

**Department of Health and Human Services  
Office of Inspector General  
Projects**



**PUBLIC HEALTH AGENCIES  
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## CENTERS FOR DISEASE CONTROL AND PREVENTION

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### **Oversight of HIV/AIDS Prevention Grantees**

We will evaluate how and how well CDC's Division of HIV/AIDS Prevention oversees its grantees. We will examine the extent to which CDC monitors, or requires evidence of, grantees' oversight of their subgrantees' program management, effectiveness, and compliance with funding requirements. We will also determine how CDC uses this information to identify and react to concerns about grantee performance.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2003/2004*

### **CDC and Grantee Administration of HIV/AIDS Prevention Funds**

As part of a departmental effort, we will conduct a comprehensive review of CDC's HIV/AIDS programs and activities. At the headquarters level, we will evaluate whether CDC followed applicable laws, regulations, and other guidance in making funding decisions and determine how Global AIDS Program funds were allocated and expended. At the grantee and subgrantee levels, we will determine whether grantees complied with the programs' financial and performance reporting requirements and met grant performance expectations.

*OAS; W-00-02-52300; Various CINs*

*Expected Issue Date: FY 2003/2004*

### **Oversight of Immunization Grants**

We will assess the effectiveness of CDC's fiscal and programmatic review of both cash and "in kind" immunization grants, which represent CDC's largest grant program--currently funded at \$1.4 billion. These grants provide states and selected localities with funds and vaccine to establish and maintain programs to immunize individuals against vaccine-preventable diseases ranging from childhood diseases to influenza and pneumonia. Vaccines purchased and distributed under this program may be provided to private practitioners who agree not to charge patients. We will review grant requirements, examine grantee performance and financial reports for completeness and timeliness, determine if CDC appropriately evaluates the reports and conducts site visits, and evaluate whether corrective action is being taken as warranted.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2003*

## **Oversight of Preventive Health and Health Services Block Grants**

We will assess the extent to which CDC holds states accountable for achieving their objectives and performing their chosen activities under the \$135 million Preventive Health and Health Services Block Grants. This program provides the primary source of flexible funding for states to meet the broad objectives of Healthy People 2010. The grants require states to submit a state plan with selected health outcome objectives, descriptions of health problems, identified target populations, and planned activities. States are also required to submit reports detailing program activities and their impact, which CDC uses as its primary monitoring system. We will review the timeliness and completeness of these reports, CDC's enforcement of the reporting requirement, and actions taken when a state does not submit a timely or complete report.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2003*

## **National Breast and Cervical Cancer Early Detection Program**

This study will evaluate CDC's policies and practices for ensuring that grantees of the National Breast and Cervical Cancer Early Detection Program perform planned activities, assess progress, and achieve planned program goals as well as meet requirements for obtaining nonfederal matching funds and spending 60 percent of federal funds for screening, tracking, follow-up, and support services. We will assess CDC's procedures for obtaining and verifying such information from grantees and the corrective actions required of grantees that demonstrate poor programmatic or fiscal performance. This \$140 million cooperative agreement program, the largest of the three components of the National Cancer Prevention and Control Program, is intended to ensure breast and cervical cancer screening for low-income, underserved women.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2003*

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## **FOOD AND DRUG ADMINISTRATION**

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### **Human-Subject Protections for Children**

We will evaluate the role of institutional review boards in overseeing clinical research on children. The Office for Human Research Protections and FDA, the two departmental agencies that oversee clinical research, have regulations to protect children enrolled in clinical trials. Both rely on institutional review boards to monitor and carry out these regulations. Since the recent increase in clinical research on children is expected to continue, an examination of the protections afforded to them is needed.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2003*

## **Dietary Supplement Labels**

This study will assess the effectiveness of dietary supplement labels as a consumer safeguard. The Dietary Supplement Health and Education Act of 1994 does not require safety warnings on dietary supplements. However, the Federal Food, Drug, and Cosmetic Act authorizes FDA to require the disclosure of material facts concerning representations or consequences that may result from using a product. Since dietary supplements are self-care products, their product claims and warnings serve as key sources of consumer information about their intended effects, possible side effects, cautions for vulnerable populations, and potential drug interactions.

*OEI; 01-01-00120*

*Expected Issue Date: FY 2003*

## **FDA's New Drug Application Process**

At the request of FDA's Center for Drug Evaluation and Research, we will examine the FDA process for reviewing new drug applications under the Prescription Drug User Fee Act. Our review will identify any processes and program areas that can improve the effectiveness and stringency of these reviews and determine the effects of the act on the regulatory review of new drug applications.

*OEI; 01-01-00590*

*Expected Issue Date: FY 2003*

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# **HEALTH RESOURCES AND SERVICES ADMINISTRATION**

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## **Oversight of Ryan White CARE Act Grantees**

We will evaluate HRSA's oversight of Ryan White CARE Act Title I and II grantees and grantees' oversight of their subgrantees. We will examine the mechanisms HRSA uses to monitor grantees and the grantees' reporting obligations to HRSA, review the requirements HRSA places on grantees to monitor subgrantees and convey the results of that monitoring to HRSA, and determine how HRSA verifies this information and uses it to identify and react to concerns about grantee performance.

*OEI; 02-01-00640*

*Expected Issue Date: FY 2003*

## **Grantee Administration of Ryan White CARE Act Funds**

Based on our initial Title I and II review results, performed at the request of the Senate Committee on Finance, we will expand our work to the largest eligible metropolitan areas and

states: New York City, San Francisco, Miami, Los Angeles, and Washington, D.C., which account for over \$250 million, or over 40 percent, of Title I funding, and New York, California, Florida, Texas, and New Jersey, which receive almost \$450 million, or over 50 percent, of Title II funding. We will examine the grantees' expenditures, fiscal capabilities, and program performance. Our initial reviews identified questioned costs, including grantee and subgrantee costs that were not adequately supported. This study is being performed in conjunction with the above evaluation of oversight of Ryan White grantees.

*OAS; W-00-03-54250; Various CINs*

*Expected Issue Date: FY 2003/2004*

### **Ryan White Grant Programs as a Payer of Last Resort for HIV/AIDS Patients**

We will examine the use of Ryan White grant programs as a payer of last resort for HIV/AIDS patients. The Ryan White Care Act of 1990 states that funds received under the act may not be used to pay for services that would otherwise be covered "under a State compensation program, an insurance policy, or a Federal or State health benefits program." Therefore, if a Ryan White grantee provides services to a patient who qualifies for and/or is enrolled in Medicaid, Medicaid must be billed for the services. Ryan White funds are intended for those HIV/AIDS patients who are uninsured or underinsured.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2003*

### **Oversight of Grants to Community Health Centers**

This study will evaluate the effectiveness of HRSA's policies and practices for monitoring financial and program performance and for enforcing program requirements for Community Health Center grantees. This \$1.3 billion program funds more than 3,500 health care sites serving 11 million patients, of whom about 40 percent are uninsured, according to HRSA. The President seeks to expand this program to more than 4,500 sites caring for 16 million patients by 2006. Over the past decade, however, a series of reviews by OIG and the General Accounting Office (GAO) have highlighted potential program vulnerabilities, including insufficient oversight and financial management deficiencies. We will review grant requirements, examine grantee performance and financial reports for completeness and timeliness, determine if HRSA appropriately evaluates the reports and conducts site visits, and evaluate whether corrective action is being taken as warranted.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2003*

## **Effectiveness of Community Health Center Grants**

We will evaluate HRSA's measurement and tracking of Community Health Center grantees' performance to ensure that they effectively produce the intended outcome of this \$1.3 billion program--providing health care to the uninsured. We will also review HRSA's enforcement of grantee accountability for this outcome and the actions taken when a grantee demonstrates insufficient progress toward this end. Although HRSA relies heavily on required annual grantee reports through the Uniform Data System, GAO has found deficiencies in the timeliness, completeness, and accuracy of these data. This study will evaluate the quality of the data and review HRSA's processes for verifying the data.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2004*

## **Grant Oversight in the Children's Hospital Graduate Medical Education Program**

We will evaluate grantee compliance and performance under the Children's Hospital Graduate Medical Education Program and examine HRSA's enforcement of program requirements. In FY 2002, this \$285 million program funded 59 children's hospitals in 31 states. These hospitals train approximately 30 percent of the nation's pediatricians and nearly 50 percent of all pediatric subspecialists. We will review grant requirements, examine grantee performance and financial reports for completeness and timeliness, determine if HRSA appropriately evaluates the reports and conducts site visits, and evaluate whether corrective action is being taken as warranted.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2004*

## **Management of Nurse Training and Education Grants**

We will examine the effectiveness of HRSA's mechanisms for reviewing the approximately \$83 million Nurse Training and Education grant program, including oversight of reporting requirements and strategies to address noncompliance. Based on current trends, the nation is expected to face a 13-percent nursing shortage by 2010. Under the Health Professions Partnership Act of 1998, Title VIII, HRSA awards grants to accredited schools of nursing; nursing centers; academic health centers; state and local governments; and other private, nonprofit entities to support nursing workforce development. Title VIII provides funding preference to applicants with projects that will substantially benefit rural or underserved populations or help meet public health nursing needs in state and local health departments. We will review grant requirements, examine grantee performance and financial reports for completeness and timeliness, determine if HRSA appropriately evaluates the reports and conducts site visits, and evaluate whether corrective action is being taken as warranted.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2003*

## **Effectiveness of Nurse Training and Education Grants**

We will evaluate HRSA's effectiveness in tracking and ensuring that Nurse Training and Education grantees fulfill their performance obligations. This program awards about \$93 million in training grants to institutions and loan repayment grants to individuals. We will assess HRSA's process for tracking and enforcing grantee accountability for performance outcomes. For accredited nursing programs, performance outcomes include the enrollment and training of students who will practice nursing in understaffed areas. For an individual who received a loan repayment grant, the outcome is practicing nursing for a specified duration or in a designated area.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2004*

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## **INDIAN HEALTH SERVICE**

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### **Medical Credentialing and Privileging**

At the request of the Indian Health Service (IHS), we will assess whether IHS components that hire and employ medical professionals have complied with policies and procedures for credentialing and privileging medical personnel. The agency made the request following newspaper accounts that IHS had hired medical personnel with histories of convictions. We will follow up on a 1996 review of credentialing policies and procedures and identify information to assist IHS in screening health care professionals.

*OAS; W-00-02-55050; A-15-02-40001*

*Expected Issue Date: FY 2003*

### **Management of Controlled Substances**

We will review IHS's progress in improving accountability practices for controlled substances at IHS facilities. We will examine procedures for documenting, storing, dispensing, and administering these drugs and review inventory control procedures. The Office of Investigations has reported cases in which narcotics were dispensed in excess of prescribed doses; health care personnel acquired drugs through unauthorized removal from medicine cabinets, lock boxes, and crash carts; and charts were falsified.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2003*

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## NATIONAL INSTITUTES OF HEALTH

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### **Superfund Financial Activities for Fiscal Year 2002**

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 2001, agency obligations and disbursements of Superfund resources amounted to \$65.9 million and \$67.3 million, respectively.

*OAS; W-00-03-56001; A-04-03-00000*

*Expected Issue Date: FY 2003*

### **Commitment of Principal Investigators' Effort in Grant Applications**

This review will determine whether major research universities committed more than 100 percent of principal investigators' effort when applying for National Institutes of Health (NIH) training grants and, if so, whether the resulting grant awards were inflated. Recent work found that one major research university routinely overcommitted the principal investigator's efforts on applications for federal training awards. The NIH funds grant proposals on a cost-reimbursable basis and considers the investigator's role in deciding whether to fund the proposal. If a university promises more of the proposed investigator's time than is available, the NIH funds intended to pay for salary could possibly be used for costs not included in the proposal and the research quality could be affected.

*OAS; W-00-03-56002; A-05-03-00000*

*Expected Issue Date: FY 2004*

### **Management and Oversight of Research Grants**

We will assess the adequacy of NIH's postaward financial and programmatic review of extramural research grants. In FY 2001, NIH awarded approximately \$16.8 billion to more than 50,000 researchers affiliated with about 2,000 university, hospital, and other research facilities. Prior work by GAO found problems with the internal controls for overseeing research project and program project grants at several NIH institutes. Focusing on other funding mechanisms, including cooperative agreements, we will review oversight practices at several institutes. We will review grant requirements, examine grantee performance and financial reports for completeness and timeliness, determine if NIH appropriately evaluates the

reports and conducts site visits, and evaluate whether corrective action is being taken as warranted.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2003*

### **Grantee Administration of Funds**

We will evaluate whether selected NIH grantees have followed laws, regulations, and other federal guidance (such as Office of Management and Budget circulars) in their administration of grant activities and use of grant funds. We will assess each grantee's performance against the objectives outlined in the grant award and examine actual expenditures.

*OAS; W-00-03-56200; Various CINs*

*Expected Issue Date: FY 2004*

### **College and University Compliance With Grant Requirements**

This study will evaluate the policies and procedures that colleges and universities, which received more than \$12 billion in NIH awards in FY 2001, use to comply with NIH requirements for the programmatic administration of grants. The NIH requires grantees to comply with all provisions of its Grants Policy Statement. Previous OIG work revealed problems with universities' procedures for financial reporting and monitoring of NIH funds. We will review grant requirements, examine grantee performance and financial reports for completeness and timeliness, determine if NIH appropriately evaluates the reports and conducts site visits, and evaluate whether corrective action is being taken as warranted.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2003*

### **Clinical Research Center Construction Project**

This review will determine why costs have increased for construction of the Mark O. Hatfield Clinical Research Center and whether any "lessons learned" might help strengthen controls over costs and improve accountability on future construction projects. The NIH estimates that overall costs for this project will total \$505 million, which is \$145 million more than estimated in March 2000. The project is being constructed through a General Services Administration contract.

*OAS; W-00-02-56003; A-03-02-00371*

*Expected Issue Date: FY 2003*

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

We will assess the effectiveness of NIH procedures for awarding funds to general clinical research centers, whose mission is to provide a research infrastructure for clinical investigators

who receive their primary support from NIH and other federal agencies. For FY 2002, NIH estimated that it would award \$260 million to more than 75 centers nationwide. The NIH uses two approaches to fund the centers, discrete and per diem. 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-00-03-56004; Various CINs*

*Expected Issue Date: FY 2004*

### **Monitoring Adverse Events in Clinical Research**

We will determine the adequacy of NIH practices to ensure that grantees comply with federal regulations on reporting and monitoring adverse events in clinical trials. We will also examine the use of data safety monitoring boards, which provide scientifically based reviews vital to the safety of subjects and required by NIH for later stage clinical trials. These boards analyze adverse event reports during clinical trials to determine if the trials are safe enough to continue. In FY 2001, NIH awarded \$6.3 billion in competing and noncompeting clinical research grants. This review will examine NIH's policies and procedures and grantees' policies and procedures to comply with NIH requirements.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2004*

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## **SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION**

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### **Oversight of Grants**

We will assess the effectiveness of the Substance Abuse and Mental Health Services Administration's grant management and oversight. Our review will include vulnerability assessments of the grant award and monitoring system, an assessment of the overall grantmaking procedures, and reviews of selected grantees.

*OAS; W-00-03-57200; Various CINs*

*Expected Issue Date: FY 2004*

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## PUBLIC HEALTH AGENCIES-WIDE ACTIVITIES

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### **Risk Determinations in Grant Management**

We will examine NIH, CDC, and HRSA compliance with departmental grant policy directives to (1) determine each grantee's risk of poor programmatic use or financial stewardship of funds, (2) use the HHS Alert List in making risk determinations, and (3) impose and monitor special award conditions for high-risk grantees. For each agency, we will also assess the criteria and process for determining grantee risk and the development and monitoring of corrective action plans for high-risk grantees. The NIH, CDC, and HRSA awarded \$22.8 billion in grants in FY 2001.

*OEI; 00-00-00000*

*Expected Issue Date: FY 2003*