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 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

<table>
<thead>
<tr>
<th>Query method</th>
<th>Fee per name in query, by method of payment</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorized Entity query</td>
<td>$5.00</td>
<td>10 names in query: 10 × $5 = $50.00.</td>
</tr>
<tr>
<td>Self-query</td>
<td>$10.00</td>
<td>10 self-queries 10 × 10 = $100.</td>
</tr>
</tbody>
</table>


Michael F. Mangano,
Acting Inspector General.

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

BILLING CODE 4152–01–U

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. ² Also, in the early 1990s, the OIG’s Office of Evaluation and Inspections issued reports relating to prescription drug promotional practices.³

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, May 31, 2001.

¹As 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).

²The Advisory Opinions and the Special Fraud Alert can be found on the OIG web site at http://www.hhs.gov/oig.

³The 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. 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.


Michael F. Mangano,
Acting Inspector General,
[FR Doc. 01–14598 Filed 6–8–01; 8:45 am]
BILLING CODE 4152–01–U

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,

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
dangered 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

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.