EFFECTIVE DATE: This increase will be effective on October 1, 2001.

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 such information, and the 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 requires that the Department recover the full costs of operating the HIPDB through user fees. In determining any changes in the amount of the user fee, the Department is employing 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 $4 for each separate query submitted by authorized entities was announced in a **Federal Register** notice on March 3, 2000 (65 FR 11589). Based on the above criteria and our analysis of the comparative costs of the various methods for filing and paying for queries, the Department is now increasing the fee for each query submitted by authorized entities by one dollar—from $4 to $5.[1]

When an authorized entity query is submitted for information on one or more health care practitioners, providers or suppliers, the appropriate total fee will be $5 multiplied by the number of individuals or organizations about whom information is being requested.

In order to minimize administrative costs, the Department will accept queries submitted by authorized entities by credit card or electronic funds transfer. The Department will continue to accept payment for self-queries only by credit card. The HIPDB accepts Visa, MasterCard, and Discover. To submit queries, registered entities (including law enforcement agencies) must use the HIPDB web site at www.npdb-hipdb.com.

The Department will continue to review the user fee periodically, and will revise it as necessary. Any future changes in the fee and its effective date will be announced through notice in the **Federal Register**.

Examples

Query method	Fee per name in query, by method of payment	Examples
Authorized Entity query	$5.00	10 names in query: 10 × $5 = $50.00.
Self-query	$10.00	10 self-queries 10 × 10 = $100.

Dated: May 31, 2001.

Michael F. Mangano,

Acting Inspector General.

[FR Doc. 01–14599 Filed 6–8–01; 8:45 am]

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[1] As part of its obligations under the Privacy Act, the Department previously announced a $10 fee for health care practitioners, providers or suppliers to self-query (64 FR 58851; November 1, 1999).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Solicitation of Information and Recommendations for Developing a Compliance Program Guidance for the Pharmaceutical Industry

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

ACTION: Notice.

SUMMARY: This **Federal Register** notice seeks the input and recommendations of interested parties as the OIG develops a compliance program guidance for the pharmaceutical industry, especially those segments of the industry related to manufacturing, marketing or providing goods or services to Medicare, Medicaid and other Federal health care program beneficiaries. The pharmaceutical industry has experienced a number of instances of fraud and abuse and has expressed interest in increasing the awareness of the industry to assist in protecting against such conduct. In response to the industry's concerns, the OIG has written Advisory Opinions on a variety of industry-related issues and, in 1994, published a Special Fraud Alert relating to Prescription Drug Marketing Schemes.[1] Also, in the early 1990s, the OIG's Office of Evaluation and Inspections issued reports relating to prescription drug promotional practices.[2]

In an effort to provide further guidance, the OIG is soliciting comments, recommendations and other suggestions from concerned parties and organizations on how best to develop a compliance program guidance for the pharmaceutical industry to reduce the potential for fraud and abuse.

DATES: To assure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on August 10, 2001.

ADDRESSES: Please mail or deliver your written comments, recommendations and suggestions to the following address:Department of Health and Human Services,Office of Inspector General,Attention: OIG–8–CPG,Room 5527 A, Cohen Building,330 Independence Avenue, SW.,Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to the file code OIG–8–CPG. Timely-filed comments will be available for public inspection as they are received, generally beginning approximately 3 weeks after receipt of a document, in Room 5541 of the Office of Inspector General at 330 Independence Avenue, S.W., Washington, D.C. 20201 on Monday

[1] The Advisory Opinions and the Special Fraud Alert can be found on the OIG web site at *http://www.hhs.gov/oig.*

[2] The reports issued by the Office of Evaluation and Inspections also can be found on the OIG web site.

through Friday of each week from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Mary E. Riordan or Nicole C. Hall, Office of Counsel to the Inspector General, (202) 619–2078.

SUPPLEMENTARY INFORMATION: The development of compliance program guidances has become a major initiative of the OIG in its effort to engage the private health care industry in addressing and combating fraud and abuse. Over the past several years, the OIG has developed and issued compliance program guidances directed at various segments of the health care industry.[3] These guidances are designed to provide clear direction and assistance to specific sections of the health care industry that are interested in reducing and eliminating fraud and abuse within their organizations.

The guidances have represented the culmination of the OIG's suggestions on how providers can most effectively establish internal controls and implement monitoring procedures to identify, correct and prevent fraudulent or wasteful activities. The suggestions contained in the guidances are not mandatory for providers, nor do they represent an exclusive discussion of the advisable elements of a compliance program.

The compliance program guidance for the pharmaceutical industry will be designed to reach segments of the health care industry which have not been covered by previous guidances, but which have recently been the subject of increasing scrutiny, such as pharmaceutical manufacturers and retail pharmacy chains. As the public debate about prescription drug costs and a potential expansion of the Medicare drug benefit continues, this scrutiny is likely to intensify.

Through this **Federal Register** notice, the OIG is seeking input from interested parties as the OIG considers developing a compliance program guidance directed at the pharmaceutical industry. The OIG will consider all comments, recommendations and suggestions received within the time frame indicated above.

We anticipate that the guidance for the pharmaceutical industry will contain the seven elements that we consider necessary for a comprehensive compliance program. These seven elements have been discussed in our previous guidances and include:

- The development of written policies and procedures;
- The designation of a compliance officer and other appropriate bodies;
- The development and implementation of effective training and education programs;
- The development and maintenance of effective lines of communication;
- The enforcement of standards through well-publicized disciplinary guidelines;
- The use of audits and other evaluation techniques to monitor compliance; and
- The development of procedures to respond to detected offenses and initiate corrective action.

The OIG would appreciate specific comments, recommendations and suggestions on (1) risk areas for the pharmaceutical industry, and (2) aspects of the seven elements contained in the previous guidances that may need to be modified to reflect the unique characteristics of the pharmaceutical industry. Detailed justifications and empirical data supporting any suggestions would be appreciated.

We request that any comments, recommendations and suggestions be submitted in a format that addresses the topics outlined above in a concise manner, rather than in the form of a comprehensive draft guidance that mirrors previous guidances.

Dated: May 31, 2001.

Michael F. Mangano,

Acting Inspector General,

[FR Doc. 01–14598 Filed 6–8–01; 8:45 am]

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[3] The OIG has issued compliance program guidance for the following nine industry sectors: hospitals, clinical laboratories, home health agencies, durable medical equipment suppliers, third-party medical billing companies, hospices, Medicare+Choice organizations offering coordinated care plans, nursing facilities, and individual and small group physician practices. The compliance program guidances for these industry sectors can be found on the OIG web site at *http://www.hhs.gov/oig* or by calling the OIG Public Affairs office at (202) 619–1343.

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Intent To Prepare a Comprehensive Conservation Plan

AGENCY: U.S. Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of intent to prepare a Comprehensive Conservation Plan and Associated National Environmental Policy Act Document for the Sacramento River National Wildlife Refuge, Butte, Glenn, and Tehama Counties, California.

SUMMARY: The U.S. Fish and Wildlife Service (Service) is preparing a Comprehensive Conservation Plan (CCP) and National Environmental Policy Act (NEPA) document for Sacramento River National Wildlife Refuge (NWR). This notice advises the public that the Service intends to gather information necessary to prepare a CCP and environmental documents pursuant to the National Wildlife Refuge System Administration Act of 1966, as amended, and NEPA. The public is invited to participate in the planning process. The Service is furnishing this notice in compliance with the Service CCP policy:

1. To advise other agencies and the public of our intentions, and
2. To obtain suggestions and information on the scope of issues to include in the environmental documents.
3. To announce a series of public open houses to occur in May and June 2001. Information about the time and location of the open house is available by contacting the Refuge.

DATES: To ensure that the Service has adequate time to evaluate and incorporate suggestions and other input into the planning process, comments should be received on or before July 11, 2001.

ADDRESSES: Send written comments or requests to be added to the mailing list to the following address: Planning Team Leader—Sacramento River NWR, California / Nevada Refuge Planning Office, U.S. Fish and Wildlife Service, 2800 Cottage Way, W–1916, Sacramento, California, 95825.

FOR FURTHER INFORMATION CONTACT: Mr. Miki Fujitsubo, Planning Team Leader, (916) 414–6507.

History and Background

The Refuge was established in 1989 by the authority provided under the Endangered Species Act of 1973 and the Emergency Wetlands Resources Act of 1986, using monies made available through the Land and Water Conservation Fund Act of 1965. The Service proposed acquisition of 18,000 acres of land for establishment of the multi-unit Sacramento River NWR. The multiple units of the refuge are located along both banks of the Sacramento River between Red Bluff and Princeton in Glenn, Butte, and Tehama Counties, California. A combination of fee title and conservation easement acquisitions was used to protect this habitat.

Riparian habitat along the Sacramento River has been identified as critically important for various threatened and endangered species, fish, migratory birds, plants, and to the natural ecosystem of the River itself. There has been an 89 percent reduction of riparian vegetation throughout the Sacramento