



Department of Health and Human Services

Office of Inspector General

Work Plan Public Health Service Agencies Projects

Fiscal Year 1999

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Inspector General**



Office of Inspector General

MISSION:

Under the authority of the IG Act, we improve HHS programs and operations and protect them against fraud, waste, and abuse. By conducting independent and objective audits, evaluations, and investigations, we provide timely, useful, and reliable information and advice to Department officials, the Administration, the Congress, and the public.

VISION

WE ARE GUARDIANS OF THE PUBLIC TRUST

-  Working with management, we will ensure effective and efficient HHS programs and operations.
-  Working with decision-makers, we will minimize fraud, waste and abuse in HHS programs.
-  Working with our talented and motivated staff, we will manifest the highest standards as a Federal OIG.

VALUES

WE VALUE:

-  Quality products and services that are timely and relevant.
-  A service attitude that is responsive to the needs of decision-makers.
-  Fairness, integrity, independence, objectivity, proficiency, and due care in performing our work.
-  Teamwork and open communication among OIG components.
-  A positive environment that supports our personal and professional needs and encourages us to be innovative and reach our full potential.

Department of Health and Human Services

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Work Plan for Fiscal Year 1999

INTRODUCTION

The Office of Inspector General (OIG) Work Plan is set forth in five chapters encompassing the various projects to be addressed during Fiscal Year (FY) 1999 by the Office of Audit Services, Office of Evaluation and Inspections, Office of Investigations, and Office of Counsel to the Inspector General. The first four chapters present the full range of projects planned in each of the Department of Health and Human Services' (HHS) major entities: the Health Care Financing Administration, the Public Health Service agencies, the Administration for Children and Families, and the Administration on Aging. The fifth chapter embraces those projects related to issues that cut across Department programs, including State and local government use of Federal funds, as well as the functional areas of the Office of the Secretary.

In preparing this edition of the OIG Work Plan, we have provided a brief description of the various project areas that we perceive as critical to the mission of the OIG and the Department. Unless otherwise noted, reports on all projects are expected to be issued in FY 1999. However, as the work planning process tends to be ongoing and dynamic, the focus and timing of many of these projects can evolve in response to new information, new issues, and shifting priorities of the Congress, the President, and the Secretary and may be altered over time.

Given these variables, the OIG objective still remains the targeting of available resources on those projects that best identify vulnerabilities in the Department's programs and

activities that have been designed to serve and protect the safety, health, and welfare of the American people and promote the economy, efficiency, and effectiveness of the Department's programs. The Health Insurance Portability and Accountability Act of 1996, strengthened by the Balanced Budget Act of 1997, brought much needed authorities and resources to achieving this objective.

Program Audits

The Office of Audit Services (OAS) conducts comprehensive financial and performance audits of departmental programs and operations to determine whether program objectives are being achieved and which program features need to be performed in a more efficient manner. The OAS also provides overall leadership and direction in carrying out the responsibilities mandated under the Chief Financial Officers Act of 1990 and the Government Management Reform Act of 1994 relating to financial statement audits.

The audit portion of the OIG Work Plan represents the most significant audit work that will be conducted in FY 1999.

Program Inspections

The Office of Evaluation and Inspections (OEI) seeks to improve the effectiveness and efficiency of departmental programs by conducting program inspections to provide timely, useful, and reliable information and advice to decision makers. These inspections are program and management evaluations that focus on specific issues of concern to the Department, the Congress, and the public. The inspections identified in this Work Plan focus on programs with significant expenditures of funds and services to program beneficiaries or in which important management issues have surfaced. The results of these inspections should generate accurate and up-to-date information on how well those programs are operating and offer specific recommendations to improve their overall efficiency and effectiveness.

Investigative Focus Areas

The OIG's Office of Investigations (OI) conducts investigations of fraud and misconduct to safeguard the Department's programs and protect the beneficiaries of those programs from individuals and activities that would deprive them of rights and benefits.

The OIG concentrates its resources on the conduct of criminal investigations relating to the programs and operations of HHS. These investigative activities are designed to prevent fraud and abuse in departmental programs by identifying systemic weaknesses in areas of program vulnerability that can be eliminated through corrective management actions, regulation or legislation, by pursuing criminal convictions; and by recovering the maximum dollar amounts possible through judicial and administrative processes, for recycling back to the intended beneficiaries.

Legal Counsel Focus Areas

The Office of Counsel to the Inspector General (OCIG) coordinates the OIG's role in the resolution of health care fraud and abuse cases, including the litigation and imposition of administrative sanctions, such as program exclusions, and civil monetary penalties and assessments; the global settlement of cases arising under the Civil False Claims Act; and the development of corporate agreements for providers that have settled their False Claims Act liability with the Federal Government. It also develops and promotes industry awareness of models for corporate integrity and compliance programs and monitors ongoing integrity agreements. The OCIG also provides all administrative litigation services required by OIG, such as patient dumping cases and all administrative exclusion cases. In addition, OCIG issues special fraud alerts and advisory opinions regarding the application of OIG's sanction statutes and is responsible for developing new, and modifying existing, safe harbor regulations under the anti-kickback statute. Finally, OCIG counsels OIG components on personnel and operations issues, subpoenas, audit and investigative issues, and other legal authorities.

Internet Address

The FY 1999 OIG Work Plan and other OIG materials, including final reports issued and OIG program exclusions, may be accessed on the Internet at the following address:

<http://www.hhs.gov/progorg/oig>

Department of Health and Human Services

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Public Health Service Agencies

Table of Contents

CENTERS FOR DISEASE CONTROL AND PREVENTION

Control and Oversight of Grantee Operations	1
Collaboration Between Public Health Agencies and Managed Care Organizations	1

FOOD AND DRUG ADMINISTRATION

Food Safety Inspections	2
Biennial Inspection Requirement	2
FDA Warning Letters	2
Arkansas Regional Laboratory Costs	3
Drug Adverse Event Reporting System	3
Blood Safety Consent Decrees	3
Sanctions of Clinical Investigators	4

HEALTH RESOURCES AND SERVICES ADMINISTRATION

State Licensure Boards and Discipline of Physicians	4
Managed Care Organizations' Reporting to the National Practitioner Data Bank	4
Training Programs in the Maternal and Child Health Bureau	5
Ryan White Comprehensive AIDS Resources Act	5
New York's Use of CARE Act Funding	6
Referral of Hospital Deaths to Organ Procurement Organizations	6
Grantee Satisfaction with HRSA Technical Assistance and Monitoring	6

Primary Care Effectiveness Reviews and Community Health Centers	7
HRSA's Management of the National Health Service Corps	
Scholarship and Loan Repayment Program	7
Cash Management Practices at Institutions Participating in the Health	
Professions and Nursing Student Loan Programs	8
Hemophilia Treatment Centers' Purchase of Drugs at Discount Prices	8

INDIAN HEALTH SERVICE

Impact of Self-Governance on IHS Services	8
Use of Self-Governance Funds by the Cherokee Nation of Oklahoma	9
Tribal Self-Governance Compact Award Process	9
Medicare Pricing for Contract Health Services Program: Outpatient Services ..	9

NATIONAL INSTITUTES OF HEALTH

Superfund Financial Activities for Fiscal Year 1998	10
Compliance with Federal Depository Library Program	10
Reporting Under the Bayh-Dole Act	10

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES

ADMINISTRATION

State Systems Development Program	11
Substance Abuse Treatment Needs of Welfare Recipients	11

PHS AGENCIES-WIDE ACTIVITIES

Year 2000 Computer Renovation Plans	12
Disclosure Statements Filed by Colleges and Universities	12
Recipient Capability Audits	13
Reimbursable Audits	13
Indirect Cost Audits	13
Follow-Up on Nonfederal Audits	13

INVESTIGATIONS

Referrals by Office of Research Integrity	14
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CENTERS FOR DISEASE CONTROL AND PREVENTION

Control and Oversight of Grantee Operations

We will determine whether CDC's internal and management controls are adequate to ensure that grantees accomplish program objectives effectively and efficiently. The CDC awards more than \$1.2 billion annually—more than half of its total budget authority—in grants to State, local, and territorial health departments; colleges and universities; nonprofit organizations; and other entities. Activities funded through these grants are essential to the accomplishment of CDC's mission in childhood immunization, disease prevention, AIDS education, and other programs. Building upon findings previously identified in nonfederal audits and in OIG audits (including those of CDC's financial statements), we will assess preaward and postaward policies, procedures, and practices related to the control and oversight of grantee operations.

OAS; W-00-99-50003; A-04-99-00000

Collaboration Between Public Health Agencies and Managed Care Organizations

We will provide an overview of the existing collaboration between managed care organizations and State and local government public health agencies. Funded through several Federal public health programs (including CDC), State and local agencies are responsible for providing population-based public health services and medical care to the uninsured, in addition to conducting surveillance and data collection to maintain the Nation's public health infrastructure. Before the growth of Medicaid managed care, they were also a major supplier of medical care to Medicaid clients. Now, Medicaid clients in most States receive care through managed care arrangements, and public health agencies no longer receive Medicaid reimbursement. Previously, many of the agencies had used this revenue to defray the cost of providing infrastructure and population-based services, as well as the cost of providing uncompensated care. As a result of this change, many public health agencies have begun to work collaboratively with managed care organizations to ensure that population-based services continue to be provided.

OEI; 01-98-00170

FOOD AND DRUG ADMINISTRATION

Food Safety Inspections

We will assess the progress made by the Food and Drug Administration in implementing the recommendations made in the 1991 OIG report on low-risk inspections and food safety. A number of recent outbreaks have brought national attention to the dangers of food-borne diseases. Several of these outbreaks have involved products used by food firms historically considered low-risk by the FDA. Concurrently, through the President's Food Safety Initiative, the Administration and the Department are focusing on food safety issues.

OEI; 00-00-00000

Biennial Inspection Requirement

We will assess FDA's ability to meet its statutory requirement to inspect drug and device manufacturers every 2 years. Such inspections are critical for FDA to ensure that firms are complying with good manufacturing practices. Previous OIG work in this area 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-00-99-50004; A-15-99-00000

FDA Warning Letters

We will evaluate FDA's process and effects of issuing warning letters for violations identified during inspections of drug and device manufacturing practices. The FDA issues warning letters to notify regulated entities about violations of a given regulation or policy under the agency's authority. The warning letter represents the first-line and most readily available of FDA's regulatory actions that may be taken against a regulated company not in compliance.

OEI; 09-97-00380

Arkansas Regional Laboratory Costs

As part of its plans to regionalize its laboratory structure, FDA is currently constructing a new, multidisciplinary regulatory laboratory facility in Arkansas for use by the Office of Regulatory Affairs. Our review will examine the reasons for cost increases of almost 40 percent for the Arkansas Regional Laboratory facility project. The cost to complete the laboratory is now estimated to be \$37.9 million. This assignment is being undertaken as part of a congressional request.

OAS; W-00-98-50004; A-15-98-50002

Drug Adverse Event Reporting System

We will assess FDA's system for obtaining, analyzing, and responding to adverse drug event reports. The FDA conducts postmarket surveillance on drugs to obtain information on rare, latent, or long-term effects not identified during premarket testing. Because the receipt of these reports is critical to FDA's ability to monitor the safety and effectiveness of marketed drugs, FDA is developing the Adverse Event Reporting System to compile and analyze more than 250,000 individual reports received each year. Results of our assessment will be periodically provided as the new reporting system is being developed.

OAS; W-00-98-50004; A-15-98-50001

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 collection 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-00-99-50004; A-03-99-00000

Sanctions of Clinical Investigators

We will assess the adequacy of departmental oversight of clinical investigators subject to FDA regulation. As part of its regulatory function, FDA has the power 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 parts of the Federal Government. 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 parts of the Department, such as the Medicare program and the NIH, have procedures for protecting their program beneficiaries from FDA-sanctioned researchers who may pose a threat.

OEI; 00-00-00000

HEALTH RESOURCES AND SERVICES ADMINISTRATION

State Licensure Boards and Discipline of Physicians

We will assess the performance of State boards responsible for the licensure 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 HRSA's relationship with the health professions and its own quality assurance activities (such as the National Practitioner Data Bank), HRSA has a longstanding interest in licensing board activities.

OEI; 00-00-00000

Managed Care Organizations' Reporting to the National Practitioner Data Bank

We will evaluate reporting to the National Practitioner Data Bank by managed care organizations. A managed care organization gives physicians authority to treat its

patients through a contractual relationship that makes the physician eligible for a panel. When such an organization decides to terminate or restrict the physician's membership on the panel, this adverse action, if taken because of competency or substandard care problems, must be reported to the data bank. Specifically, any professional review action that adversely affects the clinical privileges of a physician or dentist for a period longer than 30 days must be reported. Because of the national increase in the number of managed care organizations and the low level of reporting to the data bank, HRSA requested this review.

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 approximately 15 percent of funds appropriated for the Maternal and Child Health Block Grant be set aside for these special projects. Funding for training has generally been a major portion of the set-aside. According to HRSA budget data, \$37 million of the \$100 million set-aside in FY 1995 was used to fund training grants or projects. The training program has never been evaluated. We will address several issues, including how grants are awarded, what is being done to establish outcome data, the extent training is being targeted to meet demand, and the impact the grants have had on improving Maternal and Child Health services.

OEI; 04-98-00090

Ryan White Comprehensive AIDS Resources Act

We will review the progress made by HRSA and grantees in implementing past OIG recommendations. According to the Department’s FY 1998 budget, HHS is requesting over \$1 billion to fund the Ryan White Program for the next fiscal year, a 42 percent increase from FY 1994. In 1995, OIG issued a series of reports on Ryan White which included recommendations that the program place more emphasis on outcome evaluations at both the local and systems levels. The size of the program has increased significantly since these reports, making a follow-up study timely.

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 Resources Emergency (CARE) Act funds relative to the State's reimbursement pools for uninsured costs. The State administers three programs for HIV uninsured care: AIDS Drug Assistance (ADAP), ADAP Plus (Primary Care Services), and HIV Homecare Services. The CARE Act represents the largest authorization of Federal funds specifically designed to provide health and social services for people infected with HIV/AIDS. As part of this review, we will determine whether the State has systems and procedures in place to ensure applicants' eligibility for enrollment in the uninsured program (i.e., medical and income criteria) and the appropriateness and accuracy of payments made to providers. In addition, we will review the reasonableness, allocability, and allowability of the administrative costs claimed by the State for operating the programs.

OAS; W-00-99-50005; A-02-99-00000

Referral of Hospital Deaths to Organ Procurement Organizations

We will assess the implementation and impact on organ procurement organizations of State laws requiring hospitals to refer all deaths for consideration as organ donations. More than 55,000 Americans are waiting for life-saving organ transplants, yet only about 20,000 received transplants last year. Eight States have enacted laws requiring referrals as a way to address the shortage. Data from one State show that such a law has led to a 40 percent increase in donors. The Health Care Financing Administration has proposed such an approach in its draft Medicare "conditions of participation" for hospitals.

OEI; 00-00-00000

Grantee Satisfaction with HRSA Technical Assistance and Monitoring

We will survey community health centers to obtain feedback on technical assistance and monitoring activities provided by HRSA. These centers serve a population that includes Medicaid, Medicare, and the uninsured. Total HRSA funding to these centers amounts

to about \$700 million annually. This study was requested by the Bureau of Primary Health Care.

OEI; 00-00-00000

Primary Care Effectiveness Reviews and Community Health Centers

We will evaluate HRSA's oversight of community health centers. The HRSA uses the Primary Care Effectiveness Review, a multipart protocol, to monitor centers. The review covers a community health center's finances, administration, governance, and clinical or quality of care issues. We will focus on the use of the protocol in conducting quality of care reviews.

OEI; 00-00-00000

HRSA's Management of the National Health Service Corps Scholarship and Loan Repayment Program

We will review the National Health Service Corps' process for awarding scholarships and repaying educational loans. Under Section 338 of the Public Health Service Act, the Corps awards scholarships and loan repayments to health profession students and to fully trained health professionals who contractually agree to provide primary health services in health profession shortage areas. Expenditures for these activities amounted to over \$590 million for the 5-year period ending in fiscal year 1997, and receivables totaled \$124 million as of June 30, 1997. We will assess the effectiveness of the Corps' monitoring of recipients to ensure timely fulfillment of their contract obligations or timely recognition and collection of receivables in the event the recipients breach their contract obligations.

OAS; W-00-98-50005; A-15-98-00037

Cash Management Practices at Institutions Participating in the Health Professions and Nursing Student Loan Programs

The Health Professions Student Loan (HPSL) and Nursing Student Loan (NSL) Programs were established by the Congress in response to anticipated shortages of doctors, nurses, and other health professionals. The laws establishing these programs authorized funds for use by educational institutions in making long-term, low-interest loans to eligible students. Our review will determine how well institutions are managing funds made available to them for these loan programs.

OAS; W-00-98-50005; Various CINs

Hemophilia Treatment Centers' Purchase of Drugs at Discount Prices

At HRSA's request, we will examine hemophilia treatment centers' efforts to purchase an anti-hemophilic factor drug at 340B discounted prices. Section 340B of the Public Health Service Act provides that drug manufacturers that sell to eligible PHS entities must not charge more for covered drugs than the average manufacturers' price decreased by a rebate percentage. Hemophilia treatment centers are funded by HRSA and qualify for discount pricing under the law as eligible PHS entities; one of the drugs covered under Section 340B is the anti-hemophilic factor drug. Our review will also determine why some centers are not participating in the 340B program.

OAS; W-00-98-50005; A-01-98-01505

INDIAN HEALTH SERVICE

Impact of Self-Governance on IHS Services

We will assess the effect of Indian self-governance on 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-00-99-50006; A-06-99-00000

Use of Self-Governance Funds by the Cherokee Nation of Oklahoma

In response to a congressional request, we will review the use of Federal health care funds awarded to the Cherokee Nation of Oklahoma through the Indian Self-Determination and Education Assistance Act of 1975, as amended. This act allows tribes to operate their own health care programs with funds provided by IHS through self-governance compacts and annual funding agreements. Specifically, we will assess whether Federal funds have been spent in accordance with applicable laws, regulations, and policies.

OAS; W-00-98-50006; A-06-98-00060

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—39 compacts totaling \$410 million in FY 1998 and slated to increase—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-00-97-50006; A-15-97-50001

NATIONAL INSTITUTES OF HEALTH

Superfund Financial Activities for Fiscal Year 1998

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 1997, agency obligations and disbursements of Superfund resources amounted to \$54 million and \$60.4 million, respectively.

OAS; W-00-99-50025; A-04-99-00000

Compliance with Federal Depository Library Program

We will review NIH's commercial printing program to determine whether copies of publications are being provided to the Government Printing Office for distribution to depository libraries and foreign governments, where applicable. The Depository Library Program generally requires Government publications to be made available to depository libraries (usually located in existing public or academic libraries) through the Superintendent of Documents. The Congressional Joint Commission on Printing has expressed interest in this issue.

OAS; W-00-97-50025; A-15-98-80001

Reporting Under the Bayh-Dole Act

Through two reviews, we will evaluate NIH's procedures for ensuring that grantees disclose new inventions developed with NIH grant funds. Our first review will follow up on weaknesses identified several years ago with procedures for monitoring

compliance with reporting requirements of the Bayh-Dole Act at the Scripps Research Institute. We will also examine the accuracy and completeness of invention reporting by several other major research institutions, and we will assess NIH's system for ensuring that grantees make timely election regarding title of inventions, acknowledge NIH support in their patent applications, and provide NIH with a nonexclusive paid-up license to use the invention and obtain it without a royalty fee. Our second review will look at NIH's procedures for ensuring that recipients of Small Business Innovation Research program grants comply with Bayh-Dole Act invention reporting requirements regarding commercialization activities.

OAS; W-00-98-50025; A-15-98-00030, A-15-98-00039

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

State Systems Development Program

At SAMHSA's request, we will determine the impact of the agency's technical assistance to States under the State Systems Development Program. This program, which is administered by SAMHSA's Center for Substance Abuse Treatment, evaluates State treatment programs through "technical reviews" conducted by a private company under contract with the Center. Results are reported to the States. Technical assistance plans are developed as a result of these reports, and technical assistance is subsequently provided to States. States are reviewed every 3 years.

OEI; 00-00-00000

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. 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 evaluate the efforts of the 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 well before December 31, 1999, to avoid widespread system failures. As of May 1998, the Department reported to OMB that the PHS agencies had 127 mission-critical systems and that the Program Support Center had 8. This review is part of our Departmentwide Year 2000 compliance review.

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

Expected Issue Date: Periodic Reporting FYs 1999 and 2000

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-00-98-50007; Various CINs

Recipient Capability Audits

At the PHS agencies' request, 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-00-99-50013; Various CINs

Reimbursable Audits

We will conduct a series of audits in response to OMB Circular A-21, 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 Circular A-21.

OAS; W-00-99-50012; 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-00-99-50010; 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-00-99-50019; 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.