

or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

**DATES:** Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by May 14, 2012, for the vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by May 14, 2012.

**ADDRESSES:** All letters of interest and nominations should be submitted in writing to Bryan Emery (see: **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:** Bryan Emery, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike (HFM-71), Rockville, MD 20852-1448, 301-827-1277, Fax: 301-827-0294, email: [bryan.emery@fda.hhs.gov](mailto:bryan.emery@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Agency intends to add a nonvoting industry representative to the following advisory committee:

#### **I. Blood Products Advisory Committee for the Center for Biologics Evaluation and Research**

Members are selected by the Commissioner of Food and Drugs (the Commissioner) or designee from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions.

#### **II. Selection Procedure**

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry

interests for the committee. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

#### **III. Application Procedure**

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, a current curriculum vitae, and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the blood and blood products manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: April 9, 2012.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

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#### **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 (240) 276-1243.

##### **Project: Notification of Intent To Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction Under 21 U.S.C. 823(g)(2) (OMB No. 0930-0234)—Extension**

The Drug Addiction Treatment Act of 2000 ("DATA," Pub. L. 106-310) amended the Controlled Substances Act (21 U.S.C. 823(g)(2)) to permit practitioners (physicians) to seek and obtain waivers to prescribe certain approved narcotic treatment drugs for the treatment of opiate addiction. The legislation sets eligibility requirements and certification requirements as well as an interagency notification review process for physicians who seek waivers. The legislation was amended in 2005 to eliminate the patient limit for physicians in group practices, and in 2006, to permit certain physicians to treat up to 100 patients.

To implement these provisions, SAMHSA developed a notification form (SMA-167) that facilitates the submission and review of notifications. The form provides the information necessary to determine whether practitioners (*i.e.*, independent physicians) meet the qualifications for waivers set forth under the new law. Use of this form will enable physicians to know they have provided all information needed to determine whether practitioners are eligible for a waiver.

However, there is no prohibition on use of other means to provide requisite information. The Secretary will convey notification information and determinations to the Drug Enforcement Administration (DEA), which will assign an identification number to qualifying practitioners; this number will be included in the practitioner's registration under 21 U.S.C. 823(f).

Practitioners may use the form for three types of notification: (a) New, (b) immediate, and (c) to notify of their intent to treat up to 100 patients. Under "new" notifications, practitioners may make their initial waiver requests to SAMHSA. "Immediate" notifications inform SAMHSA and the Attorney General of a practitioner's intent to prescribe immediately to facilitate the treatment of an individual (one) patient under 21 U.S.C. 823(g)(2)(E)(ii). Finally, the form may be used by physicians with waivers to certify their need and intent to treat up to 100 patients.

The form collects data on the following items: Practitioner name; state medical license number and DEA registration number; address of primary location, telephone and fax numbers; email address; name and address of

group practice; group practice employer identification number; names and DEA registration numbers of group practitioners; purpose of notification new, immediate, or renewal; certification of qualifying criteria for treatment and management of opiate dependent patients; certification of capacity to refer patients for appropriate counseling and other appropriate ancillary services; certification of maximum patient load, certification to use only those drug products that meet

the criteria in the law. The form also notifies practitioners of Privacy Act considerations, and permits practitioners to expressly consent to disclose limited information to the SAMHSA Buprenorphine Physician Locator.

Since July 2002, SAMHSA has received over 25,000 notifications and has certified almost 27,000 physicians. Fifty-one percent of the notifications were submitted by mail or by facsimile, with approximately forty-one percent submitted through the Web based online

system. Approximately 60 percent of the certified physicians have consented to disclosure on the SAMHSA Buprenorphine Physician Locator.

Respondents may submit the form electronically, through a dedicated Web page that SAMHSA will establish for the purpose, as well as via U.S. mail.

There are no changes to the forms and burden hours.

The following table summarizes the estimated annual burden for the use of this form.

Purpose of submission	Number of respondents	Responses per respondent	Burden per response (hr.)	Total Burden (hrs.)
Initial Application for Waiver .....	1,500	1	.083	125
Notification to Prescribe Immediately .....	50	1	.083	4
Notice to Treat up to 100 patients .....	500	1	.040	20
Total .....	2,050	.....	.....	149

Written comments and recommendations concerning the proposed information collection should be sent by May 14, 2012, to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov). Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,  
Statistician.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning

opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

#### Proposed Project: Minority AIDS Initiative (MAI) Rapid HIV Testing Clinical Information Form (OMB No. 0930-0295)—Revision

This request is for a three-year generic clearance to continue rapid HIV testing data collection among 63 TCE-HIV Grantees and their clients and the additional 11 MAI-HIV Grantees and their clients. The primary purpose of the MAI Rapid HIV Testing Clinical Information Form is to use a standardized data collection instrument to fully capture essential clinical

information to enhance preventive services for those who test HIV-negative and refer to quality treatment/medical care those who test HIV-positive.

The aim of the project is to implement and increase rapid HIV testing among racial and ethnic minorities and collect rapid HIV testing data using the MAI Rapid HIV Testing Clinical Information Form. To meet this requirement, all Grantees must offer their clients rapid HIV preliminary antibody testing during outreach, pretreatment, or program enrollment. In addition, rapid HIV testing may be made available to the sexual and/or injection partners of clients. Grantees must provide onsite rapid HIV testing in accordance with their respective State and local requirements. If a client requests an off-site rapid HIV test, the Grantee must provide a referral to a rapid HIV testing site certified by the local health department.

Grantees are currently using the MAI Rapid HIV Testing Clinical Information Form in the field to systematically collect information from clients on demographics, previous rapid HIV test results, substance use and sexual risk behaviors, current rapid HIV test results, types of services received, and confirmatory HIV test result. Once a client is offered a rapid HIV test, the Grantee staff completes the MAI Rapid HIV Testing Clinical Information Form with the client present and then enters the data into a secure Web site that allows for real-time data submission.

The estimated annualized burden is summarized below.