

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Proposed Project: The Evaluation of the Buprenorphine Waiver Program—Survey of Physicians with Waivers—New—The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapies, (DPT), is evaluating a program that permits office-based physicians to obtain Waivers from the requirements of the Narcotic Addict Treatment Act of 1974 (21 U.S.C. 823(g)). Under the Drug Addiction Treatment Act of 2000 (21 U.S.C. 823(g)(2)), the Waiver Program permits qualified physicians to dispense or prescribe schedule III, IV, and V narcotic drugs or combinations of such drugs approved by the Food and Drug Administration (FDA) for the treatment of addiction to opiates. Subutex and

Suboxone, two formulations of buprenorphine, a schedule III narcotic drug, were approved by the FDA in October 2002, for the treatment of opiate addiction and are now being used under the Waiver Program. The Drug Abuse Treatment Act (DATA) also specifies that the Secretary of the Department of Health and Human Services may make determinations concerning whether: (1) Treatments provided under the Waiver Program have been effective forms of maintenance treatment and detoxification treatment in clinical settings; (2) the Waiver Program has significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and, (3) the Waiver Program has adverse consequences for the public health. This Evaluation will provide data to: Inform the determinations listed in DATA; describe the impact of the Waiver-based treatment on the existing treatment system; guide and refine the processing/monitoring system being developed and maintained by CSAT/DPT; and inform future research and policy concerning the mainstreaming of addiction treatment.

The evaluation by SAMHSA/CSAT of the Buprenorphine Waiver Program will be accomplished using three survey efforts. The first survey, now completed, was a mail survey of addiction-specialist physicians from the American Society of Addiction Medicine (ASAM), the American Academy of Addiction

Psychiatry (AAP), and the American Osteopathic Academy of Addiction Medicine (AOAAM). The survey provided early data about the availability, effectiveness, and public health consequences associated with buprenorphine treatment under the Waiver Program. A second longitudinal telephone study, now being conducted, focuses on patient responses to buprenorphine, including its effectiveness and availability.

The third survey, the subject of this **Federal Register** notice, focuses on the clinical experience of waived physicians who are currently prescribing buprenorphine and who represent a range of medical specialties. The survey is designed to identify broad clinical issues in providing buprenorphine treatment, particularly whether physicians (1) perceive it to be an effective treatment, (2) are aware of important moderators of treatment effectiveness, such as specific clinical subpopulations or particular clinical practices (e.g. detoxification appearing to be more effective than long-term maintenance) and (3) perceive significance to its use, including clinical, financial, administrative, and logistic factors. The survey is also designed to identify issues related to treatment availability and possible adverse public health consequences associated with the drug.

The estimated response burden over a period of one year is summarized below.

Respondents	Number of respondents	Responses per respondent	Hours per response	Total hour burden
All Physicians Who Have Submitted a Waiver	1,833	1	.42	770

Written comments and recommendations concerning the proposed information collection should be sent by August 16, 2004, to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-6974.

Dated: July 12, 2004.

Anna Marsh,

Executive Officer, SAMHSA.

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DEPARTMENT OF HOMELAND SECURITY

Environmental Planning Program

AGENCY: Department of Homeland Security.

ACTION: Reopening of comment period for Draft Environmental Directive.

SUMMARY: The Department of Homeland Security (DHS) is issuing this notice to advise the public that DHS is reopening the comment period for the draft directive containing policy and procedures for implementing the National Environmental Policy Act of 1969 (NEPA), as amended, Executive Order 11514, as amended, Executive Order 12114, and Council on Environmental Quality (CEQ) regulations for implementing the

procedural provisions of NEPA (40 CFR parts 1500-1508).

DATES: Comments and related material must be received by August 16, 2004.

ADDRESSES: Please submit your comments by only one of the following means:

(1) By mail to: Environmental Planning, Office of Safety and Environmental Programs, Management Directorate, Department of Homeland Security, Washington, DC 20528.

(2) By hand delivery to: Environmental Planning, Office of Safety and Environmental Programs, Management Directorate, Department of Homeland Security, Anacostia Naval Annex, Building 410, 245 Murray Lane, SW., Washington, DC 20528.

(3) By Fax to: 202-772-9749.

(4) By e-mail to: *ADMIN-SE@hq.dhs.gov*.