

Public Health Agencies

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Agency for Health Care Research & Quality

Grants Management Activities

We will evaluate the Agency for Healthcare Research and Quality (AHRQ) monitoring and oversight of its research and training grant program, which was funded at \$113 million for FY 2004. For FY 2005, AHRQ has requested \$85.8 million for research grants and \$13.1 million for training grants. We will evaluate whether selected AHRQ grantees, including patient safety grantees, have followed Federal guidance in their administration of grants activities and use of grant funds.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Centers for Disease Control and Prevention

Strategic National Stockpile

We will review efforts by the Centers for Disease Control and Prevention (CDC) to ensure that pharmaceutical stockpiles are secure from theft, tampering, or other loss; are maintained in an environmentally appropriate condition; and are available for immediate use as needed. The Strategic National Stockpile Program, for which CDC and the Department of Homeland Security share management responsibility, is designed to supplement and restock State and local public health agency pharmaceutical supplies in the event of a biological or chemical incident in the United States or its territories. These stockpiles are stored at strategic locations for the most rapid response possible, and CDC is responsible for ensuring that the materials in these facilities are adequately protected and stored.

(OAS; W-00-04-52001; A-04-04-00000; expected issue date: FY 2005; work in progress)

Bioterrorism Preparedness: Distribution of CHEMPACK

This study will evaluate the extent of State and local government preparedness for distribution of the Strategic National Stockpile (SNS) CHEMPACK assets and determine the extent of CDC's role in providing support for these activities. The Stockpile Program, established in 1999, is a repository of drugs, antidotes, and medical supplies designed to supply States and localities in the event of biological or chemical disasters. The program has developed a pilot project in a limited number of States and localities for the forward placement of nerve gas antidotes, known as the "SNS CHEMPACK." Because exposure to chemical agents requires immediate response, States and localities need to have pharmaceuticals on hand at all times to ensure rapid distribution in the event of a disaster.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Oversight of Bioterrorism Preparedness and Response Cooperative Agreements: Oversight of Grants Monitoring

We will review current mechanisms for monitoring grants awarded by CDC's Bioterrorism Preparedness and Response Cooperative Agreement Program. This Program began in 1999 with \$40 million and has rapidly grown to over \$2 billion dollars in funding available for grantees. CDC has undertaken considerable efforts to assist States and localities in implementing the Program, and has recently issued new guidance. At the same time, CDC has a limited number of staff dedicated to monitoring States' use of these funds. We will review various aspects of grants monitoring, including grant requirements, roles and responsibilities of grants officers and project officers, as well as training for these staff and education for grantees. *(OEI; 00-00-00000; expected issue date: FY 2005; new start)*

Local Health Departments' Bioterrorism Preparedness

We will follow up on our 2002 report, "State and Local Bioterrorism Preparedness," which found that all 12 sampled States and 36 sampled local health departments were underprepared to detect and respond to bioterrorism. This study will assess the progress made by the same local health departments during the last 2 years. We will ask health department officials to complete a self-assessment tool based on the Core Capacity Project, which included CDC's most current preparedness benchmarks in 2002, and to provide documentation on how they fund their preparedness programs.

(OEI; 02-03-00056; expected issue date: FY 2005; work in progress)

Bioterrorism Preparedness: State 24/7 Reporting Systems

We will determine the capacity of State and local health departments to receive and process disease reports 24 hours a day, 7 days a week (24/7). Most health departments use communicable disease reporting as their primary method for bioterrorism surveillance. However, our 2002 review found that many local health departments still did not have the capacity to receive and process these reports on a 24/7 basis. CDC's Bioterrorism Preparedness and Response Cooperative Agreement Program has funded the improvement of surveillance capacity since 1999. As of 2002, States were required to develop the "capacity for detecting biopathogens through a highly functioning mandatory reportable disease surveillance system . . ." and to prepare a timeline for developing such a system at the State and local levels. We will assess States' progress in meeting this required critical capacity.

(OEI; 04-03-00540; expected issue date: FY 2005; work in progress)

State Public Health Laboratories' Bioterrorism Preparedness

We will determine the extent to which laboratories that confirm the presence of bioterror agents are prepared to handle increased testing in a bioterrorism event or public health emergency, and we will assess the extent to which these laboratories are receiving support from CDC to strengthen their testing capacity. Since 1999, CDC has funded State public health laboratories,

with a goal of helping laboratories build up their own capacity as well as to help strengthen collaboration among laboratories through the formation of the Laboratory Response Network. A recent OIG review, “States’ Laboratory Response Programs for Bioterrorism: Level A Laboratory Participation” (OEI-02-03-00030), examined the coordination between sentinel laboratories (referred to as Level A) and reference laboratories, and found that although some coordination is occurring between them, many were overwhelmed during the 2001 anthrax events. This study will address whether reference laboratories are now better prepared to handle a bioterror event.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Health Alert Network

We will evaluate State health departments’ implementation of the Health Alert Network, which CDC established to improve communication between public health agencies and their partners and to aid in CDC distance learning activities. Our 2002 review of State and local bioterrorism preparedness found that while the network appeared to work at the State and Federal levels, it was not fully operational at the local level. Specifically, two-way communication between States and local health departments was not common, and information technology capacity was limited.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Early Implementation of Biowatch: An Interagency Review

As part of an interagency effort with the Department of Homeland Security’s (DHS) and Environmental Protection Agency’s (EPA) OIGs, we will review the early implementation of the Biowatch Program. DHS provides the funding, management, and policy oversight for Biowatch; through CDC, HHS provides laboratory expertise. CDC’s role is to provide separate laboratories within the Laboratory Response Network to analyze daily readings collected by EPA. In addition, CDC provides guidance to State and local health departments on planning for public health emergencies which might arise from the detection of a biological pathogen. We will assess current capacities of Network laboratories to undertake these tasks and review how CDC is assisting the coordination of State and local entities responsible for this initiative.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Compliance With Select Agent Regulations by Private and State Laboratories

We will assess private and State laboratory compliance with HHS select agent regulations. Select agents are substances that could be used in bioterrorist attacks. Earlier reviews assessed compliance only at Federal and university laboratories. Consistent with the objectives of our FY 2004 university reviews, we will assess select agent management oversight, security planning and implementation, accountability, and the identification and screening of personnel with access to select agents.

(OAS; W-00-05-52006; A-00-00-00000; expected issue date: FY 2005; new start)

Review of Surveillance System

We will follow up our FY 2004 review of CDC's National Electronic Disease Surveillance System, which is being developed to transfer appropriate public health, laboratory, and clinical data efficiently and securely over the Internet. CDC contracted for systems development and awarded grants to State and local health agencies for implementation. We will determine (1) the overall project status, (2) States' progress, (3) whether CDC is monitoring the extent of States' progress, and (4) whether CDC is monitoring the contractor to ensure it meets project needs and schedule goals.

(OAS; W-00-05-40022; A-03-00-00000; expected issue date: FY 2005; new start)

Tuberculosis Control Among Undocumented Immigrant Detainees Released Into the Community

We will evaluate whether undocumented immigrant detainees with tuberculosis (TB) who are released into the community are completing TB treatment. CDC is responsible for preventing, controlling, and eliminating TB in the United States. CDC funds State and local health departments to carry out many of these activities at a level of about \$136 million annually. Undocumented persons apprehended by the Department of Homeland Security's Bureau of Immigration and Customs Enforcement are detained pending deportation or released into the community in the U.S. to await a court hearing of their immigration case. The TB rate in the bureau's processing centers (where many detainees are held) is 12 times higher than the national average and 2.5 times the rate for the U.S. foreign-born population. Of particular concern is compliance with the TB treatment regimen after release from detention into the community; if treatment is discontinued, a person can develop multidrug-resistant TB. We will examine the procedures and practices in place to screen and treat detainees for TB and to follow up with released detainees to assure TB treatment is completed.

(OEI; 00-00-0000; expected issue date: FY 2005; new start)

Controls Over Grantee Cash Withdrawals

We will determine whether CDC and the Division of Payment Management have properly managed open grant accounts on the Payment Management System. This system is used to transfer cash available from Federal grants to grantees. We will review the management and accounting controls that CDC and the system use to ensure that grantees' withdrawals are limited to authorized amounts and within appropriate time limits.

(OAS; W-00-05-52007; A-04-00-00000; expected issue date: FY 2006; new start)

Food and Drug Administration

Integrity of Research Involving Human Subjects

We will determine whether the Food and Drug Administration (FDA) is conducting research involving human subjects in a manner consistent with applicable laws, regulations, and policies. The Commissioner of Food and Drugs requested that we assess the effectiveness of corrective actions the agency has implemented in recent years to strengthen the integrity of clinical research conducted within the agency. Such corrective actions include implementing quality control programs and requiring training and certifications of its clinical investigators.

(OAS; W-00-04-53001; A-06-03-00087; expected issue date: FY 2005; work in progress)

Implementation of Clinical Trials Data Bank

We will evaluate drug industry compliance with the 1997 statutory requirement (Public Law 105-115 § 113) that drug manufacturers submit information on clinical trials involving life-threatening or serious conditions to the clinical trials data bank (<http://ClinicalTrials.gov>) maintained by the National Library of Medicine. Effective May 2002, drug sponsors are to submit clinical trial protocol information to the Web site including descriptive information on the trial, recruitment information, location/contact information, and administrative data (protocol number/study sponsor). FDA estimated that drug companies would submit about 1,600 protocols annually. As of April 2004, drug manufacturers submitted a total of 750 protocols for clinical trials that were recruiting patients. We will assess FDA's efforts and identify reasons for the discrepancy.

(OEI; 00-00-0000; expected issue date: FY 2005; new start)

FDA Monitoring of Postmarketing Studies

We will determine to what extent FDA monitors postmarketing study commitments agreed to by drug applicants (pharmaceutical companies), and whether applicants complete postmarket study commitments in a timely manner. FDA requires all pharmaceutical companies seeking approval to market a new drug undertake testing to demonstrate the drug's effectiveness and safety prior to its approval for sale in the United States. Because premarket clinical trials are limited, pharmaceutical companies often agree to conduct additional postmarket studies at the time a drug is approved. As of September 2002, FDA reported that 1,339 postmarket commitments were not yet completed. In prior work, OIG found problems with FDA's ability to monitor postmarket study commitments. We will determine whether FDA has made improvements since our prior work.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

FDA Oversight of Reassignments of National Drug Codes

We will examine FDA's oversight of National Drug Code (NDC) reassignments for pharmaceuticals currently in commercial distribution. The Drug Listing Act of 1972 requires drug manufacturers to register their establishments and list all of their commercially marketed drug products with FDA. Each drug product is assigned an NDC. Drug manufacturers assign a product number and package size code to each drug or class of drugs. Manufacturers must notify FDA of any changes in product characteristics, assign a new NDC number to the new product version, and submit that information to FDA. We will determine the effectiveness of FDA's oversight and monitoring of such reassignments.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

FDA Oversight of Direct-to-Consumer Advertising

We will examine the effectiveness of FDA's oversight of direct-to-consumer advertising. According to the Government Accountability Office, direct-to-consumer advertising is the fastest-growing expenditure for pharmaceutical companies. In 2001, pharmaceutical companies spent \$2.7 billion on such advertising, up from \$55 million just 10 years earlier. Many restrictions on direct marketing were relaxed in 1997. We will determine the effectiveness of FDA procedures for monitoring direct-to-consumer advertisements and what actions are taken against drug companies that provide false or misleading advertisements.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

FDA Oversight of Off-Label Drug Promotion

We will assess FDA's oversight and review of allowable promotion of off-label drug uses by drug manufacturers and describe FDA's oversight and enforcement of prohibited promotion of off-label drug uses by manufacturers, including challenges to monitoring and enforcing compliance. Under 21 CFR § 201.56(c), "no implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness." However, well-publicized accounts of off-label use of drugs suggest that off-label prescribing practices may put patients at risk. Prohibited off-label promotion of drugs presents particular challenges and vulnerabilities because FDA generally does not have access to internal information on drug manufacturers' marketing practices and materials and cannot systematically monitor manufacturers' compliance.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

State Licensure of Drug Wholesalers

We will determine how and to what extent FDA ensures that States are carrying out their licensing responsibilities as stated in the Prescription Drug Marketing Act of 1987. The Act includes a provision that requires a wholesale distributor of prescription drugs to be State licensed and requires the FDA to establish minimum requirements for State licensing. We will also determine how and to what extent wholesale drug distributors that do not meet the

minimum Federal requirements receive licenses from the States. Licensing of wholesale distributors helps to ensure the integrity of the Nation's drug supply. An inadequate system can permit distribution of outdated or counterfeit drugs.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

FDA Oversight of Blood Establishments

We will assess FDA's oversight and review of blood establishments to ensure the safety of the nation's blood supplies. FDA is statutorily required to inspect all registered blood establishments every 2 years. These inspections are conducted by FDA's Office of Regulatory Affairs in coordination with its Center for Biologics Evaluation and Research, which regulates the collection of blood and blood components and regulates related products such as blood collection containers. The center oversees these areas through licensure and inspection of all blood establishments and by monitoring reports of biological product deviations in the manufacturing process.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Adverse Event Reporting for Medical Devices

We will determine the extent to which manufacturers and user facilities comply with mandatory reporting requirements for adverse events associated with medical devices. FDA requires medical device manufacturers to report deaths, serious injuries, and device malfunctions to FDA within 30 calendar days, or within 5 working days if the event requires remedial action to prevent substantial harm to the public. We will assess how and to what extent FDA ensures that manufacturers and user facilities comply with adverse event reporting requirements for medical devices. Device reporting is a key part of FDA's oversight of new medical devices, providing an early warning of problems with devices new to the market. We will also evaluate how and to what extent FDA uses medical device adverse event reports to identify and address safety concerns.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

FDA's Financial Disclosure Requirements for Clinical Investigators

We will assess the nature of financial interests disclosed by clinical investigators to FDA; the extent to which drug, biologic, and device applicants monitor their clinical investigators for conflicting financial interests; and the extent to which FDA monitors the financial interests disclosed by clinical investigators. FDA regulations require clinical investigators who conduct studies in support of a product to disclose their financial interest. Financial conflicts of interest create a potential for bias that may have a negative impact on the integrity of the data and on the protection of human subjects.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Review of FDA Employee Outside Activities

We will describe how FDA addresses issues related to employees' outside activities, which may represent potential conflicts of interest. Federal employees must adhere to both governmentwide and program-specific ethical standards, which include provisions on conflict of interest. The provisions typically require that employees disclose outside activities, which are then screened for their potential to create conflicts of interest, and which should be dealt with by agency officials. A recent incident raised questions about the potential for FDA employees to engage in outside activities with significantly regulated entities.
(*OEI: 00-00-00000; expected issue date: FY 2005; new start*)

Health Resources and Services Administration

Hospital Surge Capacity

This review will focus on the surge capacity guideline of the Health Resources and Services Administration (HRSA) Hospital Bioterrorism Preparedness Program, which calls for States to accommodate 500 patients per 1 million population. We will conduct onsite evaluations in a small number of States to determine the extent to which the guideline is being met. We will also survey all States to gain a broad overview of how this guideline is being met, if States are encountering barriers, and their interaction with HRSA to facilitate preparedness.
(*OEI; 04-03-00500; expected issue date: FY 2005; work in progress*)

Ryan White CARE Act—Analysis of the Use of Funding

This review will examine the distribution and use of Ryan White CARE Act funding over a 5-year period by all Title I and II grantees. Based on a recent Institute of Medicine publication and the observations made during our recent audits of Title I and II grantees, we plan to examine the use of funds, including carryover funds, by all grantees. Our analysis will identify variations among grantees and address whether HRSA has adequate authority over the distribution and allocation of funds.
(*OAS; W-00-03/04-54250; A-02-00-00000; expected issue date: FY 2005; work in progress*)

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 Title I of 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 or another Federal health benefit program, Medicaid or the other program must be billed first for the services.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Oversight of Maternal and Child Health Block Grant

We will review HRSA's monitoring of the \$750 million Maternal and Child Health Block Grant, which includes funding for special projects of regional and national significance as well as statewide programs for the development and expansion of integrated community service systems. Our evaluation will examine HRSA's use of programmatic and fiscal oversight mechanisms, such as Government Performance and Results Act measures, required reporting by grantees, site visits, and subgrantee monitoring. Several years ago, our review of a set-aside grant identified problems involving monitoring and incomplete data. We will also assess progress in addressing the problems identified in our previous review.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Oversight of 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 2003, this \$290 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 2005; new start)

HRSA's Oversight of the Nursing Workforce Development Grants

We will examine the effectiveness of HRSA's oversight and monitoring of the Nursing Workforce Development grant program. Funded at \$142 million in FY 2004, this program focuses on ensuring adequate supply and distribution of qualified nurses to meet the Nation's health care needs. Our review will include oversight of reporting requirements, examine grantee financial and performance reporting for completeness and timeliness and determine if HRSA appropriately evaluates the reports and conducts site visits, and evaluate whether appropriate action is being taken as warranted. The Health Professions Partnership Act of 1998 was amended by the Nurse Reinvestment Act of FY 2002 and gives HRSA additional authorities to enhance the nursing workforce.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Oversight of Organ Procurement and Transplantation Network

We will assess the nature and extent of the Department's oversight of the Organ Procurement and Transplantation Network. The National Organ Transplant Act of 1984 established the

network, which is charged with operating and monitoring an equitable system for allocating organs, maintaining a waiting list of potential recipients, matching potential recipients with donors, and increasing donation. All transplant centers and organ procurement organizations must be network members to receive Medicare reimbursement. HRSA contracts with the United Network for Organ Sharing for administration of the network. In 1999, the Institute of Medicine found that Federal oversight of the organ transplantation system fell short. Our assessment will encompass the Department's response to the Institute's recommendations. (OEI; 00-00-00000; expected issue date: FY 2005; new start)

Followup Actions to 340B Drug Discount Program Report, "Appropriateness of 340B Prices"

OIG will follow up on the price discrepancies discovered in our 2004 evaluation of the 340B Drug Discount Program by exploring potential reasons for price discrepancies within the Department and will provide information to pharmaceutical manufacturers, wholesalers, and covered entities to independently resolve discrepancies. Our report, "Appropriateness of 340B Pricing" (OEI-05-02-00070), found that over one-third of the sampled covered entities' prices exceeded the ceiling price guaranteed in law, resulting in an estimated \$41 million in overpayments in 1 month. Thirty-one percent of drug prices sampled were above the mandatory ceiling price, and 36 of the 37 sampled entities were overcharged at least once. The focus of this followup work is to identify the possible reasons for price discrepancies at the Departmental level.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Indian Health Service

Safeguards Over Controlled Substances at IHS

We will evaluate control procedures for pharmaceuticals used in Indian Health Service (IHS) facilities, with emphasis on safeguards over controlled substances. Using criteria established by FDA, the Drug Enforcement Administration, and IHS, we will evaluate the practices used to purchase, inventory, dispense, and administer pharmaceuticals. Weaknesses in these practices could result in the misappropriation of costly pharmaceutical products, especially controlled substances.

(OAS; W-00-05-55100; A-06-00-00000; expected issue date: FY 2006; new start)

Management of the Special Diabetes Program

We will evaluate IHS grants management activities involving the Special Diabetes Program for Native Americans. The Congress reauthorized the program in 2004 at a level of \$150 million for each of the next 5 years. IHS has awarded over 300 noncompetitive grants to tribes and Urban Indian Programs for diabetes prevention/treatment under the authority of the program.

Diabetes has been the most frequently identified health problem in IHS Area Office budget discussions. Type 2 diabetes occurs at dramatically higher rates among Native American adults, who are almost three times more likely to have diabetes than the general U.S. population.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

National Institutes of Health

University Administrative and Clerical Salaries

We will determine whether colleges and universities have appropriately charged administrative and clerical salaries to federally sponsored grants and cooperative agreements. OMB Circular A-21 provides that such costs should usually be treated as indirect costs. However, direct charging of these costs may be appropriate when the nature of the work performed under a particular project requires extensive administrative or clerical support.

(OAS; W-00-05-56009; A-00-00-00000; expected issue date: FY 2005; new start)

Recharge Centers

We will determine whether colleges and universities have complied with Federal cost principles. A previous OIG review of recharge centers found that 11 of 12 universities did not maintain adequate accounting systems and records. Weaknesses resulted in duplicate or unallowable costs in billing rates, use of recharge center funds for unrelated purposes, and accumulated surplus fund balances.

(OAS; W-00-05-56008; A-00-00-00000; expected issue date: FY 2005; new start)

Level of Commitment

We will determine whether major research universities committed more than 100 percent of principal investigators' effort when applying for National Institutes of Health (NIH) grants and, if so, whether the resulting grant awards were inflated. 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-00-05-56002; A-00-00-00000; expected issue date: FY 2005; new start)

Safeguards Over Controlled Substances at NIH

We will evaluate control procedures for pharmaceuticals used in NIH intramural clinical settings, with emphasis on safeguards over controlled substances. Using criteria established by FDA, the Drug Enforcement Administration, and NIH, we will evaluate the practices used to purchase, inventory, dispense, and administer pharmaceuticals. Weaknesses in these practices

could result in the misappropriation of costly pharmaceutical products, especially controlled substances.

(OAS; W-00-05-56006; A-00-00-00000; expected issue date: FY 2006; new start)

Royalty Income From Intramural Inventions

We will determine whether NIH collects the royalty income earned from new technologies developed by Federal employees in its research laboratories. NIH has a statutory mandate to ensure that such promising new technologies are transferred to the private sector for commercialization. Typically, NIH seeks patent protection for these inventions and enters into a royalty-bearing licensing agreement with private entities to use or commercialize the technology. This technology transfer licensing program generates over \$52 million a year in NIH revenue. Our review will determine whether NIH ensures that it receives royalty income on all products to which it is entitled, the royalties are calculated correctly, and payments are received in a timely manner.

(OAS; W-00-04-56007; A-03-00-00000; expected issue date: FY 2005; work in progress)

Employee Conflicts of Interest at NIH

We will describe how NIH addresses issues related to employee conflicts of interest. Federal employees must adhere to both governmentwide and program-specific ethical standards, which include provisions on conflict of interest. The provisions require that employees disclose all conflicts of interest, which are then screened for severity and handled accordingly. A recent investigation raised questions about employee conflicts of interest at NIH and cited several cases in which senior-level NIH officials responsible for overseeing millions of dollars in research grants concurrently had private business relationships with organizations that had business pending before their divisions. We will compare NIH's policies and practices for employee conflict of interest to those of other Federal agencies, both within and outside of the Department, as well as private organizations to assess their relative rigor and comprehensiveness.

(OEI; 01-04-00150; expected issue date: FY 2005; work in progress)

Superfund Financial Activities for Fiscal Year 2004

As required by Superfund legislation, we will conduct this annual financial audit of payments, obligations, reimbursements, and other uses of Superfund monies by the National Institute of Environmental Health Sciences. The institute's Superfund activities, carried out by its own staff and through cooperative agreements, include training for people engaged in hazardous waste activities and studying the effects of exposure to specific chemicals. During FY 2003, agency obligations and disbursements of Superfund resources amounted to \$85.7 million and \$81.3 million, respectively.

(OAS; W-00-05-56001; A-04-04-00000; expected issue date: FY 2005; new start)

Cross-Cutting Public Health Activities

Implementation of Select Agent Regulations by University Laboratories

Following our first series of reviews, which identified a pattern of weakness in select agent security, we will assess the security of additional university laboratories that have select agents. At each university, we will determine whether (1) laboratories have adequate physical security to prevent unauthorized entry to areas with select agents, (2) adequate inventory controls have been implemented to keep track of select agents, (3) CDC regulations on possessing and transferring select agents are followed, and (4) the institution forwards the names of persons handling select agents to the Attorney General's office for a background search. These additional reviews are important because new legal requirements have been imposed on institutions having select agents since our initial reviews. Further, for selected universities reviewed during FY 2003, we will assess the corrective actions taken in response to our recommendations.

(OAS; W-00-04-56100; various reviews; expected issue date: FY 2005; work in progress)

Implementation of Select Agent Regulations by Departmental Laboratories

We will determine whether CDC, FDA, and NIH have complied with CDC regulations on possessing and transferring select agents and with the Secretary's March 2002 memorandum, which directed the agencies to implement 12 requirements to better control and secure the select agents in their laboratories.

(OAS; W-00-05-58004; various reviews; expected issue date: FY 2005; new start)

Bioterrorism Preparedness Expenditures

Based on the results of limited-scope reviews in 18 States, we will perform detailed reviews of bioterrorism preparedness expenditures in several States with the largest grant awards. In FY 2004, HHS awarded approximately \$1.5 billion through cooperative agreements between States and HRSA or CDC for bioterrorism preparedness. We will determine whether States used these funds in accordance with the cooperative agreements and departmental regulations.

(OAS; W-00-05-58005; A-05-00-00000; expected issue date: FY 2005; new start)

Risk Determinations in Grant Management

We will examine CDC and HRSA compliance with departmental grant policy directives (1) to use the HHS Alert List in making risk determinations, and (2) to impose and monitor special award conditions for high-risk grantees on such 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. CDC and HRSA awarded \$9.2 billion in grants in FY 2003.

(OEI; 02-03-00010; expected issue date: FY 2005; work in progress)

Grants to Community Health Centers

We will determine whether HHS-funded community health centers provided nonduplicative services, met program performance measures, and ensured that Federal funds were spent appropriately. Community health centers may receive grants from HRSA, CDC, the Substance Abuse and Mental Health Services Administration, and the Office of Minority Health. Our review of program performance will include an assessment of whether the funded level of services was provided for each HHS program and whether similar program services reached different populations and clients. Our financial reviews will determine whether costs claimed on each grant complied with Federal guidelines, with emphasis on the allocation of costs among the various grants.

(OAS; W-00-04-58006; various reviews; expected issue date: FY 2005; work in progress)

Review of Adverse Event Reports by Institutional Review Boards

We will assess how institutional review boards (IRBs) use adverse event reports as a tool to protect human subjects. Adverse event reports can serve as a key tool to protect human subjects by helping IRBs understand the potential risks associated with ongoing studies. Federal regulations require clinical investigators to report to IRBs “any unanticipated problems involving risks to human subjects or others.” The OIG’s previous work surfaced concerns with IRBs’ use of adverse event reports. We intend to assess the extent to which IRBs receive useful information in adverse event reports, have adequate processes for reviewing adverse event reports, and factor adverse event reports into their decisions to recommend changes to a clinical trial.

(OEI; 00-00-00000; expected issue date: FY 2005; new start)

Privacy of Medical Records

We will conduct an early assessment of colleges’ and universities’ policies and procedures for protecting the privacy of medical records of persons participating in NIH-funded clinical trials and other research. In response to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandate, HHS developed the first Federal privacy standards to protect patients’ medical records. These new standards, which were effective in April 2003, provide patients with access to their medical records and more control over how their personal health information is used and disclosed. The HHS Office for Civil Rights (OCR) oversees and enforces the standards at colleges and universities that are covered universities. We will seek advice from OCR to ensure that the universities we select for review are covered by the HIPAA privacy rule.

(OAS; W-00-05-58007; A-01-00-00000; expected issue date: FY 2005; new start)

Time and Effort Reporting Compliance Through Single Audits

We will determine how and to what extent single audits assess and document colleges’ and universities’ compliance with time and effort reporting requirements of OMB Circular A-21.

The single audit process, required by OMB Circular A-133, represents the Federal Government's primary internal control over costs claimed under Federal projects. The annual OMB Circular A-133 Compliance Supplement directs auditors of research and development programs to test the time and effort reporting system to support the distribution of salaries and wages. However, the extent to which the single audits currently assess time and effort reporting systems is largely unknown.

(OEI; 05-03-00230; expected issue date: FY 2005; work in progress)

Investigations

Violations of Select Agent Regulations

Since the events of September 11, 2001, we have received numerous requests for information and investigations on terrorist and bioterrorist activities. On December 13, 2002, HHS issued an interim final rule on Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73). We are developing an initiative to pursue violations of these new regulations through civil monetary penalties.

We are also working with CDC, the FBI, and the Department of Agriculture to establish a protocol for the investigation of potential criminal violations of the statute governing the registration, storage, and transfer of select agents and toxins.

Legal Counsel

In addition to providing day-to-day internal legal advice and representation to OIG, the Office of Counsel to the Inspector General coordinates OIG's role in the resolution of civil and administrative fraud cases and promotes compliance measures by recipients of HHS grant funding. Work planned in FY 2005 includes the following:

Compliance Program Guidance for Recipients of Research Grants

One major initiative of OIG is the issuance of compliance program guidance to assist recipients of HHS funding in establishing voluntary compliance programs and in developing effective internal controls that promote adherence to applicable Federal statutes, regulations, and program requirements. The adoption and implementation of voluntary compliance programs significantly advances the stewardship responsibilities of the Department's grantee institutions. Similar to the compliance program guidance OIG has published for the health care industry, we are developing Draft Compliance Program Guidance for Recipients of NIH Research Grants. We are reviewing public comments received in FY 2004 in response to a Solicitation of Information and Recommendations and plan to issue draft guidance in FY 2005 for further comment.

Resolution of False Claims Act Cases

We will continue to work closely with OIG investigators and auditors and with prosecutors from DOJ to develop and pursue False Claims Act cases against institutions which receive grant funds from NIH and other PHS agencies. We will provide further assistance to DOJ prosecutors in litigation and in settlement negotiations arising from these cases.