reports (FCC Form 398). The Commission's rules currently state that such reports shall be filed on an annual basis for an experimental period of three years, from January 1998 through January 2000. Continuation of the annual filing requirement will permit the Commission to continue to enforce the Children's Television Act of 1990 ("CTA"), and its rules implementing the CTA, by monitoring the amount and quality of educational television programming for children and industry compliance with the FCC's children's educational programming requirements.

DATES: Comments are due on or before June 12, 2000; reply comments are due on or before July 12, 2000.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW, Room TW-A306, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Kim Matthews, Policy and Rules Division, Mass Media Bureau, (202) 418-2154.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking* ("NPRM"), MM 00-44; FCC 00-93, adopted March 9, 2000; released April 6, 2000. The full