

## VII. Reporting Requirements

An annual financial status report (FSR) (SF-269) is required. The original and two copies of the report must be submitted to FDA's Grants Management Officer within 90 days of the budget period expiration date of the agreement. Failure to file an annual FSR in a timely fashion may be grounds for suspension or termination of the agreement.

An annual program progress report is also required. The noncompeting continuation application (PHS 2590) will be considered the annual program progress report.

A final program progress report, FSR and invention statement must be submitted within 90 days after expiration of the project period of the cooperative agreement.

## VIII. Review Procedures and Evaluation Criteria

### A. Review Procedures

The application submitted by IIT will first be reviewed by grants management and program staff for responsiveness. The requested budget must not exceed \$2,750,000 (direct and indirect costs) for the first year. The application will be considered nonresponsive if it is not in compliance with this document. If the application is found to be nonresponsive, it will be returned to the applicant without further consideration.

The application submitted by IIT will undergo noncompetitive dual peer review. The application will be reviewed for scientific and technical merit by an ad hoc panel of experts based upon the applicable evaluation criteria. If the application is recommended for approval, it will then be presented to the National Advisory Environmental Health Sciences Council for their concurrence.

### B. Review Criteria

The application will be reviewed and evaluated according to the following criteria:

1. The application clearly demonstrates an understanding of the purpose and objectives of the cooperative agreement regarding a collaborative food safety and security program.
2. The application clearly describes the steps and a proposed schedule for planning, implementing, and accomplishing the activities to be carried out under the cooperative agreement. The application presents a clear plan and schedule of steps to accomplish the goals of the cooperative agreement.
3. The application establishes the applicant's ability to perform the

responsibilities under the cooperative agreement including the availability of appropriate staff and sufficient funding.

4. The application specifies the manner in which interaction with FDA will be maintained throughout the life of the project.

5. The application specifies how IIT will monitor progress of the work under the cooperative agreement and how progress will be reported to FDA.

6. The application shall include a detailed budget that shows the following items: (1) Anticipated costs that are allowable and allocable to the project; and (2) the sources of funds to meet those needs.

## IX. Mechanism of Support

Support for this project will be in the form of a cooperative agreement. This agreement will be subject to all policies and requirements that govern the research grant programs of the PHS, including the provisions of 42 CFR part 52, 45 CFR part 74, and PHS grants policy statement. The regulations issued under Executive Order 12372 do not apply. The length of support will be 1 year. Cost sharing or matching is not a requirement of this program. The NIH modular grant program does not apply to this FDA program.

## X. Dun and Bradstreet Number Requirement

Beginning October 1, 2003, applicants will be required to have a Dun and Bradstreet Number (DUNS) to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, call 1-866-705-5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

## XI. Legend

Unless disclosure is required under the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: April 29, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-10266 Filed 5-5-04; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### Healthcare Integrity and Protection Data Bank: Change in Self-Query Fee

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Notice.

**SUMMARY:** The Department is authorized under 45 CFR part 61, the regulations implementing the Healthcare Integrity and Protection Data Bank (HIPDB), to assess a fee on all requests for information, except requests from Federal agencies. In accordance with the HIPDB regulations, we are announcing a two-dollar decrease in the fee to practitioners, providers, and suppliers who request information about themselves (self-query) from the HIPDB. The new fee to self-query the HIPDB will be \$8.00. There will be no change to the \$4.25 charged for each query submitted by authorized entities to access the data bank.

**EFFECTIVE DATE:** The fee is effective on July 1, 2004.

**FOR FURTHER INFORMATION CONTACT:** Joel Schaer, Office of Management and Policy, (202) 619-0089.

### SUPPLEMENTARY INFORMATION:

#### User Fee Amount

Section 1128E(d)(2) of the Social Security Act (the Act), as added by section 221(a) of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, specifically authorizes the establishment of fees for the costs of processing requests for disclosure and for providing information from the Healthcare Integrity and Protection Data Bank (HIPDB). Final regulations at 45 CFR part 61 set forth the criteria and procedures for information to be reported to and disclosed by the HIPDB. The Act also requires that the Department recover the full costs of operating the HIPDB through such user fees. In determining any changes in the amount of the user fee, the Department employs the criteria set forth in § 61.13(b) of the HIPDB regulations.

Specifically, § 61.13(b) states that the amount of each fee will be determined based on the following criteria:

- Direct and indirect personnel costs;

- Physical overhead, consulting, and other indirect costs including rent and depreciation on land, buildings and equipment;
  - Agency management and supervisory costs;
  - Costs of enforcement, research and establishment of regulations and guidance;
  - Use of electronic data processing equipment to collect and maintain information, *i.e.*, the actual cost of the service, including computer search time, runs and printouts; and
  - Any other direct or indirect costs related to the provision of services.
- The current fee structure of \$10.00 for each self-query by a practitioner,

provider, or supplier was announced in a **Federal Register** notice on March 3, 2000 (65 FR 11589). Based on the above criteria and our analysis of operational costs and the comparative costs of the various methods for filing and paying for queries, the Department is now lowering the self-query fee by two dollars—from \$10.00 to \$8.00.

When an authorized self-query is submitted for information by a practitioner, provider, or supplier, the appropriate total fee will be \$8.00 multiplied by the number of individuals or organizations about whom the information is being requested.

In order to minimize administrative costs, the Department will continue to accept payment for self-queries only by credit card. The HIPDB accepts Visa, MasterCard, and Discover. To submit queries, practitioners, providers, and suppliers must use the HIPDB Web site at <http://www.npdb-hipdb.com>.

The Department will continue to review user fees periodically for the HIPDB, and will revise such fees as necessary. Any future changes in fees and their effective date will be announced through notice in the **Federal Register**.

**Examples**

| Query method     | Fee per name in query, by method of payment | Examples                                   |
|------------------|---|--|
| Self-query ..... | \$8.00                                      | 10 self-queries:<br>10 × \$8.00 = \$80.00. |

Dated: April 12, 2004.  
**Dara Corrigan**,  
*Acting Principal Deputy Inspector General*.  
 [FR Doc. 04-10330 Filed 5-5-04; 8:45 am]  
 BILLING CODE 4152-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society**

Pursuant to Public Law 92-463, notice is hereby given of the fourth meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to 5 p.m. on June 14, 2004, and 8 a.m. to 3 p.m. on June 15, 2004, at the Marriott Hotel Bethesda at 5151 Pooks Hill Road, Bethesda, Maryland. The meeting will be webcast. The meeting will be open to the public with attendance limited to space available.

The first half of the first day will be devoted to an informational update on the status of genetic nondiscrimination legislation and presentation and discussion of an information gathering activity conducted by the Committee's education task force. In addition, the Committee will be reviewing a draft resolution on genetics education and training. The second half of the first day will consist of discussion and deliberation on a draft report on the

issue of coverage and reimbursement for genetic technologies. The second day will be devoted to discussions around a draft resolution on the issue of direct-to-consumer marketing and consideration of a draft Vision Report. Time will be provided each day for public comment.

Under authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic technologies and, as warranted, to provide advice on these issues.

The draft meeting agenda and other information about SACGHS, including information about access to the webcast, will be available at the following Web site: <http://www4.od.nih.gov/oba/sacghs.htm>. Individuals who wish to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301-496-9838 or e-mail at [sc112c@nih.gov](mailto:sc112c@nih.gov). The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892.

Dated: April 29, 2004.  
**LaVerne Stringfield**,  
*Director, Office of Federal Advisory Committee Policy*.  
 [FR Doc. 04-10321 Filed 5-5-04; 8:45 am]  
 BILLING CODE 4140-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society**

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