

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320(a)(2)(ii). This is necessary to ensure compliance with an initiative of the Administration. We cannot reasonably comply with the normal clearance procedures because of an unanticipated event, as stated in 5 CFR 1320.13(a)(2)(iii).

The Centers for Medicare & Medicaid Services (CMS) is submitting an emergency information collection request for the approval of the information collection requirements associated with two new exceptions to section 1877 of the Social Security Act (the Act). The approval of this collection process is essential to protect the Medicare program and its beneficiaries against fraud and abuse. In addition, emergency approval is essential to permit members of the health care industry to immediately reap the benefits of this important regulation. Once the new exceptions are effective, entities that furnish certain designated health services to Medicare beneficiaries will be permitted to assist physicians with the implementation of electronic prescribing and electronic health records technology. The benefits of this technology include reducing medical errors, coordinating care, improving efficiency, and decreasing health care costs by eliminating unnecessary and/or duplicative diagnostic services.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Physician Self-Referral Exceptions for Electronic Prescribing and Electronic Health Records; *Use:* Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), directs the Secretary of the Department of Health and Human Services ("HHS") to create an exception to the physician self-referral prohibition in section 1877 of the Social Security Act (the Act) for certain arrangements in which a physician receives compensation in the form of items or services (not including cash or cash equivalents) ("nonmonetary remuneration") that is necessary and used solely to receive and transmit electronic prescription information. In

addition, using our separate legal authority under section 1877(b)(4) of the Act, this rule creates a separate regulatory exception for certain arrangements involving the provision of nonmonetary remuneration in the form of electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, and receive electronic health records.

The conditions for both exceptions require that arrangements for the items and services provided must be set forth in a written agreement, signed by the involved parties, specify the items or services being provided and the value of those items or services, and cover all of the electronic health records technology to be furnished by the entity. We have suggested that instead of one master contract that is updated with each new donation, the parties may choose to create a specific new contract and then reference other agreements or cross-reference a master list.

The requirements associated with these exceptions are limited to donations made to physicians by providers, members of integrated delivery systems, Federally Qualified Health Centers, or rural health clinics (for purposes of this Collection of Information Requirement, "Providers"); by group practices to their physician members, and by Prescription Drug Plan (PDPs) sponsors and Medicare Advantage (MA) organizations to prescribing physicians. The paperwork burden is the creation of the written contracts. The burden associated with the written agreement requirement is the time and effort necessary for documentation of the agreement between the parties, including signatures of the parties. *Form Number:* CMS-10207 (OMB#: 0938-NEW); *Frequency:* Recordkeeping and Reporting—On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 87,230; *Total Annual Responses:* 87,080; *Total Annual Hours:* 50,731.

CMS is requesting OMB review and approval of this collection by September 22, 2006, with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by September 18, 2006.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at <http://www.cms.hhs.gov/regulations/prra> or E-mail your request,

including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by September 18, 2006: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—B, Attn: William N. Parham, III, Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850 and, OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395-6974.

Dated: August 2, 2006.

**Michelle Shortt,**

*Director, Regulations Development Group,  
Office of Strategic Operations and Regulatory  
Affairs.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. 2006N-0219]**

#### **Antiviral Drugs Advisory Committee; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee:* Antiviral Drugs Advisory Committee.

*General Function of the Committee:*

To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on October 19, 2006, from 8 a.m. to 4 p.m. and on October 20, 2006, from 8 a.m. to 4 p.m.

*Addresses:* Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "2006N-0219—Clinical Trial Design Issues in the Development of Products for Treatment of Chronic Hepatitis C" and follow the prompts to

submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on October 5, 2006. All comments received will be posted without change, including any personal information provided. Comments received on or before October 5, 2006, will be provided to the committee before the meeting.

*Location:* Hilton Washington DC/ Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

*Contact Person:* Cicely Reese, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail:

[cicely.reese@fda.hhs.gov](mailto:cicely.reese@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512531. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* On both days, the committee will discuss clinical trial design issues in the development of products for treatment of chronic hepatitis C infection. This meeting is being convened in response to the growing number of products in development for this indication. The primary objectives for committee deliberations are to discuss issues relating to the identification of appropriate control arms, populations for study, endpoints, and long-term followup. On October 20, 2006, the meeting will be open to the public from 8 a.m. to 12 noon, unless public participation does not last that long; from 1 p.m. to 4 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information.

The background material will become available no later than 1 business day before the meeting and will be posted on FDA's Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2006 and scroll down to the Antiviral Drugs Advisory Committee meeting.)

*Procedure:* On October 19, 2006, from 8 a.m. to 4 p.m. and on October 20, 2006, from 8 a.m. to 12 noon, the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the Division of Dockets Management on or before October 5, 2006, as previously stated (see *Addresses*). Oral

presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on October 19, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and contact information of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 5, 2006.

*Closed Presentation of Data:* On October 20, 2006, from 1 p.m. to 4 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Cicely Reese at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 2, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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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: School Climate Survey for the National Cross-Site Evaluation of Safe School/Healthy Student (SS/HS) Initiative Grants—NEW

The SS/HS Initiative is a collaborative grant program supported by three Federal departments—the U.S. Departments of Health and Human Services, Education, and Justice. The program is authorized under the Elementary and Secondary Education Act of 1965, as amended, and the Higher Education Act of 1965, Title IV, part A, subpart 2 (National Programs), Section 4121 (Federal Activities).

This initiative, instituted by Congress following the murderous assaults at Columbine High School in Colorado, is designed to provide Local Educational Agencies (LEAs), including school districts and multi-district regional consortia, with three years of funding to simultaneously improve school safety, student access to mental health services, the reduction of violence and substance abuse, school relationships with the larger community, and early childhood preparation for learning. Collectively, Congress expects these changes to be reflected in improved school climate.

Local Education Agencies (LEAs) serve as the primary applicants for SS/HS grants, but the LEAs are required to establish formal partnerships with the local mental health system, the local law enforcement agency, and the local juvenile justice agency. Other partners often include public and private social services agencies, businesses, civic organizations, the faith community, and private citizens. As a result of these partnerships, comprehensive plans are developed, implemented, evaluated, and sustained with the goals of promoting the healthy development of children and youth, fostering their resilience in the face of adversity, and preventing violence.

From FY-1999 through FY-2004, grants of \$1 million to \$3 million annually for three years were awarded