

associated with participation in the program. Finally, Part I.L. generally prohibits the company from misrepresenting the price of any weight loss program.

#### *Health Risks Claims*

According to the complaint, Jenny Craig provides its customers with diet protocols that require the customers to come into one of proposed respondents' centers once a week for monitoring of their progress, including weighing in. In the course of regularly ascertaining weight loss progress, respondents, in some instances, have been presented with weight loss results indicating that customers are losing weight significantly in excess of their projected goals, which is an indication that they may not be consuming all of the food prescribed by their diet protocol. According to the complaint, such conduct could, if not corrected promptly, result in health complications. The Commission's complaint alleges that Jenny Craig failed to disclose to consumers who were losing weight significantly in excess of their projected goals that failing to follow the diet protocol and consume all of the food prescribed could result in health complications.

The proposed consent order seeks to address this allegation in two ways. First, the proposed order, in Part I.K., requires Jenny Craig to disclose in writing to all participants, when they enter the program, that failure to follow the program protocol and eat all of the food recommended may involve the risk of developing serious health complications. Second, the proposed order, in Part I.L., generally prohibits any misrepresentation concerning the safety of any weight loss program.

#### *Customer Satisfaction Claims*

The complaint also alleges that Jenny Craig deceptively advertised that "nine out of ten" Jenny Craig clients would recommend Jenny Craig to their friends. The complaint further alleges that the company's claim that competent and reliable studies or surveys substantiate the "nine out of ten" claim was false.

The proposed order seeks to address these claims in two ways. First, Part I.M. would require respondents to possess competent and reliable evidence (which when appropriate must be competent and reliable scientific evidence) for any representation that participants on any weight loss program recommend or endorse the program. Second, Part I.N. would prevent respondents from misrepresenting the existence, contents, validity, results, conclusions, or

interpretations of any test, study, or survey.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order, or to modify in any way their terms.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 97-14678 Filed 6-4-97; 8:45 am]

BILLING CODE 6750-01-M

### GENERAL ACCOUNTING OFFICE

#### **Federal Accounting Standards Advisory Board; Meeting**

**AGENCY:** General Accounting Office.

**ACTION:** Notice of meeting.

**SUMMARY:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. No. 92-463), as amended, notice is hereby given that the Federal Accounting Standards Advisory Board will meet on Thursday, June 3, 1997, from 9:00 A.M. to 4:00 P.M. in the Elmer Staats Briefing Room, room 7C13 of the General Accounting Office building, 441 G St., NW., Washington, DC.

The purpose of the meeting is to discuss the following issues: (1) Proposed amendments to the Property, Plant, and Equipment standard, (2) comments on the Management's Discussion and Analysis (MD&A) document, and (3) pensions.

Any interested persons may attend the meeting as an observer. Board discussions and reviews are open to the public.

#### **FOR FURTHER INFORMATION CONTACT:**

Wendy Comes, Executive Director, 441 G St., NW., Room 3B18, Washington, DC 20548, or call (202) 512-7350.

**Authority:** Federal Advisory Committee Act. Pub. L. No. 92-463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101-6.1015 (1990).

Dated: June 2, 1997.

**Wendy M. Comes,**

*Executive Director.*

[FR Doc. 97-14724 Filed 6-4-97; 8:45 am]

BILLING CODE 1610-01-M

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **Notice of Meetings of the National Bioethics Advisory Commission (NBAC); Correction**

The Notice published on March 24, 1997, at 62 FR 13887, is corrected as follows:

The date and times for the meeting to be held on June 7, 1997, are corrected to read:

**DATES:** Saturday, June 7, 1997: full Commission Meeting, 7:30 a.m.-11:30 a.m.; Human Subjects Subcommittee, 1:00 p.m.-5:00 p.m.; and Genetics Subcommittee, 1:00 p.m.-4:00 p.m.

**FOR FURTHER INFORMATION CONTACT:** Ms. Henrietta Hyatt-Knorr, National Bioethics Advisory Commission, MSC-7508, 6100 Executive Boulevard, Suite 3C01, Rockville, Maryland 20892-7508, telephone 301-402-4242, fax number 301-480-6900.

Dated May 27, 1997.

**Henrietta Hyatt-Knorr,**

*Acting Deputy Director, National Bioethics Advisory Commission.*

[FR Doc. 97-14208 Filed 6-4-97; 8:45 am]

BILLING CODE 4160-17-P

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **Office of Inspector General**

#### **Statement of Organization, Functions and Delegations of Authority**

This Notice amends Part A (Office of the Secretary) of the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (HHS) to reflect recent changes in Chapter AF, Office of Inspector General (OIG). Chapter AF was last published in its entirety on May 13, 1996 (61 FR 22059).

The statement of organization, functions and delegations of authority reflects the original transfer of the statutory basis for the Office of Inspector General from Public Law 94-505 to Public Law 95-452 (and made under the Inspector General Act Amendments of 1988, Public Law 100-504), and conforms to and carries out the statutory requirements for operating the Office of Inspector General. A number of revisions have been made to reflect the consolidation of the Inspector General Division of the Office of the General Counsel and the Office of Litigation Coordination into the new Office of Counsel to the Inspector General (OCIG), and the incorporation of OCIG into the OIG organizational structure. In addition, several technical changes have been made to reflect revised component functions and duties in accordance with new or amended authorities and responsibilities resulting from the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). These organizational changes have been made in an effort to assist the

Office of Inspector General in accomplishing its mission with greater efficiency and effectiveness.

As amended, Chapter AF now reads as follows

*Section AF.00, Office of Inspector General (OIG)—Mission.* This organization was established by law as an independent and objective oversight unit of the Department to carry out the mission of promoting economy, efficiency and effectiveness through the elimination of waste, abuse and fraud. In furtherance of this mission, the organization engages in a number of activities:

A. Conducting and supervising audits, investigations, inspections and evaluations relating to HHS programs and operations.

B. Identifying systemic weaknesses giving rise to opportunities for fraud and abuse in HHS programs and operations and making recommendations to prevent their recurrence.

C. Leading and coordinating activities to prevent and detect fraud and abuse in HHS programs and operations.

D. Detecting wrongdoers and abusers of HHS programs and beneficiaries so appropriate remedies may be brought to bear.

E. Keeping the Secretary and the Congress fully and currently informed about problems and deficiencies in the administration of such programs and operations and about the need for and progress of corrective action, including imposing sanctions against providers of health care under Medicare and Medicaid who commit certain prohibited acts.

In support of its mission, the Office of Inspector General carries out and maintains an internal quality assurance system and a peer review system with other Offices of Inspectors General, that include periodic quality assessment studies and quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards and other requirements are followed; are effective; and are functioning as intended in OIG operations.

*Section AF.10, Office of Inspector General—Organization.* There is at the head of the OIG a statutory Inspector General, appointed by the President and confirmed by the Senate. The Office of Inspector General consists of seven organizational units:

A. Immediate Office of the Inspector General (AFA).

B. Office of Management and Policy (AFC).

C. Office of Evaluation and Inspections (AFE).

D. Office of Enforcement and Compliance (AFF).

E. Office of Counsel to the Inspector General (AFG).

F. Office of Audit Services (AFH).

G. Office of Investigations (AFI).

*Section AF.20, Office of Inspector General—Functions.* The component sections which follow describe the specific functions of the organization.

*Section AFA.00, Immediate Office of the Inspector General (IOIG)—Mission.* The Inspector General is directly responsible for meeting the statutory mission of the OIG as a whole and for promoting effective OIG internal quality assurance systems, including quality assessment studies and quality control reviews of OIG processes and products. The Office of Inspector General also plans, conducts and participates in a variety of inter-agency cooperative projects and undertakings relating to fraud and abuse activities with the Department of Justice (DoJ), the Health Care Financing Administration (HCFA) and other governmental agencies.

*Section AFA.10, Immediate Office of the Inspector General—Organization.* The Immediate Office is comprised of the Inspector General, the Principal Deputy Inspector General, and an immediate staff.

*Section AFA.20, Immediate Office of the Inspector General—Functions.* As the senior official of the organization, the Inspector General supervises the Chief Counsel to the Inspector General and the Deputy Inspectors General who head the major OIG components. The Inspector General is appointed by the President, with the advice and consent of the Senate, and reports to and is under the general supervision of the Secretary or, to the extent such authority is delegated, the Deputy Secretary, but does not report to and is not subject to supervision by any other officer in the Department. In keeping with the independence intended in the statutory basis for the OIG and its mission, the Inspector General assumes and exercises, through line management, all functional authorities related to the administration and management of the OIG and all mission related authorities stated or implied in the law or delegated directly from the Secretary.

The Inspector General provides executive leadership to the organization and exercises general supervision over the personnel and functions of its major components. The Inspector General determines the budget needs of the OIG, sets OIG policies and priorities, oversees OIG operations and provides reports to the Secretary and the Congress. In this capacity the Inspector General is

empowered under the law with general personnel authority, e.g., selection, promotion, assignment of employees, including members of the senior executive service. The Inspector General delegates related authorities as appropriate.

The Principal Deputy Inspector General assists the Inspector General in the management of the OIG, and during the absence of the Inspector General, acts as the Inspector General.

*Section AFC.00, Office of Management and Policy (OMP)—Mission.* This office is responsible for the reporting and legislative and regulatory review functions required in the law; for formulating and executing the OIG budget; for managing external affairs; and for establishing functional policies for the general management of the OIG. In support of its mission, the office carries out and maintains an internal quality assurance system. The system includes quality assessment studies and quality control reviews of OMP processes and products to ensure that policies and procedures are followed effectively and function as intended.

*Section AFC.10, Office of Management and Policy—Organization.* This office is directed by the Deputy Inspector General for Management and Policy, and comprises the Deputy Inspector General for OMP and an immediate staff.

*Section AFC.20, Office of Management and Policy—Functions.* Through the Deputy Inspector General for Management and Policy:

A. The office conducts and coordinates OIG reviews of existing and proposed legislation and regulations related to HHS programs and operations to identify their impact on economy and efficiency and their potential for fraud and abuse. It serves as contact for the press and electronic media and serves as OIG congressional liaison. The office prepares or coordinates congressional testimony and confers with officials in the Office of the Secretary staff divisions on congressional relations, legislation and public affairs. It develops and publishes OIG newsletters, recruitment brochures and other issuances to announce and promote OIG activities and accomplishments.

B. The office coordinates the development of the OIG long-range strategic plan. It compiles the Semiannual and other legislatively-mandated reports to the Congress and operates the Executive Secretariat. It formulates and oversees the execution of the OIG budget and confers with the Office of the Secretary, the Office of Management and Budget and the

Congress on budget issues. It issues quarterly grants to States for Medicaid fraud control units. It conducts management studies and analyses and establishes and coordinates general management policies for the OIG and publishes those policies in the OIG Administrative Manual. It serves as OIG liaison to the Office of the Secretary for personnel issues and other administrative policies and practices, and on equal employment opportunity and other civil rights matters. It coordinates internal control reviews for the OIG.

C. The office is responsible for OIG information resources management (IRM), as defined by the Paperwork Reduction Act, OMB Circular A-130, the Federal Information Resources Management regulations, the Computer Security Act of 1987, HHS IRM Circulars, and by related guidance. The office also provides information technology support to the OIG through management of its local area networks nationwide, provision of headquarters computer end-user support, and support of OIG information systems as required. Through this office, the Deputy Inspector General for Management and Policy serves as the OIG Chief Information Officer.

*Section AFE.00, Office of Evaluation and Inspections (OEI)—Mission.* The Office of Evaluation and Inspections is responsible for conducting inspections of HHS programs, operations and processes to identify vulnerabilities, to prevent and detect fraud, waste and abuse, and to promote economy, efficiency and effectiveness in HHS programs and operations.

*Section AFE.10, Office of Evaluation and Inspections—Organization.* This office is directed by the Deputy Inspector General for Evaluation and Inspections, and comprises the Immediate Office, including the Deputy Inspector General for OEI and an immediate staff, and eight regional offices.

*Section AFE.20, Office of Evaluation and Inspections—Functions.* The office is responsible for carrying out inspections supporting the OIG mission. The Deputy Inspector General provides general supervision to the OEI immediate office staff and supervises the Regional Inspectors General for Evaluation and Inspections who carry out OEI's mission and activities in assigned geographic areas. The Immediate Office carries out OEI's mission in headquarters.

A. The immediate office develops OEI's evaluation and inspections policies, procedures and standards. It manages OEI's human and financial

resources. It develops and monitors OEI's management information systems. It conducts management reviews within the HHS/OIG and for other OIG's upon request. The office carries out and maintains an internal quality assurance system. The system includes quality assessment studies and quality control reviews of OEI processes and products to ensure that policies and procedures are effective; are followed; and are functioning as intended.

B. The immediate office manages OEI's work planning process, and develops and reviews legislative, regulatory and program proposals to reduce vulnerabilities to fraud, waste and mismanagement. It develops evaluation techniques and coordinates projects with other OIG and departmental components. It provides programmatic expertise and information on new programs, procedures, regulations and statutes to OEI regional offices. It maintains liaison with other components in the Department, follows up on implementation of corrective action recommendations, evaluates the actions taken to resolve problems and vulnerabilities identified, and provides additional data or corrective action options, where appropriate.

C. The immediate office provides statistical and data base advice and services for inspections conducted by the regional offices. It carries out analyses of large data bases to identify potential areas of fraud and abuse, and provides technical assistance to the regional offices for these purposes. It operates a toll-free hotline for the OIG to permit individuals to call in suspected fraud or waste, refers the calls for appropriate action by HHS agencies or other OIG components, and analyzes the body of calls to identify trends and patterns of fraud and abuse needing attention.

D. The regional offices carry out OEI's mission in the field. The regional offices evaluate HHS programs and produce the results in inspection reports. They conduct data and trend analyses of major HHS initiatives to determine the effects of current policies and practices on program efficiency and effectiveness. They recommend changes in program policies, regulations and laws to improve efficiency and effectiveness, and to prevent fraud, abuse, waste and mismanagement. They analyze existing policies to evaluate options for future policy, regulatory and legislative improvements.

*Section AFF.00, Office of Enforcement and Compliance (OEC)—Mission.* The Office of Enforcement and Compliance is responsible for the imposition of those mandatory and permissive

program exclusions and civil money penalty (CMP) and assessment actions not handled by the Office of Counsel to the Inspector General (OCIG), Civil Recoveries Branch. The office serves as a liaison with HCFA, State licensing boards and other outside organizations and entities with regard to exclusion, compliance and enforcement activities. It develops models for corporate integrity, compliance and enforcement programs; monitors ongoing compliance, exclusion, enforcement activities and HCFA suspension agreements; and promotes industry awareness of corporate integrity and enforcement agreements developed by the OIG.

*Section AFF.10, Office of Enforcement and Compliance—Organization.* This office is directed by the Deputy Inspector General for Enforcement and Compliance, and comprises the Deputy Inspector General for OEC and an immediate staff.

*Section AFF.20, Office of Enforcement and Compliance—Functions.* Through the Deputy Inspector General for Enforcement and Compliance:

A. The office develops, coordinates and effectuates all health care mandatory and permissive exclusions, with the exception of those handled by the OCIG, Civil Recoveries Branch. The office develops standards governing the imposition of the mandatory and permissive exclusion authorities within the scope of its responsibility, and develops criteria for evaluating when it will impose such permissive exclusions against health care providers. It reviews all applications for readmission to program participation for purposes of determining whether an excluded provider has demonstrated the ability to comply with program requirements; and ensures enforcement of exclusions imposed through liaison with HCFA, DoJ and other governmental and private sector entities. The office coordinates with the Public Health Service to effectuate repayment agreements with those excluded individuals who have defaulted on HEAL loans.

B. The office is responsible for developing, improving and maintaining a comprehensive and coordinated OIG data base on all OIG exclusion actions, and promptly and accurately reports all exclusion actions within its authority to the data base. It informs appropriate regulatory agencies, health care providers and the general public of all OIG exclusion actions, and is responsible for improving public access to information on these exclusion actions to ensure that excluded individuals and entities are effectively barred from program participation.

C. The office imposes CMPs and other assessments in accordance with the CMP law on those cases not handled by the OCIG, Civil Recoveries Branch, and ensures that all monetary recoveries are promptly and accurately reported to the appropriate OIG data base.

D. The office monitors corporate and provider compliance plans adopted as part of settlement agreements, and develops audit and investigative review standards for monitoring such plans in cooperation and coordination with other OIG components. It resolves breaches of compliance plans through the development of corrective action plans, on-site reviews, and when appropriate, refers material breaches of compliance plans to the OCIG, Civil Recoveries Branch for potential sanctioning.

E. The office serves to increase industry awareness of corporate compliance issues by proactively promoting voluntary adoption of corporate compliance plans through speeches, articles, visits and other liaison activities with governmental and private sector groups, as well as developing model or best practice recommendations to be utilized by the health care industry.

F. The office represents the OIG in coordinating all CMP actions initiated by other Federal health care programs that are authorized to prosecute health care providers. The office provides guidance and monitors all actions in this area until completion of these actions.

*Section AFG.00, Office of Counsel to the Inspector General (OCIG)—Mission.* The Office of Counsel to the Inspector General (OCIG) is responsible for providing all legal services and advice to the Inspector General, Principal Deputy Inspector General and all the subordinate components of the Office of Inspector General, in connection with OIG operations and administration, OIG fraud and abuse enforcement activities, and OIG activities designed to promote efficiency and economy in the Department's programs and operations. The OCIG is also responsible for litigating civil money penalty (CMP) and program exclusion cases within the jurisdiction of the OIG, for the coordination and disposition of False Claims Act *qui tam* and criminal, civil and administrative matters involving the Department of Justice (DoJ), and for the resolution of voluntary disclosure and program compliance activities.

*Section AFG.10, Office of Counsel to the Inspector General—Organization.* The office is directed by the Chief Counsel to the Inspector General, and the Assistant Inspector General for Legal

Affairs. The office is comprised of the following components:

- A. Advice.
- B. Civil Recoveries.
- C. Administrative Litigation.
- D. Industry Guidance.

*Section AFG.20, Office of Counsel to the Inspector General—Functions.* A. *Advice.* This office provides legal advice to the various components of the OIG on legal issues that arise in the exercise of the OIG's responsibilities under the Inspector General Act of 1978. Such issues include the scope and exercise of the Inspector General's authorities and responsibilities; investigative techniques and procedures (including criminal procedure); the sufficiency and impact of legislative proposals affecting the OIG; and the conduct and resolution of investigations, audits and inspections. The office evaluates the legal sufficiency of OIG recommendations and develops formal legal opinions, in coordination with the HHS Office of the General Counsel, to support those recommendations. The office provides legal advice on OIG internal administration and operations, including appropriations, delegations of authority, ethics, OIG regulations, personnel matters, the disclosure of information under the Freedom of Information Act and the safeguarding of information under the Privacy Act. The office is responsible for conducting and coordinating litigation activities on personnel and Equal Employment Opportunity matters and Federal tort actions involving OIG employees. The office is responsible for the clearance and enforcement of subpoenas issued by the OIG, and defends the OIG in litigation matters as necessary.

B. *Civil Recoveries.* This office oversees all False Claims Act cases, including *qui tam* cases, and handles final sign-off on False Claims Act settlements for the Department. It coordinates DOJ resource requests, participates in settlement negotiations and provides litigation support. It coordinates the Department's response to all settlement proposals in cases involving DOJ, including the amount of restitution and resolution of the selected CMP and program exclusion liability. Where necessary, the office litigates appeals of program exclusions imposed in such cases before the Department Appeals Board (DAB) and assists DOJ in handling any subsequent appeals of such cases to the Federal courts. The office coordinates and resolves all voluntary disclosure cases through: (1) liaison activities with DOJ and the U.S. Attorney's office; (2) the disclosure verification efforts of OAS and OI; and (3) final disposition and sign-off of the

matter. The office, in coordination with other OIG components, develops both the standards governing the use of program exclusion authorities in cases involving other Federal agencies, including DOJ, and the criteria for evaluating whether to impose program exclusions against health care providers in such cases. It is responsible for ensuring that all program exclusion actions not handled by OEC are promptly and accurately reported to the appropriate OIG data base. The office is responsible for developing and maintaining a comprehensive and coordinated data base on all settled and pending False Claims Act and CMP cases under its authority.

C. *Administrative Litigation.* This office is responsible for providing legal advice to OEC concerning the legal sufficiency of proposed program exclusions, issues relating to the scope and effect of program exclusions, and the reinstatement of excluded persons or entities. The office assists OEC in developing standards governing the imposition of program exclusions. The office litigates appeals of program exclusions imposed by OEC before the DAB and assists DOJ in handling any subsequent appeals of such cases to the Federal courts. The office reviews all patient anti-dumping cases referred by the Health Care Financing Administration, makes recommendations regarding the handling of these cases, and negotiates settlements with hospitals and physicians of their liability for CMPs and program exclusions. Where appropriate, the office litigates CMPs and program exclusions imposed on hospitals and physicians for violations of the patient anti-dumping statute. The office also reviews, negotiates settlements, and litigates other CMP cases that have been referred by OEC. In addition, the office provides legal advice to OEC on matters involving the development and monitoring of corporate compliance plans, the resolution of breaches of such plans, and the development of corrective action plans. The office also has primary responsibility for developing and promulgating all OIG sanction and interpretative regulations for codification into the Code of Federal Regulations, all OIG-related **Federal Register** notices, and the review and drafting of legislative proposals relating to fraud and abuse enforcement activities.

D. *Industry Guidance.* This office is responsible for drafting and issuing advisory opinions to the health care industry and members of the public on whether an activity (or proposed

activity) would constitute grounds for the imposition of a sanction under the anti-kickback statute, the CMP law or the program exclusion authorities, and on other issues pertaining to the anti-kickback statute. The office develops and updates procedures for the submission of requests for advisory opinions and for determining the fees that will be imposed. The office solicits and responds to proposals for new regulatory safe harbors to the anti-kickback statute, modifications to existing safe harbors, and new fraud alerts. The office consults with, and obtains the concurrence of, DOJ on all proposed advisory opinions and safe harbors before issuance or publication. The office provides legal advice to the various components of the OIG, other offices of the Department, and DOJ concerning matters involving the interpretation of the anti-kickback statute and assists those components or offices in analyzing the applicability of the anti-kickback statute to various practices or activities under review.

**Section AFH.00, Office of Audit Services (OAS)—Mission.** The Office of Audit Services provides policy direction for and conducts and oversees comprehensive audits of HHS programs, operations, grantees and contractors, following generally accepted Government auditing standards (GAGAS), the Single Audit Act of 1984, applicable Office of Management and Budget (OMB) circulars and other legal, regulatory and administrative requirements. It maintains an internal quality assurance system, including periodic quality assessment studies and quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards and other requirements are followed in all audit activities performed by, or on behalf of, the Department. In furtherance of this mission, the organization engages in a number of activities:

A. The office coordinates and confers with officials of the central Federal management agencies (OMB, the General Accounting Office (GAO), the Office of Personnel Management (OPM) and the Department of the Treasury) on audit matters involving HHS programs and operations. It provides technical assistance to Federal, State and local investigative offices on matters concerning the operation of the Department's programs. It participates in interagency efforts implementing OMB Circulars A-128 and A-110, which call for use of the single audit concept for most external audits. It performs audits of activities administered by other Federal

departments, following the system of audit cognizance administered by OMB. It participates in the President's Council on Integrity and Efficiency (PCIE) initiatives and other Government-wide projects. It works with other OIG components on special assignments and projects. It responds to congressional oversight interests related to audit matters in the Department.

B. The Office of Audit Services helps HHS operating divisions and the Office of the Secretary staff divisions to develop policies to manage grants and procurements and policies to establish indirect cost rates. It performs pre-award audits of grant or contract proposals to determine the financial capability of the grantees or contractors and conducts post-award audits.

C. The office reviews legislative, regulatory and policy proposals for audit implications. It recommends improvements in the accountability and integrity features of legislation, regulations and policy. It prepares reports of audits and special studies for the Secretary, heads of HHS operating divisions, Regional Directors and others. It gathers data on unresolved audit findings for the statutorily required Semiannual Reports to the Congress and for the Deputy Secretary as Chairman of the Audit Resolution Council. It conducts follow-up examinations and special analyses of actions taken on previously reported audit findings and recommendations to ensure completeness and propriety.

D. The office decides when audits can or may be performed by audit organizations outside the Department, including those by other Federal or nonfederal governmental agencies, contractors, or public accounting firms. It assures that any audit performed by non-OIG auditors complies with the Government auditing standards established by the Comptroller General of the United States. It evaluates audits performed for the Department by outside organizations. It coordinates the development of the OIG Annual Work Plan and produces summaries of both (1) the Orange Book—a summary of unimplemented program and management improvements recommended—and (2) the Red Book—a summary of significant monetary recommendations not yet implemented.

E. The office serves as the focal point for all financial audit activity within the Department and provides the primary liaison conduit between the OIG and departmental management. The office provides overall leadership and direction in carrying out the responsibilities mandated under the

Chief Financial Officers Act relating to financial statement audits.

**Section AFH.10, Office of Audit Services—Organization.** The Office of Audit Services comprises the following components:

- A. Immediate Office.
- B. Audit Operations and Financial Statement Activities.
- C. Health Care Financing Audits.
- D. Administrations of Children, Family and Aging Audits.
- E. Public Health Audits.

**Section AFH.20, Office of Audit Services—Functions.** A. **Immediate Office of the Deputy Inspector General for Audit Services.** This office is directed by the Deputy Inspector General for Audit Services who carries out the functions designated in the law for the position, Assistant Inspector General for Auditing. The Deputy Inspector General for Audit Services is responsible to the Inspector General for carrying out OIG's audit mission and supervises the Assistant Inspectors General heading OAS offices described below.

The Immediate Office manages the human and financial resources of the Office of Audit Services including developing staffing allocation plans and issuing policy for, coordinating and monitoring all budget, staffing, recruiting and training activities of the office. Included in this is the responsibility to track court ordered or agreed-to costs of audits recouped from health care providers found to have violated Medicare fraud and abuse program provisions. It maintains a professional development program for Office of Audit Services staff which meets the requirements of Government auditing standards. The office provides liaison with the General Accounting Office. It reviews all replies to GAO reports to ensure they are responsive, properly coordinated and representative of HHS policy and advises the Secretary and other officials about significant findings.

B. **Audit Operations and Financial Statement Activities.** This office is directed by the Assistant Inspector General for Audit Operations and Financial Statement Activities. In addition to directing this office, the Assistant Inspector General supervises the eight Regional Inspectors General for Audit Services. The office's principal functions include providing direction and oversight to OAS through its work planning and quality assurance activities; the direct-line responsibility for audits of financial statements and financial related audits, including internal audits of functional areas

within the Department; and directing field audit operations.

1. The office serves as the focal point for all financial statement and financial related audit activity within the Department and serves as the primary liaison conduit between the OIG and departmental management.

2. The office operates an internal quality assurance system that provides reasonable assurance that applicable laws, regulations, policies, procedures, standards and other requirements are followed in all audit activities performed by, or on behalf of, the Department.

3. The office evaluates audit work, including performing quality control reviews of audit reports, and develops and monitors audit work plans. It develops audit policy, procedures, standards, criteria and instructions for all audit activities performed by, on behalf of, or conforming with departmental programs, grants, contracts or operations in accordance with GAGAS and other legal, regulatory and administrative requirements.

4. The office tracks, monitors and reports on audit resolution and follow-up in accordance with OMB Circular A-50.

5. The office provides oversight for audits of governments, universities and nonprofit organizations conducted by nonfederal auditors and those under contract with the OIG (external audit resources).

6. The office coordinates with the other OIG components in developing the semiannual report to Congress.

**C. Health Care Financing Audits.** This office is directed by the Assistant Inspector General for Health Care Financing Audits. The office conducts programmatic and fraud and abuse oriented audits of HCFA program operations and oversees nationwide the audits of the Medicare and Medicaid programs, their contractors, and providers of services and products. It maintains an internal quality assurance system, including periodic quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards and other requirements are followed in all HCFA audit activities performed by, or on behalf of, the Department.

**D. Administrations of Children, Family and Aging Audits.** This office is directed by the Assistant Inspector General for Administrations of Children, Family and Aging Audits. The office conducts and oversees audits of the operations and programs of the Administration for Children and Families and the Administration on

Aging, as well as statewide cost allocation plans. It maintains an internal quality assurance system, including periodic quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards and other requirements are followed in its audit activities.

**E. Public Health Audits.** This office is directed by the Assistant Inspector General for Public Health Audits. The office conducts and oversees audits of the programs and activities of the public health related agencies, including the Food and Drug Administration; the National Institutes of Health; the Health Resources and Services Administration; the Alcohol, Drug Abuse, and Mental Health Administration; the Centers for Disease Control and Prevention; the Agency for Toxic Substances and Disease Registry; the Indian Health Service and the Surgeon General, as well as those colleges, universities and nonprofit organizations that receive research grants from the Federal Government. It maintains an internal quality assurance system, including periodic quality control reviews, to provide reasonable assurance that applicable laws, regulations, policies, procedures, standards and other requirements are followed in all public health related audit activities performed by, or on behalf of, the Department.

**Section AFJ.00, Office of Investigations (OI)—Mission.** The Office of Investigations is responsible for conducting and coordinating investigative activities related to fraud, waste, abuse and mismanagement in HHS programs and operations, including wrongdoing by applicants, grantees, or contractors, or by HHS employees in the performance of their official duties. It serves as OIG liaison to DoJ on all matters relating to investigations of HHS programs and personnel, and reports to the Attorney General when the OIG has reasonable grounds to believe Federal criminal law has been violated. It works with other investigative agencies and organizations on special projects and assignments. In support of its mission, the office carries out and maintains an internal quality assurance system. The system includes quality assessment studies and quality control reviews of OI processes and products to ensure that policies and procedures are followed effectively, and are functioning as intended.

**Section AFJ.10, Office of Investigations—Organization.** The Office of Investigations comprises the following components:

- A. Immediate Office.
- B. Criminal Investigations.

C. Investigations Policy and Oversight.

**Section AFJ.20, Office of Investigations—Functions.** A. **Immediate Office of the Deputy Inspector General for Investigations.** This office is directed by the Deputy Inspector General for Investigations who is responsible for the functions designated in the law for the position, Assistant Inspector General for Investigations. The Deputy Inspector General for Investigations supervises the Assistant Inspectors General who head the OI offices described below.

The Deputy Inspector General for Investigations is responsible to the Inspector General for carrying out the investigative mission of the OIG and for leading and providing general supervision to the OIG investigative component. The Immediate Office coordinates quality assurance studies to ensure that applicable laws, regulations, policies, procedures, standards and other requirements are followed in all investigative activities performed by, or on behalf of, the Department.

**B. Criminal Investigations.** This office is directed by the Assistant Inspector General for Criminal Investigations who supervises a headquarters policy and review staff and the Regional Inspectors General for Investigations who carry out investigative activities in their assigned geographic areas.

1. The headquarters staff assists the Deputy Inspector General for Investigations to establish investigative priorities, to evaluate the progress of investigations, and to report to the Inspector General on the effectiveness of investigative efforts. It develops and implements investigative techniques, programs, guidelines and policies. It provides programmatic expertise and issues information on new programs, procedures, regulations and statutes. It directs and coordinates the investigative field offices.

2. The headquarters staff reviews completed reports of investigations to ensure accuracy and compliance with guidelines. It issues the reports to pertinent agencies, management officials and the Secretary and recommends appropriate debarment actions, administrative sanctions, CMPs and other civil actions, or prosecution under criminal law. It identifies systemic and programmatic vulnerabilities in the Department's operations and makes recommendations for change to the appropriate managers.

3. The staff provides for the personal protection of the Secretary.

4. The field offices conduct investigations of allegations of fraud, waste, abuse, mismanagement and

violations of standards of conduct and other investigative matters within the jurisdiction of the OIG. They coordinate investigations and confer with HHS operating divisions, staff divisions, OIG counterparts and other investigative and law enforcement agencies. They prepare investigative and management improvement reports.

*C. Investigations Policy and Oversight.* This office is directed by the Assistant Inspector General for Investigations Policy and Oversight who leads outreach activities to State and local investigative agencies, and the general management functions of the Office of Investigations.

1. The office oversees State Medicaid fraud control units and is responsible for certifying and recertifying these units and for auditing their Federal funding. The office provides pertinent information from HHS records to assist Federal, State and local investigative agencies to detect, investigate and prosecute fraud. It manages the HHS Hotline to receive complaints and allegations of fraud, waste and abuse, and to refer the information for investigation, audit, program review, or other appropriate action. It coordinates with the GAO hotline and hotlines from other agencies.

2. The office maintains an automated data and management information system used by all OI managers and investigators. It provides technical expertise on computer applications for investigations and coordinates and approves investigative computer matches with other agencies.

3. The office develops general management policy for the OI. It develops and issues instructional media on detecting wrongdoing and on investigating and processing cases. The office reviews proposed legislation, regulations, policies and procedures to identify vulnerabilities and recommends modification where appropriate. It reviews investigative files in response to Privacy and Freedom of Information Act requests. It plans, develops, implements and evaluates all levels of employee training for investigations, management, support skills and other functions, and serves as OIG liaison to the Office of the Secretary for Freedom of Information and Privacy Act requests. It coordinates general management processes, e.g., compiles reports on the budget, on awards and on other personnel matters for OI as a whole; implements policies and procedures published in the OIG Administrative Manual; and processes procurement requests and other service related actions.

Dated: May 15, 1997.

**June Gibbs Brown**

*Inspector General.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[Announcement Number 747]

#### Research Programs for the Development of Methods for the Toxicity Assessment of Environmental Chemical Mixtures

##### Introduction

The Agency for Toxic Substances and Disease Registry (ATSDR) announces the availability of fiscal year (FY) 1997 funds for a cooperative agreement based research program to develop methods to determine the health effects of hazardous substances in combination with other substances with which they are commonly found at National Priorities List (NPL) sites and facilities. Such combinations are referred to as "chemical mixtures." The objective of this program is to develop methods of toxicity assessment of chemical mixtures so as to promote public health practices based on current scientific understanding and to evaluate exposure to environmental chemicals of populations living in the vicinity of hazardous waste sites.

ATSDR is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the Healthy People 2000 priority areas of Environmental Health, Surveillance and Data Systems, and Occupational Safety and Health. (For ordering a copy of "Healthy People 2000," see the Section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

##### Authority

This program is authorized under sections 104(i)(5)(A) and (15) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980 as amended by the Superfund Amendments and Reauthorization Act (SARA) of 1986 ((42 U.S.C. 9604(i)(5)(A) and (15)).

##### Eligible Applicants

Eligible applicants are the official public health agencies of the States or

their bona fide agents or instrumentalities. This includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments. State organizations, including State universities, State colleges, and State research institutions, must affirmatively establish that they meet their respective State's legislative definition of a State entity or political subdivision to be considered an eligible applicant.

Funding preference will be given to the three applicants that are currently funded under this cooperative agreement program.

##### Smoke-Free Workplace

ATSDR strongly encourages all cooperative agreement recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

##### Availability of Funds

Approximately \$400,000 will be available in FY 1997 to fund up to 3 cooperative agreement awards. It is expected that the average award will be approximately \$125,000, ranging from \$50,000 to \$250,000. The awards are expected to begin on or about September 30, 1997, for a 12-month budget period within a project period of 5 years. Continuation awards within the project period will be made on the basis of satisfactory progress and availability of funds. The funding estimate above may vary and is subject to change.

##### Purpose

The purpose of this program to develop methods for the assessment of health effects of chemical mixtures found at hazardous waste sites. Specific areas of funded research may include to: (1) Identify hazards associated with chemical mixtures found in the environment that impact public health; (2) evaluate potential toxicity to human populations from exposure to chemical mixtures; (3) study the pharmacokinetic behavior of chemical mixtures; (4) study the various endpoints that would be affected and the target organs that would be impacted; (5) study the mechanisms of action, progression and repair of the injury caused by chemical