

implementation, and ongoing maintenance necessary to keep an adverse event terminology updated and distributed to users. It recommends adopting VEDDRA (Veterinary Medicinal Dictionary for Drug Regulatory Authorities) as the controlled list of terminology for adverse event reports. Specific recommendations include an independent joint industry and government oversight board as well as a funding model that will allow use by all regulatory agencies and even the smallest companies in industry. The two background paragraphs provide insight into the deliberations, recommendations, and comments from the Expert Working Group charged by VICH to the VICH Steering Committee on this issue.

FDA and the VICH will consider comments about the draft guidance document. Ultimately, FDA intends to adopt the VICH Steering Committee's final guidance and publish it as a final guidance.

**III. Significance of Guidance**

This draft document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." Because guidance documents are not binding, unless specifically supported by statute or regulation, mandatory words such as "must," "shall," and "will" in the original VICH documents have been substituted with "should." Similarly, words such as "require" or "requirement" have been replaced by "recommendation" or "recommended" as appropriate to the context.

The draft guidance represents the agency's current thinking on developing a controlled list of terms for reporting an adverse event associated with the use of an approved new animal drug. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

**IV. Comments**

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may

submit written or electronic comments regarding this draft guidance document. Written or electronic comments should be submitted to the Dockets Management Branch (address above). Submit written or electronic comments by March 8, 2002, to ensure adequate consideration in preparation of the final guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**V. Electronic Access**

Electronic comments may be submitted on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select "02D-0005 Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms (VICH GL30)" and follow the directions.

Copies of the draft guidance entitled "Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms" (VICH GL30) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>. The draft guidance is also available at <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: January 30, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the

clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)-443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

**Proposed Project: Children's Hospitals Graduate Medical Education Payment Program (CHGME) (OMB No. 0915-0247): Revision**

The CHGME Payment Program was enacted by Public Law 106-129 to provide Federal support for graduate medical education (GME) to "freestanding" children's hospitals. This legislation attempts to provide support for GME comparable to the level of Medicare GME support received by other, non-children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. Direct payments are designed to offset the expenses associated with operating approved graduate medical residency training programs and indirect payments are designed to compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

Technical assistance workshops and consultation with applicant hospitals resulted in an opportunity for hospital representatives to raise issues and provide suggestions resulting in proposed revisions in the CHGME application forms and instructions.

Eligible children's teaching hospitals submit relevant data such as weighted and unweighted full-time equivalent (FTE) resident counts, inpatient discharges and case mix index information by which direct and indirect payments are made to the participating hospitals. Data are submitted by children's hospitals in an annual CHGME application in order to receive funding. Through a reconciliation process, participating hospitals are required to correct and furnish final FTE resident count numbers reflecting changes in counts reported in the annual application form. The reconciliation process begins with fiscal year (FY)2002 and occurs before the end of the fiscal year.

*The estimated burden is as follows:*

Form	Number of respondents	Responses per respondent	Hours per response	Total burden hours
HRSA 99-1 .....	60	1	24	1,440
HRSA 99-1 (Reconciliation) .....	60	1	8	480

Form	Number of respondents	Responses per respondent	Hours per response	Total burden hours
HRSA 99-2 .....	60	1	14	840
HRSA 99-4 .....	60	1	14	840
Total .....	60	.....	.....	3,600

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, 725 17th St., NW, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 30, 2002.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 02-2754 Filed 2-5-02; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of a Teleconference Call meeting of the Center for Substance Abuse Prevention (CSAP) National Advisory Council in February 2002.

The agenda of the open meeting will include an update of CSAP's budget, updates on strategic planning and restructuring, and administrative matters and announcement.

If anyone needs special accommodations and for persons with disabilities, please notify the contact listed below.

A summary of this meeting and roster of committee members may be obtained from Carol Watkins, Committee Management Specialist, Rockwall II Building, Suite 900, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-0365.

Substantive program information may be obtained from the contact listed below.

*Committee Name:* Center for Substance Abuse Prevention National Advisory Council.

*Meeting Date:* February 15, 2002, 12 noon-2 p.m.

*Place:* Center for Substance Abuse Prevention, 5515 Security Lane, 9th Floor, Conference Room I, Rockville, Maryland 20852.

*Contact:* Carol Watkins, 5515 Security Lane, Rockwall II Building, Suite 900, Rockville, Maryland 20852, Telephone: (301) 443-0365.

Dated: January 30, 2002.

**Toian Vaughn,**

*Executive Secretary, Committee Management Officer, Substance Abuse and Mental, Health Services Administration.*

[FR Doc. 02-2755 Filed 2-5-02; 8:45 am]

**BILLING CODE 4162-20-P**

## DEPARTMENT OF THE INTERIOR

### Office of Historical Trust Accounting; Historical Accounting of Individual Indian Money Accounts: Collection of Documents Related to Oil and Gas Production on Allotted Lands

**AGENCY:** Office of Historical Trust Accounting, Interior.

**ACTION:** Notice regarding records relating to indian allotted land and individual indian money accounts.

**SUMMARY:** Notice is hereby given that the Department of the Interior is requesting that anyone who possesses records related to the Individual Indian Money (IIM) trust funds to notify the Department, and to preserve and maintain such records indefinitely until further notice. If preferred, such records custodians should contact the Office of Historical Trust Accounting, 1951 Constitution Avenue, NW., MS 16 SIB, Washington, DC, 20240, so that arrangements can be made for the Department to take custody of such records. The purpose of this request is to ensure that such records are not destroyed so that they may be used to support an accounting of IIM trust funds. Generally, this request applies to entities that have or had business with the Department or individual Indians involving the payment of money for use of or access to Indian allotted lands, and would include entities in the oil and gas industry, the timber industry, farming and grazing operations, financial institutions, public utilities (e.g., gas, electric and telephone companies), Indian Tribes, other federal agencies, state and local government archives, and non-governmental depositories such as historical societies, and possibly

others. Relevant records would include any records which pertain to revenue generated on Indian allotted land from 1887 to the present, revenue generated due to Tribal judgment or per capita payments, and any other records which pertain to IIM trust institutions, public utilities (e.g., gas, electric and telephone companies), Indian Tribes, other federal agencies, state and local government archives, and non-governmental depositories such as historical societies, and possibly others. This request is pursuant to the Department's duty to account for trust funds held in IIM accounts.

#### FOR FURTHER INFORMATION CONTACT:

Stephen Swanson, Project Coordinator, Office of Historical Trust Accounting, 1951 Constitution Avenue, NW., MS 16 SIB, Washington, DC 20240, telephone 202/208-3405, or by facsimile at 202/219-1139.

#### SUPPLEMENTARY INFORMATION:

On December 21, 1999, the United States District Court for the District of Columbia declared that the Department must provide individual Indian Money (IIM) account holders "an accurate accounting of all money in the IIM trust held in trust for the benefit of [IIM account holders] without regard to when the funds were deposited." *Cobell v. Norton*, 92 F.Supp.2d, 1, 58 (D.D.C. 1999). This accounting will include, at an appropriate level of detail, an assessment of the accuracy of the balances in IIM accounts, reports to individual beneficiaries of the money and real property held in trust for their benefit, and reports to individual beneficiaries that contain sufficient information to allow beneficiaries to determine whether the trust has been faithfully performed. In furtherance of accomplishing the overall duty to account, the District Court held that the Department was in breach of a specific duty to have "written policies and procedures for collecting from outside sources missing information necessary to render an accounting of the IIM trust[.]" *Id.* On appeal, the Court of Appeals for the District of Columbia Circuit stated that written policies and procedures for the collection of such records are "necessary for the government to discharge its fiduciary