

Department of Health and Human Services

Office of Inspector General Projects



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CENTERS FOR DISEASE CONTROL AND PREVENTION

National Immunization Tracking System

We will describe how the current national immunization tracking system is functioning. We will specifically address concerns that have been raised about the coordination and tracking of vaccines provided to children in private settings, access to the data base by private providers and other practitioners, and the handling of patient privacy. The Comprehensive Childhood Immunization Act of 1993 was created to improve the Nation's immunization delivery system. The act calls for the Secretary to purchase and provide free vaccines, to establish a national tracking system or registries, to ensure that the National Vaccine Injury Compensation Program remains operational, and to continue vaccine infrastructure enhancements.

OEI; 05-99-00270

Controls Over Program Budgeting and Accounting

We will determine whether the Centers for Disease Control and Prevention (CDC) has established internal and management controls adequate to ensure that (1) budgets established for individual programs reflect any guidance provided by the Congress and the Department; (2) costs charged to those programs are based on the actual efforts of employees and use of other resources; and (3) financial reports provided to the Congress and the Department regarding the nature and extent of costs for specific programs and activities are timely, complete, and accurate.

Although most of its funding is provided through a single-line appropriation covering a wide range of activities, CDC receives guidance and direction from the Congress and HHS on establishing budgets for many individual programs. Building on information obtained during our recent review of costs charged to the Chronic Fatigue Syndrome program, we will identify programs for which CDC has received specific budgetary guidance or for which CDC officials have provided the Congress and the Department with detailed data related to program costs. We will then determine whether the costs budgeted and charged to those programs are appropriate and have been properly reported.

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

Follow-Up on Chronic Fatigue Syndrome Program Issues

We will assess the effectiveness of CDC's actions in response to our May 1999 review of the Chronic Fatigue Syndrome program. The CDC agreed to implement a number of recommended actions designed to enhance its controls over budgeting and accounting functions for programs operating within its various centers, institutes, and offices. We will determine whether CDC's actions are adequate to prevent any recurrence of the problems identified during our prior review and, if appropriate, present additional recommendations to further enhance control systems.

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

Controls Over Physical Security

We will follow up on actions taken by CDC to improve controls over physical security at headquarters facilities in Atlanta, Georgia. In response to an OIG audit report, CDC agreed in July 1996 to specific actions to improve controls at these facilities. In Fiscal Year (FY) 1997 appropriations, the Congress provided CDC \$23 million to begin security improvements. We will determine whether our previous recommendations have been implemented and whether additional safeguards are necessary.

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

FOOD AND DRUG ADMINISTRATION

State Accountability for Ensuring Food Safety

We will assess how well the Food and Drug Administration (FDA) holds States accountable for food safety inspections. While FDA has authority over food firms engaging in interstate commerce, approximately 3,000 State and local jurisdictions also have authority over food firms within their boundaries, whether or not interstate commerce is involved. Both FDA and the States conduct food safety inspections, and in recent years, FDA has delegated certain inspections work to many States for a limited number of food products. As FDA and other Federal and State agencies responsible for food safety work toward developing a "seamless" regulatory system for ensuring the safety of the Nation's food supply, accountability will become an increasingly important issue.

OEI; 01-98-00400

Biennial Inspection Requirement

We will assess whether FDA is meeting its statutory requirement to inspect drug and device manufacturers every 2 years. Such inspections are critical to ensure that firms comply with good manufacturing practices. Previous OIG work indicated that FDA is not meeting this requirement. If FDA is unable to meet this legal requirement, we will examine the agency's efforts to develop alternative methods to assess compliance with good manufacturing practices.

OAS; W-00-00-50004; A-15-00-00000

Effectiveness of MedWatch

We will evaluate the effectiveness of MedWatch, FDA's medical products safety reporting program. The FDA is responsible for ensuring the safety and efficacy of all regulated, marketed medical products, including drugs, biologics, medical and radiation-emitting devices, and special nutritional products. Created in 1996, MedWatch was designed to (1) educate health professionals about the importance of monitoring for and reporting adverse reactions and other problems to FDA and/or the manufacturer, (2) enhance the effectiveness of postmarketing surveillance of medical products, and (3) ensure that safety and labeling changes are rapidly communicated to the medical community, thereby improving patient care.

OEI; 00-00-00000

Recruiting Human Subjects for Industry-Sponsored Clinical Trials

We will assess sponsor and investigator efforts to recruit human subjects for clinical trials on a timely basis. To gain FDA approval to market new drugs, pharmaceutical companies must document the drug's safety and effectiveness through clinical trials. Recruiting an adequate number of human subjects for these trials is a large hurdle and has been blamed for 25 percent of the delays in development of 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; 01-97-00195

Clinical Investigations of Human Drugs

This review will evaluate FDA's monitoring of clinical research conducted in support of new drug applications. The FDA audits clinical investigations of human drugs to ensure that the research data submitted by drug manufacturers are valid and scientifically sound and that investigators have adequately protected research subjects. Clinical studies selected for audit generally are those for which safety and efficacy data have been determined as pivotal in the

decision to approve a new drug for marketing. Audits are also conducted in situations of possible scientific misconduct, suspicion of fraudulent data, or potential lack of human subject protection by clinical investigators. Recent media reports disclosed two cases in which clinical investigators falsified research data submitted to pharmaceutical companies to support new drug approvals.

OAS; W-00-00-50004; A-00-00-00000

Sanctions of Clinical Investigators

We will assess departmental oversight of clinical investigators subject to FDA regulation. As part of its regulatory function, FDA is authorized to sanction persons who have engaged in research misconduct, such as falsification of research data or repeated violations of regulatory requirements. Sanctioned clinical investigators are not necessarily subject to sanction action by other Federal entities. We will examine whether FDA's use of the disqualification authority adequately protects the public and the clinical research process from dishonest or noncompliant investigators and whether other departmental agencies and programs, such as Medicare, have procedures for protecting their program beneficiaries from FDA-sanctioned researchers who may pose a threat.

OEI; 05-99-00350

Blood Safety Consent Decrees

This review will evaluate FDA's oversight of consent decrees involving the two largest blood collection organizations in the United States, which collect over 60 percent of the Nation's blood supply. These decrees resulted from deficiencies identified during FDA inspections. Under the consent decrees, which are legally enforceable documents, the blood inspection organizations have agreed to improve the quality of their operations by implementing a more comprehensive quality assurance program and increasing training for all blood workers; improving data systems and records management; and strengthening policies for investigating and reporting errors, accidents, and adverse reactions.

OAS; W-00-00-50004; A-03-00-00000

Follow-Up of Blood Safety Issues

This review will examine FDA's efforts to improve its oversight of the safety of the Nation's blood supply. Our work will focus on problems the OIG previously identified regarding the blood error and accident reporting process, the blood recall process, and the inspection process

for plasma fractionators. Our objective will be to determine if FDA has implemented the specific recommendations made in earlier OIG reports.

OAS; W-00-00-50004; A-03-00-00000

FDA's Bioterrorism Program

At the request of the Subcommittee on Oversight and Investigations, House Committee on Commerce, we will assess FDA's actions to implement its bioterrorism research program. As part of the FY 2000 budget request, FDA is seeking over \$13 million to engage in research on, for example, vaccines and antidotes related to biological terrorism. The Subcommittee has specifically requested that we examine FDA's controls in such areas as safeguarding hazardous materials, securing classified research data, and ensuring that staff have adequate background reviews.

OAS; W-00-00-50004; A-00-00-00000

HEALTH RESOURCES AND SERVICES ADMINISTRATION

State Licensing Boards and Discipline of Physicians

We will assess the performance of State boards responsible for the licensing and discipline of physicians. The State boards serve as a vital front line of protection for Medicare and Medicaid beneficiaries, as well as all health care consumers. The boards are responsible for ensuring that practicing professionals meet the minimum qualifications spelled out in State practice acts. Because of the Health Resources and Services Administration's (HRSA) relationship with the health professions and its own quality assurance activities (such as the National Practitioner Data Bank), it has a longstanding interest in licensing board activities.

OEI; 00-00-00000

Training Programs in the Maternal and Child Health Bureau

We will evaluate training programs funded as "Special Projects of Regional and National Significance" under the Maternal and Child Health Program. The statute provides that about 15 percent of funds appropriated for the Maternal & Child Health block grant be set aside for these special projects. Funding for training has generally been a major portion of the set-aside. In FY 1999, about 160 training grants were funded at a cost of approximately \$42 million. The

training program has never been evaluated. As part of our evaluation, we will look at the process for awarding grants and oversight of grantee performance.

OEI; 04-98-00090

Ryan White Cost Containment Strategies

We will examine the various cost containment strategies, such as PHS 340B drug purchasing, used by AIDS drug assistance programs to purchase drugs at the lowest available cost. The Ryan White Comprehensive AIDS Resource Emergency Act requires that States use a portion of their funding to establish a drug assistance program for low-income people living with HIV/AIDS who are uninsured or underinsured and lack coverage for medication. In FY 1998, the Congress appropriated \$285.5 million for drug assistance program use. A 1998 OIG review of five such programs found that they could have purchased an additional 8 percent, or \$4.4 million, of drug therapies had they participated in 340B drug purchasing.

OEI; 00-00-00000

New York's Use of CARE Act Funding

We will assess New York State's administration and use of Ryan White Comprehensive AIDS Resource Emergency (CARE) Act funds. We will audit the State's costs (\$78 million for the year ended March 31, 1998) for program services to verify that the expenditures were reasonable and consistent with the purpose of the CARE Act. In addition, we will look at cost sharing (\$38 million for the same year) claimed by the State to determine whether it was program related and met from nonfederal sources. We will also audit subrecipient costs (\$17 million for the year) to test controls over subrecipient programs and to verify that the funds were spent appropriately.

OAS; W-00-98-50005; A-02-98-02503

Coordination of HIV/AIDS Services by HRSA, CDC, and SAMHSA

We will examine the coordination of HIV/AIDS prevention and treatment services by HRSA's Ryan White programs, CDC, and the Substance Abuse and Mental Health Services Administration (SAMHSA). The Ryan White CARE Act requires the Secretary to ensure that HRSA, CDC, and SAMHSA coordinate the planning and implementation of Federal HIV programs to facilitate the local development of a complete continuum of HIV-related services. The statute also requires the Secretary to submit, no later than October 1, 1996, and biennially

thereafter, a report concerning these coordination efforts, including a statement of whether and to what extent Federal barriers exist to integrating HIV-related programs. The required report has yet to be submitted.

OEI; 00-00-00000

Organ Donation Referral

We will review the impact of a recent change in Medicare's conditions of participation that requires all hospitals to refer potential donor families to the local organ procurement organization. About 4,000 people die each year waiting for a transplant. It is estimated that 3,000 to 4,000 donor families are never asked about donation. The new Health Care Financing Administration (HCFA) policy is designed to ensure that hospitals do not overlook suitable donors. Our study will be coordinated with HRSA's organ allocation and donation initiatives.

OEI; 01-99-00020

Patient Access to Transplantation

A series of focused reviews, based on recently released data, will examine issues relating to organ waiting lists and access to transplantation. In 1991, we issued a report entitled "The Distribution of Organs for Transplantation: Expectations and Practices." At that time, just over 20,000 people were on transplant waiting lists. In 1999, more than 61,000 people are waiting for a transplant. Our series of reviews will examine a number of issues involving patient access to transplants, including regional differences in waiting times, demographic analysis of patients who are listed at more than one transplant center, and the impact of State "resident-only laws" to ensure that organs donated within a State will be transplanted to State residents.

OEI; 01-99-00210

INDIAN HEALTH SERVICE

Impact of Self-Governance on IHS Services

We will assess the effect of Indian self-governance on the Indian Health Service's (IHS) ability to provide needed health care services to the Indian people. As an increasing number of tribes elect to manage their own health care through self-governance compacts, IHS must ensure that there are no limits or reductions in the direct care it provides to tribes that do not elect to provide their own care. We will determine (1) if there are adequate controls to ensure that needed health care services are provided with compacting funds and (2) the impact on

nearby IHS facilities should compacting tribes be unable to adequately or fully meet the health care needs of their members.

OAS; W-00-00-50006; A-06-00-00000

Tribal Self-Governance Compact Award Process

We will examine the process used by IHS to award compacts to tribes under the Tribal Self-Governance Demonstration Project. With nearly 20 percent of the IHS budget provided to Indian tribes through the compact mechanism, the agency needs to ensure that it has implemented the demonstration project as the Congress intended and has effectively used the authorities available to it. Our review will focus on project compliance with key tenets of the legislative mandate and the use of project management and evaluation tools in support of agency oversight responsibilities.

OAS; W-00-97-50006; A-15-97-50003

Medicare Pricing for Contract Health Services Program: Outpatient Services

We will analyze the potential cost savings to the IHS Contract Health Services Program if legislation is enacted that requires outpatient health service providers to accept rates similar to Medicare's. This program pays outpatient providers \$44 million annually to care for eligible beneficiaries living outside IHS' direct care boundaries or for those requiring specialty care. These health services are currently purchased using negotiated contracts, which generally do not reflect competitive rates.

OAS; W-00-00-50006; A-15-00-00000

IHS Audit Resolution Process

We will determine whether and to what extent the IHS audit resolution process meets legislative and regulatory requirements. The Office of Management and Budget (OMB) Circular A-133 requires awarding agencies to (1) ensure that Indian tribes that receive Federal funds of \$300,000 or more submit annual audits required by the Single Audit Act (as amended in 1996) and (2) resolve annual audit findings applicable to their programs. In FY 1999, IHS will award over \$900 million to Indian tribes with a projected increase in FY 2000 to \$1 billion (42 percent of the IHS budget).

OAS; W-00-00-50006; A-15-00-00000

Equal Employment Opportunity Program

We will review IHS' Equal Employment Opportunity program. The IHS employs over 14,000 individuals to administer, deliver, and facilitate the provision of health care to Native Americans and Alaska Natives. This review, requested by the Director of IHS, will cover management practices and issues of timeliness, delegations of authority, training, conflict of interest, and confidentiality.

OEI; 05-99-00290

IHS Facilities

The IHS, which is the largest property owner in the Department, asked OIG to examine the condition of its existing health care facilities compared with that of similar structures owned by the Federal Government and the private sector. According to IHS officials, the agency's buildings are old and costly to repair and could affect the quality of care provided to beneficiaries of their programs.

OAS; W-00-00-50006; A-15-00-00000

NATIONAL INSTITUTES OF HEALTH

Superfund Financial Activities for Fiscal Year 1999

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 the Superfund. 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 1998, agency obligations and disbursements of Superfund resources amounted to \$61.2 million and \$55.8 million, respectively.

OAS; W-00-00-50025; A-04-00-00000

Cooperative Agreements With the Pharmaceutical Industry

We will review the National Cancer Institute's (NCI) collaboration with the pharmaceutical industry in developing new drugs to assess the costs and benefits to the Federal Government and the taxpaying public. When NCI develops new drugs, it enters into cooperative research and development agreements with pharmaceutical companies to test the drugs and to submit the data to FDA for marketing approval. Because these cooperative agreements afford the

pharmaceutical industry benefits from the Federal investment in NCI's research, it is important to ensure that the Government's and taxpayers' interests are safeguarded. Preliminary work indicates that NCI is collaborating with the pharmaceutical industry on over 90 investigational cancer drugs.

OAS; W-00-99-50025; A-15-99-50003

Grantee Adherence to the Bayh-Dole Act

We will determine whether selected grantee institutions followed certain provisions of the Bayh-Dole Act of 1980 in regard to medical devices and drugs recently brought to market and developed with the assistance of Federal grant funds. The act transfers title and ownership of inventions developed with Federal grant funds to the grantee institutions. In return, the grantees must adhere to certain reporting requirements regarding the inventions, and any patents that may result from them, and agree to substantially manufacture any invented products in the United States. We will also determine if the grantee institutions give the Government a license to use the inventions and the right to purchase them at royalty-free prices.

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

Handling, Storage, and Disposal of Equipment Exposed to Hazardous Materials

We will determine whether the National Institutes of Health (NIH) is in compliance with HHS and Department of Transportation regulations on the handling, storage, and disposal of equipment exposed to hazardous materials. The NIH uses hazardous materials in its hospitals, clinics, and research. If not properly handled, equipment exposed to hazardous material can contaminate individuals and resources. We reported in the 1980's that NIH had surplused some contaminated equipment before decontamination.

OAS; W-00-99-50025; A-15-99-00032

Security of NIH Laboratories

This review will determine whether the NIH master plan for a security system at its laboratories complies with the President's June 1995 directive that all Federal agencies upgrade security at their facilities to meet minimum standards recommended by the

Department of Justice. The minimum standards are categorized under perimeter security, entry security, interior security, and security planning.

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

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

External Oversight of Inpatient Psychiatric Units and Facilities

We will assess the external quality review of prospective payment system-exempt inpatient psychiatric units in acute care hospitals that participate in the Medicare program. Because of the number of deaths associated with the use of restraints and seclusion, SAMHSA has recently raised concerns echoed by the OIG, the Congress, and advocacy groups for the mentally ill about the quality of care in psychiatric facilities. The SAMHSA-funded State protection and advocacy organizations are the only federally funded agencies with authority to investigate reports of abuse and neglect in psychiatric facilities. We will examine their role and the roles of the other major entities that the Federal Government relies on to ensure that psychiatric hospitals meet the minimum standards for participation in Medicare. Bills have been introduced in both the House and the Senate to address the inappropriate use of restraints and seclusion in psychiatric facilities.

OEI; 01-99-00160

Patient Abuse Reporting - Psychiatric Hospitals

To profile quality of care problems in psychiatric hospitals, as discussed above, we will describe what current data systems can tell us about abuse and death of patients. We will conduct a systematic analysis of data reporting systems which will encompass all agencies and entities that have a role in patient abuse reporting, with special emphasis on the incidence of problems associated with the use of restraints and seclusion. Our analysis will include data systems maintained by the SAMHSA-funded State protection and advocacy organizations, which are the only agencies receiving Federal funds that are authorized to investigate reports of abuse and neglect in facilities that care for or treat persons with mental illness.

OEI; 04-99-00150

Substance Abuse Treatment Needs of Welfare Recipients

We will examine the strategies States use to address the substance abuse treatment needs of welfare recipients. States' assessments of the employability of these recipients may indicate the need for appropriate substance abuse treatment. While welfare reform legislation provided additional funding for treatment programs, this funding is unlikely to meet the increased demand expected as recipients are referred to treatment programs to ultimately become employable. In FY 1999, for example, SAMHSA provided about \$1.3 billion in block grant funds to States for substance abuse treatment and prevention. We will attempt to find promising approaches for service delivery that respond to treatment needs within resource constraints.

OEI; 00-00-00000

PHS AGENCIES-WIDE ACTIVITIES

Year 2000 Computer Renovation Plans

We will continue to evaluate the efforts of the Public Health Service (PHS) operating divisions, as well as those of the Program Support Center, to meet Year 2000 computer renovation and validation goals. The Federal Government's Year 2000 project strategy regarding computer systems places emphasis on ensuring that agencies' mission-critical systems are Year 2000 compliant before December 31, 1999, to avoid widespread system failures. Our work will focus on ensuring that the most critical systems have business continuity plans in place in the event of Year 2000 systems failures. This review is part of our Departmentwide Year 2000 compliance review.

OAS; W-00-98-40007; A-15-98-80002

Disclosure Statements Filed by Colleges and Universities

The OMB Circular A-21, revised May 8, 1996, requires that colleges and universities disclose their cost accounting practices by filing 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. Our continuing reviews will determine whether disclosure statements are complete and accurate, reflect current practices, and comply with cost accounting standards and pertinent cost principles.

OAS; W-00-00-50007; Various CINs

Recipient Capability Audits

At the PHS 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-00-00-50013; Various CINs

Reimbursable Audits

We will conduct a series of audits in accordance with OMB Circular A-133, which assigns audit cognizance for approximately 95 percent of the Nation's nearly 3,000 colleges and universities to the Inspector General of HHS. 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 recently incorporated in OMB Circular A-21.

OAS; W-00-00-50012; 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 have reviewed such issues as library allocations, medical liability insurance, internal service funds, fringe benefit rates, and space allocation. These assist audits have helped to substantially reduce indirect cost rates at the institutions reviewed.

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

Follow-Up 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 group has identified certain prior audits by nonfederal auditors as having circumstances that need further investigation.

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

INVESTIGATIONS

Referrals by Office of Research Integrity

As a result of a closer relationship being 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, that cannot be addressed by the Office of Research Integrity because it lacks such authority.