### **Department of Health and Human Services**

# Office of Inspector General Projects



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## AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

### **Patient Safety Efforts**

We will evaluate the progress of the Agency for Healthcare Research and Quality in improving patient safety and reducing medical errors. In a 1999 report on medical errors and patient safety, "To Err Is Human, Building a Safer Health Care System," the Institute of Medicine noted that, based on studies in New York, Utah, and Colorado, 44,000 to 98,000 persons die each year in hospitals as a result of medical errors. The report recommended the establishment of a Center for Patient Safety in the Agency for Healthcare Research and Quality and outlined a detailed agenda for the proposed center.

OEI; 00-00-00000

## CENTERS FOR DISEASE CONTROL AND PREVENTION

### **Ethics and Conflict of Interest - Review Panels**

We will assess the Centers for Disease Control and Prevention (CDC) controls to preclude conflicts of interest on the part of employees involved in the research awards process. These employees, who are members of review panels, are responsible for evaluating the scientific or technical merit of proposals being considered for funding. The CDC funds extramural research through, for example, the Prevention Research Center Program, which supports a prevention research agenda at schools of public health throughout the country. In evaluating potential research and awarding funds, CDC employees are obliged to maintain objectivity and integrity.

OAS; W-00-02-50003; A-04-02-00000

### **Oversight of Grants**

We will review CDC's oversight of its external grants. In FY 2000, through its extramural program, CDC awarded approximately \$2.1 billion to State, local, and territorial health departments; colleges and universities; nonprofit organizations; and other entities. These awards supported CDC's initiatives in such critical areas as childhood immunization, disease prevention, and AIDS education. Our review will determine whether CDC has adequate

controls to ensure that grantees properly carry out their programmatic and fiscal management responsibilities.

OAS; W-00-02-50003; A-04-02-00000

### **Funding for AIDS Activities**

At the request of the Deputy Secretary, we will review concerns regarding CDC's fiscal and administrative practices for AIDS-related funds. In FY 2001, the agency was appropriated over \$1 billion in funding to prevent and control HIV/AIDS.

OAS; W-00-02-50003; A-04-02-00000

### **Prevention Research Center Program**

This review will evaluate the impact of the National Center for Chronic Disease Prevention and Health Promotion's Prevention Research Center Program on community public health programs and policies. Since 1986, this program has funded academic institutions across the country to develop, in collaboration with the communities they serve, health promotion and disease prevention strategies and apply them at the community level. The program has never been evaluated. This study will attempt to identify common indicators of successful community-based health promotion and disease prevention programs and best practices.

OEI: 00-00-00000

### **Breast and Cervical Cancer Medicaid Benefit for Uninsured Women**

We will assess the collaboration of CDC, the Centers for Medicare and Medicaid Services, and the States in implementing the Medicaid treatment benefit for low-income, uninsured women with breast or cervical cancer. Under the Breast and Cervical Cancer Prevention and Treatment Act of 2000, States receive enhanced matching funds to provide full Medicaid benefits to uninsured women under age 65, with incomes up to 250 percent of poverty, who are identified as needing treatment for breast or cervical cancer through CDC's National Breast and Cervical Cancer Early Detection Program. This program has been in operation since 1991. Successful implementation of the new Medicaid benefit requires a coordinated effort between State Medicaid and public health agencies and between the Centers for Medicare and Medicaid Services and CDC. This review will focus on the nature and extent of the collaboration and the impact of the new benefit on the existing CDC-funded breast and cervical cancer early detection programs.

OEI; 00-00-00000

### **Released INS Detainees With Tuberculosis**

We will assess the extent and effectiveness of the Public Health Commission Corps' efforts to control tuberculosis in paroled illegal immigrants with tuberculosis. The Immigration and Naturalization Service (INS) is responsible for the detention of illegal immigrants before their deportation. About 400 to 500 illegal immigrants in detention facilities who are awaiting dispositional hearings are paroled each month into the community. Commission Corps staff, who provide health care in INS detention facilities, give paroled individuals with tuberculosis a "starter" supply of medicine, and the individuals are expected to follow up with local medical authorities. However, neither INS nor Commission Corps personnel formally follow up on these individuals to ensure that they continue treatment once paroled. Lapses in treatment can lead to continued tuberculosis transmission and development of drug-resistant tuberculosis.

OEI; 00-00-00000

### FOOD AND DRUG ADMINISTRATION

### **Oversight of Imported Food**

We will assess the effectiveness of Food and Drug Administration (FDA) strategies for overseeing imported foods and ensuring their safety. Since 1992, the level of food imports has increased three-fold and is expected to continue to increase. Currently, about 38 percent of produce and about 50 percent of the seafood consumed in the United States is imported. The FDA relies on seven key strategies to oversee imports: border exams, foreign inspections, equivalency determinations, country assessments, technical assistance to foreign governments, sample surveys of imported foods, and responses to emergencies. We will quantify the recent growth of food imports into the United States, consider the strategies being used to oversee food imports and their effectiveness in ensuring the safety of imported food, and assess how effectively FDA is allocating its limited resources among the various strategies.

OEI: 00-00-00000

### **Prescription Drug User Fee Act**

At the request of the FDA Center for Drug Evaluation and Research, we will review the effects of the Prescription Drug User Fee Act on the regulatory review of new drug applications. We will examine the FDA process for reviewing these applications under the act

and identify process and program areas that can improve the effectiveness and stringency of these reviews.

OEI; 01-01-00590

### Sponsors' Oversight of Clinical Trials

We will examine how sponsors of clinical trials monitor the implementation of the trials by clinical investigators. Sponsors are drug, device, or biologic manufacturers that plan to submit an application for FDA approval. They are responsible for ensuring that their clinical trials are conducted in accordance with FDA's regulations by selecting qualified clinical investigators, providing the clinical investigators with the information needed to conduct the clinical investigation, and reviewing ongoing clinical investigations. Sponsors, along with institutional review boards and clinical investigators, provide the first line of defense in protecting human subjects from harm.

OEI; 00-00-00000

### **Biennial Inspection Requirement**

In a series of three reviews, we will assess FDA's strategy for meeting its statutory mandate to inspect registered human drug, animal drug, biologic, and device manufacturing establishments at least once every 2 years. According to FDA, the agency has not been able to meet this requirement because of limited resources. Our reviews will focus on the effectiveness of FDA's inspection planning and execution process and the accuracy of the computerized database of more than 100,000 establishments under the agency's jurisdiction that must be inspected. Only a fraction of these establishments are subject to the biennial inspection requirement.

OAS; W-00-01-50004; A-15-01-20001

### **Postmarketing Studies of Prescription Drugs**

We will follow up on FDA's practices regarding the monitoring of postmarketing studies of prescription drugs. A 1996 OIG report provided recommendations for improving FDA's system for monitoring and tracking studies requested after drugs were approved for marketing. We will review FDA's progress in implementing our recommendations and its tracking of postmarketing studies.

OEI: 00-00-00000

### **Effectiveness of MedWatch**

We will evaluate the effectiveness of MedWatch, the FDA Medical Products Reporting Program, and its web-based postings on product safety and labeling changes for industry and health care professionals. MedWatch provides and solicits reports of adverse events and product problems; educates providers, manufacturers, and patients; and serves as the "front door" for the drug and device adverse event reporting system database. The MedWatch program is intended to enhance the effectiveness of postmarketing surveillance of medical products as they are used in clinical practice and to rapidly identify significant health hazards associated with these products. However, it is estimated that only 1 to 10 percent of adverse events are actually reported.

OEI; 00-00-00000

### Pharmaceutical Company Gifts and Payments to Providers

We will evaluate the extent of gifts and payments to physicians from pharmaceutical companies. The pharmaceutical industry currently spends about \$12 billion a year on marketing to physicians, and some of these gifts may present an inherent conflict of interest between the legitimate business goals of manufacturers and the ethical obligation of providers to prescribe drugs in the most rational way. Depending on the facts and circumstances, gifts may also violate the Federal anti-kickback statute if they are intended to induce referrals.

*OEI*; 00-00-00000

### **Medical Device Reviews**

We will evaluate the effectiveness of FDA's premarket review processes for both new and investigational medical devices, as well as those devices that have been "grandfathered" pending approval. One of the objectives of the 1997 Food and Drug Administration Modernization Act was to shorten the time needed to approve medical devices by using contractors as auxiliary review staff. Concerns have been raised about the potential for reviewer bias and about the recall of certain medical devices soon after they come to market.

OEI; 00-00-00000

### Accreditation and Quality Oversight of Mammography Facilities

We will assess the accreditation and regulatory oversight mechanisms for mammography facilities since the enactment of the Mammography Quality Standards Act of 1992. In

response to the growing concern over breast cancer and the quality of mammography services, the act established national quality standards for mammography. Responsibility for this legislation was delegated to the FDA Center for Devices and Radiological Health Mammography Program. This study, a followup to a 1994 OIG report, will evaluate the impact on the quality of mammography screenings and services.

*OEI*; 00-00-00000

## HEALTH RESOURCES AND SERVICES ADMINISTRATION

### **Reducing Perinatally Transmitted HIV**

This study will evaluate technical assistance that the Health Resources and Services Administration (HRSA) and the Department offer to assist States in reducing the incidence of perinatal HIV transmission. Approximately 6,000 to 7,000 HIV-infected women give birth every year. Because many HIV-positive pregnant women are unaware of their HIV status and therefore do not receive treatment, the number of children born with HIV is still unacceptably high. We will estimate the total number of HIV-positive infants born in the United States during FY 1999 for whom the mother's HIV status was unknown to the attending obstetrician. We will also identify barriers that may discourage or prevent an obstetrician from routinely testing all pregnant woman and/or all newborns whose mothers' HIV status is unknown.

OEI; 05-01-00260

### **HIV/AIDS Care and Prevention: Collaboration Among HHS Grantees**

This study will evaluate the nature and extent of collaboration among community-based organizations funded by departmental grant programs to improve prevention and care for people with HIV/AIDS. In recent years, increasing Federal grant money has been distributed directly to community-based organizations serving individuals with HIV/AIDS. However, some of these organizations may be duplicating efforts or crafting programs that are not responsive to the needs of their communities.

*OEI;* 00-00-00000

### **AIDS Education and Training Centers**

We will determine whether regional AIDS education and training centers and local performance sites have adapted to significant changes in the HIV/AIDS epidemic and identify best practices for adapting to such changes. Under the Ryan White Comprehensive AIDS

Resources Emergency (CARE) Act, HRSA awards grants to 14 regional education and training centers and over 70 local performance sites to provide state-of-the-art treatment education, training, consultation, and support to health care professionals treating HIV-positive patients. Since the mid-1990s, two trends in the epidemic have become particularly relevant to this program: the increasing impact of HIV/AIDS on the underserved, minority, and marginalized segments of society and the dramatic impact of new clinical treatment modalities on health outcomes of people living with HIV/AIDS.

OEI; 00-00-00000

### Eligibility for Ryan White CARE Act Funding

This followup review will determine whether a Northeastern city and its contracted service providers ensure that clients are qualified to receive services under Title I of the Ryan White CARE Act. The act authorizes emergency funding relief to metropolitan areas with the highest incidences of HIV disease. In FY 2000, the city received \$12.5 million in CARE Act funds to be used for a range of community-based services, such as outpatient health care, home health care, housing and transportation assistance, and inpatient case management services. In a previous review, OIG identified problems with the city's ability to properly document the eligibility of CARE Act clients.

OAS; W-00-02-50005; A-01-02-00000

### **Conformity of State AIDS Drug Assistance Programs With Public Health Treatment Guidelines**

We will evaluate whether eligibility criteria and the availability of therapeutics within State AIDS Drug Assistance Programs conform to public health agencies' guidelines for the treatment of HIV/AIDS. The HRSA requires States to use a portion of Title II Ryan White CARE Act funding to establish Drug Assistance Programs for low-income people diagnosed with HIV. States have wide latitude in establishing program eligibility criteria and formularies that may not be consistent with the most recent guidelines for the treatment of HIV disease and related infections.

OEI: 00-00-00000

### Ryan White CARE Act Title III Evaluation Systems

We will assess the evaluation systems used by Ryan White Title III grantees to monitor service inputs and outputs and to track the outcomes of the people they serve and the program impact within targeted communities. Title III grants go directly to community-based organizations to expand their ability to provide early intervention and primary care services for people with

HIV/AIDS. Grantees are responsible for designing and executing their own evaluation systems. While some grantees have implemented fully functional evaluation systems, others have not. This study will follow up on our earlier reviews of Titles I and II and the AIDS Drug Assistance Program of the Ryan White CARE Act.

OEI; 00-00-00000

### Administration and Oversight of Ryan White CARE Act Funds

At the request of the Senate Committee on Finance, we will review administration of funds awarded to grantees--eligible metropolitan areas and States--and subgrantees under the Ryan White CARE Act. In FY 2001, CARE Act appropriations totaled over \$1.8 billion. We will examine the grantees' expenditures, fiscal capabilities, and program performance as well as HRSA's monitoring of grantees' administrative actions.

*OAS; W-00-02-50005; Various CINs* 

*OEI;* 00-00-00000

### **State Administration of AIDS Funds**

We will review the administration of Ryan White CARE Act funds by a State and its contractor. The HRSA asked us to focus our review on the contractor's fiscal and administrative practices and its stewardship of CARE Act funds, the State's administrative and fiscal processes related to contractor oversight, and the propriety of the State's practice of providing all Care Act funds to the contractor to carry out grantee obligations.

OAS; W-00-01-50005; A-05-01-00073

### Hemophilia Treatment Centers' Access to Blood Clotting Factor at 340B Prices

At HRSA's request, we will examine hemophilia treatment centers' ability to purchase blood clotting factor in general and at 340B discounted prices. Section 340B of the Public Health Service Act authorizes grantees to purchase covered drugs at discounted prices by entering into contracts with the prime vendor. Since this law was passed, HRSA has received anecdotal information that blood clotting factor has not been available to some hemophilia treatment centers at the 340B price.

OAS; W-00-01-50005; A-15-01-30001

### **Section 340B Drug Ceiling Prices**

We will review the rebate percentage calculations used by drug manufacturers to determine the ceiling prices for outpatient drugs sold to covered 340B entities. Manufacturers' "best price" determinations for Medicaid-covered drugs are used as a basis for computing the 340B prices. As pointed out in a March 2001 OIG report, some drug manufacturers improperly excluded from their Medicaid best price determinations sales to repackagers that were also health maintenance organizations. As a result, the Medicaid program lost drug rebates totaling \$80.7 million. This review will determine whether covered 340B entities were also overcharged and, if so, quantify the impact.

OAS; W-00-01-50005; A-06-01-00060

### **Hemophilia Treatment Centers' Disposition of 340B Program Income and Patient Choice Policy**

At HRSA's request, we will assess hemophilia treatment centers' disposition of income obtained from participating in the 340B discount pricing program for the purchase of blood clotting factor and evaluate their policies on patient choice of providers of blood clotting factor. According to grant requirements, hemophilia treatment centers are to use program income to complement or expand the services provided by the program. The HRSA officials have expressed concern that some centers that purchase blood clotting factor at the 340B price have used the profits for activities unrelated to patient care. There is also concern that some centers have limited patients' rights to choose their blood clotting factor provider.

OAS; W-00-01-50005; A-03-01-03500

### Multiple Registrations for Organ Transplantation

We will examine the United Network for Organ Sharing (UNOS) policy that allows patient registrations at more than one transplant center and the impact of the policy on Medicare costs. According to UNOS data, approximately 5 percent of patients (about 8,200 individuals) on waiting lists were registered at more than one transplant center for the period 1995 through 1999. For Medicare-eligible patients, Medicare covers all costs relating to multiple registrations, including the \$400 UNOS fee that is required for registering at each center and the costs of initial and ongoing medical evaluations and lab work. Debate about the distribution of scarce organs to transplantation has included the issue of whether patients should have the right to place themselves on waiting lists at several transplant centers, thereby gaining an advantage over other potential donors.

OEI: 00-00-00000

### **Organ Donation at Transplant Hospitals**

We will assess the performance of hospital organ transplant programs in organ donation. About 260 medical institutions operate hospital organ transplant programs in the United States. To help alleviate the organ shortage, Medicare conditions of participation required that hospitals, as of August 21, 1998, notify organ procurement organizations about individuals whose deaths are imminent or who die in the hospital. Because of their recognition of the need for organ donation, it seems logical that hospitals that operate transplant programs would be leaders in organ donation. Despite this expectation, there are indications that donation rates at hospitals with transplant programs are considerably lower than those at other hospitals.

OEI; 00-00-00000

### **Healthcare Integrity and Protection Data Bank**

We will review the implementation of the Healthcare Integrity and Protection Data Bank (HIPDB). The Health Insurance Portability and Accountability Act of 1996 directed the Secretary of the Department of Health and Human Services, acting through OIG and the U.S. Attorney General, to create HIPDB to help combat fraud and abuse in health care delivery. The HIPDB is a national data bank containing "adverse actions" taken against health care practitioners and suppliers; such adverse actions include OIG exclusions, criminal convictions, and civil judgments related to health care. The HRSA operates HIPDB under a memorandum of agreement with OIG.

OEI; 00-00-00000

### INDIAN HEALTH SERVICE

### **Alcohol and Substance Abuse Programs**

We will follow up on Indian Health Service (IHS) progress in achieving the goals of the Indian Alcohol and Substance Abuse Prevention and Treatment Act of 1986. This act was designed to provide a coordinated and comprehensive plan to address the problem of Indian alcohol and substance abuse, particularly among young people. In several studies conducted in the early 1990s, we identified a number of problems in implementing the act, including a failure to meet quality assurance objectives, ineffective information management systems, inappropriate use of funds, and a failure to establish regional treatment centers and emergency shelters. This study will focus on IHS policies and procedures that promote coordination of Indian alcohol and substance abuse programs.

OEI; 00-00-00000

### **Prescription Drug Contracts With Tribes**

We will review IHS drug distribution systems for tribes that purchase prescription drugs under Federal discount pricing programs. The IHS is authorized to access various Federal discount drug programs. Based on information and inquiries from some contractors and from the IHS Regional Supply Service Center, there is reason to believe that questionable activity may be occurring in the IHS contractors' purchase or distribution of pharmaceuticals, such as unusually large-volume orders or resale to entities not entitled to the discounts. This study will identify the extent to which these concerns need to be addressed.

OEI; 00-00-00000

### NATIONAL INSTITUTES OF HEALTH

### **Superfund Financial Activities for Fiscal Year 2001**

As required by Superfund legislation, we will conduct this annual financial audit of the National Institute of Environmental Health Sciences payments, obligations, reimbursements, and other uses of Superfund monies. The Institute's Superfund activities, carried out by its own staff and through cooperative agreements, include training people engaged in hazardous waste activities and studying the effects of exposure to specific chemicals. During FY 2000, agency obligations and disbursements of Superfund resources amounted to \$62.9 million and \$59.4 million, respectively.

OAS: W-00-02-50025: A-04-02-00000

### **Cancer Information Service Outreach Program**

This study will evaluate the National Cancer Institute's Cancer Information Service outreach program. The mission of the program is to disseminate cancer information to "the medically underserved, including minority groups and people with limited access to health information and services." Similar to the Cancer Information Service's toll-free phone service, the outreach program disseminates information via 19 regional contractors. Unlike the phone service, outreach program staff do not interact directly with the public; instead, they partner with State and regional organizations that serve the target audiences. This study will examine issues relating to the outreach program's target audiences and the effectiveness of specific outreach program activities.

OEI: 00-00-00000

### **Oversight of Grants**

We will review the National Institutes of Health (NIH) oversight of its external grants. In FY 2001, NIH spent about \$15.7 billion to support biomedical research, primarily at colleges and universities. With continuing congressional support, this amount is expected to increase significantly in the coming years. We will assess NIH's effectiveness in ensuring that grantees properly carry out their research and fiscal management responsibilities.

OAS: W-00-02-50025; A-15-02-00000

### **Funding of General Clinical Research Centers**

We will assess the effectiveness of NIH procedures for awarding funds to general clinical research centers. For FY 2001, NIH estimated that it would award \$227 million to more than 75 centers nationwide. The mission of these centers is to provide a research infrastructure for clinical investigators who receive their primary support from NIH components and other Federal agencies. The NIH uses two approaches to fund the centers. Under the discrete method, the expected cost of research days, nursing, and other fixed expenses is calculated in the grant award, and the grant must be reimbursed when the center uses the facilities for nonresearch patients. Under the per diem basis, the center is reimbursed for the research days actually used. Previous OIG reviews revealed problems with the discrete funding method. This review will determine whether NIH has an adequate process for determining the most effective form of center funding.

*OAS; W-00-01-50025; Various CINs* 

### **Recruiting Human Subjects for Clinical Trials**

This followup will assess investigator efforts to recruit human subjects for NIH clinical trials in a timely fashion. Difficulties in recruiting an adequate number of human subjects for clinical trials have been blamed for a quarter of the delays in developing new drugs. We will determine the extent and nature of these difficulties, and we will describe the range of recruitment strategies and oversight of recruitment practices.

OEI; 00-00-00000

### **Commercialization of NIH-Funded Inventions**

This evaluation will determine how NIH has applied the mandate of the Bayh-Dole Act of 1980 to commercialize publicly funded inventions on reasonable terms. Government-funded biomedical research, dominated by the NIH extramural grant program, is integral to improving public health by advancing medical technology to prevent, diagnose, and treat diseases. The

"practical application" clause of the Bayh-Dole Act applies broadly to most inventions funded in part or entirely by the Federal Government and licensed to the private sector on either an exclusive or a nonexclusive basis. The law mandates that these inventions be not merely made available to the public, but available at "reasonable terms." This study will examine the practical application of the law and its impact on commercial research.

*OEI*; 00-00-00000

## SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

### **Dissemination of Mental Health Technology Information**

This study will assess the Substance Abuse and Mental Health Services Administration (SAMHSA) role in disseminating research knowledge and best practices for treating mental illness to the treatment community. The SAMHSA supports a national network of technical assistance centers to disseminate information on promising, evidence-based prevention and treatment interventions, as well as best practices resulting from mental health research. In addition, the agency offers community action and other grants to induce communities to test new practices and adopt them if they work.

OEI: 00-00-00000

### **Community Support Program**

This review will assess SAMHSA's response to our June 1993 report on the Community Support Program. The program, which is funded at about \$20 million annually, provides grants to State mental health authorities for services, research demonstrations, and projects involving consumers and families in the development of services. Our 1993 study made a number of recommendations for improvements.

OEI; 05-01-00440

### PUBLIC HEALTH AGENCIES-WIDE ACTIVITIES

### **Government Information Security Reform Act**

As required by the Government Information Security Reform Act of 2000, we will evaluate the eight public health agencies' security programs and their critical systems. The results of

this effort will be included in the Department's annual report to the Office of Management and Budget (OMB) and the Congress, as required by law.

The purpose of the Government Information Security Reform Act is to provide a comprehensive framework for establishing and maintaining effective controls over the information resources that support Federal operations and assets. It also creates a mechanism for improved oversight of Federal agency information security programs to ensure compliance with applicable laws and regulations regarding computer security. The law has two requirements for the OIG: to conduct reviews of each operating division's security program and to test an appropriate subset of the Department's critical systems.

*OAS; W-00-02-40016; Various CINs* 

### Disclosure Statements Filed by Colleges and Universities

Our continuing reviews will assist the Department's Division of Cost Allocation in determining the adequacy and compliance of college and university disclosure statements. The OMB Circular A-21, revised May 8, 1996, requires that colleges and universities disclose their cost accounting practices in disclosure statements. The statements are designed to promote uniformity and consistency in the cost accounting practices followed by colleges and universities and to ensure that only allowable costs are claimed and that costs are equitably allocated to Federal projects. We will determine whether the cost accounting practices presented in the disclosure statements are complete, accurate, current, and consistent with cost accounting standards and OMB Circulars A-21 and A-110.

OAS: W-00-02-50007: Various CINs

### Cash Management at Colleges and Universities

We will evaluate the cash management procedures used by selected colleges and universities to account for Federal funds awarded by the Department and other agencies. In FY 2000, colleges and universities were awarded about \$10 billion from the Department alone. The OMB Circular A-110 requires that the institutions limit the amount and timing of cash withdrawals to immediate needs and remit any interest earned to the Federal Treasury. We will also evaluate the institutions' processes for determining funding requests and reconciling the Federal Cash Transactions Report with their accounting records. As a result of four similar prior audits, institutions remitted \$1.4 million in interest income.

*OAS: W-00-01-50025: Various CINs* 

### **Research Management Service Costs**

We will review the allowability of research management service costs charged by a university to federally funded awards from July 1, 1994, through June 30, 2001. The OMB Circular A-21 states that costs incurred for the same purpose in like circumstances should be treated consistently as either direct costs or facilities and administrative costs.

OAS; W-00-01-50012; A-09-01-04003

### **Recipient Capability Audits**

At the public health agencies' requests, we will perform recipient capability audits of new organizations having little or no experience managing Federal funds. These audits will determine the adequacy of the organizations' accounting and administrative systems and their financial capabilities to satisfactorily manage and account for Federal funds. Such reviews provide management with strengthened oversight of new grantees.

OAS; W-00-02-50013; Various CINs

#### **Reimbursable Audits**

We will conduct a series of audits in accordance with the Department's responsibility to negotiate the indirect cost rates for approximately 95 percent of the Nation's nearly 3,000 colleges and universities. Audit cognizance requires that we perform audits at these schools, including those requested by other Federal agencies. Our audits may include activities related to the review of disclosure statements filed by universities in conjunction with the cost accounting standards incorporated in OMB Circular A-21.

OAS; W-00-02-50012; Various CINs

#### **Indirect Cost Audits**

We will provide assistance, as requested, to the Department's Division of Cost Allocation on specific indirect cost issues at selected institutions. In previous years, we reviewed such issues as library allocations, medical liability insurance, internal service funds, fringe benefit rates, and space allocations. These audits helped to substantially reduce indirect cost rates at the institutions reviewed.

*OAS*; W-00-02-50010; Various CINs

### Followup on Nonfederal Audits

These reviews will determine whether auditees have implemented the recommendations in prior nonfederal audit reports to correct reported findings. The OIG's National External Audit Review Center has identified certain prior audits by nonfederal auditors as having circumstances that need further investigation.

OAS; W-00-02-50019; Various CINs

### **INVESTIGATIONS**

### Referrals by Office of Research Integrity

As a result of a closer relationship forged between the OIG's Office of Investigations (OI) and the Office of Research Integrity (located in the Office of the Assistant Secretary for Health), OI expects to investigate more scientific misconduct cases referred by that Office. These matters may involve allegations of fiscal improprieties, such as embezzlement or misappropriation of funds, or other fraudulent activity, such as falsification or fabrication of research data or plagiarism of confidential materials or intellectual property. Under departmental policies, the Office of Research Integrity may not directly investigate such issues but refers them to OIG when appropriate.