

Public Health Agencies

Table of Contents

Agency for Healthcare Research and Quality

Patient Safety Grants.....	1
----------------------------	---

Centers for Disease Control and Prevention

Strategic National Stockpile.....	1
State and Local Preparedness to Receive and Deploy the Strategic National Stockpile	1
Oversight of Bioterrorism Cooperative Agreements	2
Local Health Departments' Bioterrorism Preparedness.....	2
State Laboratory Response Network.....	2
Health Alert Network.....	2
Reportable Disease Surveillance.....	3
National Electronic Disease Surveillance System	3
CDC and Grantee Administration of HIV/AIDS Prevention Funds.....	3
Oversight of Immunization Grants	4
Oversight of Preventive Health and Health Services Block Grants	4
National Breast and Cervical Cancer Early Detection Program	4

Food and Drug Administration

Oversight of Intramural Clinical Trials.....	5
Integrity Issues Related to Clinical Trial	5

Health Resources and Services Administration

Hospital Bioterrorism Preparedness Program.....	5
Oversight of Ryan White CARE Act Grantees.....	6
Grantee Administration of Ryan White CARE Act Funds	6
Ryan White Grant Programs as a Payer of Last Resort for HIV/AIDS Patients	6
Financial Capabilities of Community Health Centers	6
Monitoring and Impact of Community Health Center Grants	7
Medical Malpractice Claims Against Health Centers.....	7
Oversight of Maternal and Child Health Block Grant	7
Grant Oversight in the Children's Hospital Graduate Medical Education Program	8
Management of Nursing Workforce Development Grants	8
Effectiveness of Nursing Workforce Development Grants	8

Indian Health Service

Medical Credentialing and Privileging	9
Urban Indian Health Program	9
Management of Controlled Substances.....	9

National Institutes of Health

Design and Construction of Biodefense Laboratories	9
Superfund Financial Activities for Fiscal Year 2003.....	10
Management and Oversight of Research Grants.....	10
Grantee Administration of Funds.....	10
Safeguards Over Controlled Substances	10
Monitoring Adverse Events in Clinical Trials	11
Grantee Compliance With Invention Reporting Requirements	11
Royalty Income From Intramural Inventions.....	11
Recharge Centers	11
University Administrative and Clerical Salaries.....	12

Substance Abuse and Mental Health Services Administration

SAMHSA's Role in Terrorism Preparedness	12
Oversight of Grants	12

Cross-Cutting Public Health Activities

Followup on Departmental Laboratory Security	12
Security of University Laboratories.....	13
Implementation of Select Agent Recommendations.....	13
Bioterrorism Preparedness Expenditures	13
Reporting by Family Planning Clinics.....	13
Privacy of Medical Records	14
Time and Effort Reporting Requirements.....	14

Investigations

Violations of Select Agent Regulations.....	14
---	----

Agency for Healthcare Research and Quality

Patient Safety Grants

We will evaluate Agency for Healthcare Research and Quality (AHRQ) monitoring and oversight of its patient safety grant program, which was funded at \$55 million in FY 2002. In a 1999 report, the Institute of Medicine estimated that, based on studies in New York, Utah, and Colorado, as many as 98,000 people die each year as a result of medical errors in hospitals. In response to the findings in that report, AHRQ has funded grants to improve patient safety. Our study will look at how AHRQ monitors and oversees these grants, many of which were made in response to the findings of the institute's report, as well as how the agency makes the results of the grants available to key stakeholders.

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

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 medical material in these storage facilities is rotated and kept within potency shelf-life limits.

(OAS; W-00-02-52001; A-04-02-08002; expected issue date: FY 2004)

State and Local Preparedness to Receive and Deploy the Strategic National Stockpile

This study will follow up on our 2002 review of State and local preparedness to receive and deploy the Strategic National Stockpile. We will assess the progress of States and localities in the 10 components of preparedness since our last review and since their receipt of Federal preparedness funding. While CDC and the Department of Homeland Security are responsible for managing the stockpile, States are responsible for determining the extent of a bioterrorist event and requesting stockpiled materials when needed. State and local authorities must ensure the safe and timely receipt, storage, and use of the materials. In FY 2002, CDC provided \$950 million to State and local health departments for bioterrorism preparedness,

including planning and preparedness for using the stockpile.
(*OEI; 04-03-00140; expected issue date: FY 2004*)

Oversight of Bioterrorism Cooperative Agreements

We will assess CDC's fiscal and programmatic review of States' implementation of the Bioterrorism Preparedness and Response Cooperative Agreement Program, which grew from \$67 million in FY 2001 to about \$950 million in both FYs 2002 and 2003. CDC began funding States' bioterrorism preparedness in 1999. While CDC has developed comprehensive guidelines for States to follow in expanding their bioterrorism programs, States are being asked to spend an extraordinary amount of funds with little planning time. At the same time, CDC has a limited number of staff dedicated to monitoring States' use of these funds. 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 2004*)

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 is CDC's performance guidance, and to provide documentation on how they fund their preparedness programs. The Office of the Assistant Secretary for Public Health Emergency Preparedness expressed interest in this study.
(*OEI; 00-00-00000; expected issue date: FY 2004*)

State Laboratory Response Network

We will examine barriers to developing effective and efficient practices for improving laboratory capacity and identify ways that CDC can work with State and local entities to overcome any barriers. Our 2002 review found that while CDC had outlined the Federal Laboratory Response Network to strengthen the Nation's ability to identify bioterrorism, the network was not fully implemented at the State and local levels. We also noted that State and local laboratory capacity was severely tested by the anthrax events of 2001 and that lines of communication and referral roles were not always clearly understood.
(*OEI; 02-03-00030; expected issue date: FY 2004*)

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. 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 2004)

Reportable Disease Surveillance

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. 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 24 hours a day, 7 days a week. Delays in the processing of these reports could mean a delay in detecting and responding to a bioterrorist attack. 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 "Critical Capacity to detect a terrorist event 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; 00-00-00000; expected issue date: FY 2004)

National Electronic Disease Surveillance System

This review will assess efforts to develop the National Electronic Disease Surveillance System, a sophisticated information technology network to detect the early-warning signs of bioterrorism or disease, such as the recent outbreak of Severe Acute Respiratory Syndrome. The system is a new national initiative to improve the timeliness, completeness, accuracy, and uniformity of health surveillance data. It includes use of the Internet for data collection and transmission, collection of data as close to the source as possible, electronic laboratory reporting, and uniform coding schemes and data transmission protocols. We will determine whether (1) States that received antibiterrorism funding are compliant with system requirements, (2) the system designer is meeting the needs of HHS stakeholders, and (3) system controls are adequate to ensure data integrity.

(OAS; W-00-04-40022; A-03-04-00000; expected issue date: FY 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 has established adequate oversight to ensure that grantees' financial and programmatic activities comply with laws, regulations, and other guidance. We will also evaluate CDC oversight policies and procedures, including periodic financial and programmatic reporting, onsite monitoring, technical assistance, subrecipient monitoring, and factors affecting continuation funding. At the grantee and subrecipient levels, we will determine whether these

entities implemented CDC program activities and claimed costs in accordance with Federal guidelines.

(OAS; W-00-02-52300; various reviews; expected issue date: FY 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 2005)

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 and the President's HealthierUS Initiative.

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 2004)

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 non-Federal matching funds and spending 60 percent of Federal funds for screening, tracking, followup, 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 2005)

Food and Drug Administration

Oversight of Intramural Clinical Trials

As requested by the Food and Drug Administration (FDA), we will review the effectiveness of several corrective actions that the agency is implementing to provide better control and oversight of its clinical trials. In response to concerns that have been raised about the integrity of clinical trials performed under FDA's auspices, the agency is initiating an agencywide inventory of clinical trials; developing quality control programs in each FDA center; ensuring that research is conducted under the appropriate regulatory scheme for the product being tested; and initiating a mandatory educational and certification program for all FDA clinical investigators on the scientific, regulatory, and ethical issues regarding clinical research. Our objective will be to determine if these and other actions are sufficient to avoid integrity issues with the agency's clinical research.

(OAS; W-00-04-53001; A-03-04-00000; expected issue date: FY 2004)

Integrity Issues Related to Clinical Trial

At FDA's request, we will determine whether a specific clinical trial performed under the agency's auspices followed policies and procedures on safeguarding participant records, maintaining the confidentiality of participants' personal medical records, and conforming to the requirements of the institutional review board overseeing the study. The clinical trial involved a study of whether a nutritional supplement effectively increased bone density.

(OAS; W-00-03-50014; A-03-03-00378; expected issue date: FY 2004)

Health Resources and Services Administration

Hospital Bioterrorism Preparedness Program

This review will focus on the surge capacity requirement of the Health Resources and Services Administration (HRSA) Hospital Bioterrorism Preparedness Program, which calls for State-defined regions to accommodate 500 patients for every 1 million people in the region. We will survey a projectable sample of hospital regions to determine whether they have met this requirement. Additionally, we will identify how they are incorporating nonhospital entities (such as community health centers and poison control centers) in meeting the 500-patient goal and how long they could sustain increased capacity. Using a smaller sample of States, we will follow up by interviewing officials at public health agencies and hospital associations to determine the level and effectiveness of HRSA guidance and technical assistance and identify State plans for meeting the surge capacity goals.

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

Oversight of Ryan White CARE Act Grantees

We will evaluate HRSA's oversight of grantees under the Ryan White CARE Act, titles I and II, and the AIDS Drug Assistance Program, as well as 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, -00642; expected issue date: FY 2004)

Grantee Administration of Ryan White CARE Act Funds

Based on our initial results of title I and II reviews, performed at the request of the Senate Committee on Finance, we will expand our work to three large and two small eligible metropolitan areas, which account for \$200 million, or over 33 percent, of title I funding. We will also review five States and a territory, which collectively receive more than \$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 reviews; expected issue date: FY 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 or another Federal program, Medicaid or the other program 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 2004)

Financial Capabilities of Community Health Centers

In response to the President's plan to fund 1,200 new and expanded health center sites over a 5-year period, we will work with HRSA officials to review the financial management systems of prospective grantees before funds are awarded. Such reviews assist the agency in determining whether potential grantees have adequate accounting and reporting systems to meet Federal guidelines. The President's FY 2004 budget calls for an increase of \$169 million for

community health centers, for a total budget of \$1.6 billion. The increase is expected to serve an additional 1.2 million individuals in approximately 120 new sites and 110 expanded, existing sites.

(OAS; W-00-04-54050; A-00-04-00000; expected issue date: FY 2004)

Monitoring and Impact of Community Health Center Grants

We will evaluate HRSA's programmatic oversight and tracking of community health center grantees' performance to ensure that they effectively produce the intended outcome of this \$1.6 billion program--providing health care to the underserved. 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. HRSA relies on Primary Care Effectiveness Reviews and annual grantee reports (through the Uniform Data System) to monitor the performance of grantees, and we will include both mechanisms in our study. The President seeks to expand the community health center program from 3,500 sites to more than 4,500 sites and from 11 million patients to 16 million by 2006.

(OEI; 00-00-00000; expected issue date: FY 2004)

Medical Malpractice Claims Against Health Centers

This study will evaluate the timeliness of the review process for medical malpractice claims against health centers funded by HRSA. Since 1993, health centers have had the option of being covered under the Federal Tort Claims Act and thereby avoiding payment of medical malpractice premiums. Medical malpractice claims against health centers, which increased from 3 in FY 1994 to 188 in FY 2002, are processed by three HHS components: the Program Support Center, HRSA, and the Office of General Counsel. Under the Federal Tort Claims Act, plaintiffs are allowed to file a lawsuit against HHS if HHS does not settle the claim within 180 days. Lengthy and costly litigation may then follow. This study is expected to be a forerunner to a study of health centers' risk management activities.

(OEI; 01-03-00050; expected issue date: FY 2004)

Oversight of Maternal and Child Health Block Grant

We will review HRSA's monitoring of the \$850 million Maternal and Child Health Block Grant, of which 15 percent of appropriated funding not in excess of \$600 million is set aside for special projects of regional and national significance and 12.75 percent of any funding in excess of \$600 million is set aside for the development and expansion of integrated community service systems. Any remaining funds are allocated to the States. Our evaluation will examine HRSA's oversight mechanisms, such as Government Performance and Results Act (GPRA) measures and data reporting. 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 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 2005)

Management of Nursing Workforce Development Grants

We will examine the effectiveness of HRSA's mechanisms for reviewing the approximately \$113 million Nursing Workforce Development 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 title VIII of the Health Professions Partnership Act of 1998, 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 2004)

Effectiveness of Nursing Workforce Development Grants

We will evaluate HRSA's effectiveness in tracking and ensuring that Nursing Workforce Development grantees fulfill their performance obligations. Funded at approximately \$113 million in FY 2003, this program focuses on ensuring adequate supply and distribution of qualified nurses to meet the Nation's health care needs. The program consists of multiple grants, including Advanced Education Nursing grants and Workforce Diversity grants to institutions, as well as Loan Repayment and Scholarship grants to individuals. We will assess HRSA's process for tracking and enforcing grantee accountability for performance outcomes.

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

Indian Health Service

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-00-03-55050; A-06-03-00014; expected issue date: FY 2004)

Urban Indian Health Program

This review will assess whether the IHS Urban Indian Health Program is meeting the health care needs of American Indians and Alaskan Natives who reside in urban areas. This \$30 million program provides grants and contracts to more than 34 nonprofit organizations to render such services as ambulatory medical care, dental care, community outreach, and other specialized health services needed by urban Indians. According to the most recent census, over 50 percent of U.S. Indians live in urban areas. OMB has expressed interest in this review.

(OAS; W-00-04-55101; A-00-04-00000; expected issue date: FY 2005)

Management of Controlled Substances

We will evaluate control procedures for pharmaceuticals used in 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-00-04-55100; A-06-04-00000; expected issue date: FY 2005)

National Institutes of Health

Design and Construction of Biodefense Laboratories

We will determine whether the National Institutes of Health (NIH) has ensured that biodefense facilities are designed and constructed to meet Federal laws and regulations on the safety and security of laboratories that conduct biodefense research on select agents. As part of its efforts to improve the Nation's defense against bioterrorism, NIH plans to devote substantial funding to construct more biosafety level-3 and -4 laboratories and create up to 10 regional Centers of

Excellence for Biodefense and Emerging Disease Research. The overall goal is to develop and maintain the necessary infrastructure to support research and training activities.
(OAS; W-00-04-56010; A-03-04-00000; expected issue date: FY 2004)

Superfund Financial Activities for Fiscal Year 2003

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 2002, agency obligations and disbursements of Superfund resources amounted to \$73.2 million and \$66.9 million, respectively.
(OAS; W-00-03-56001; A-04-03-08009; expected issue date: FY 2004)

Management and Oversight of Research Grants

We will determine the extent to which NIH awards noncompeting continuation grants and closes out grants on time. NIH is the largest Federal funder of health research and development. About 80 to 85 percent of its budget supports extramural grants to scientists and organizations outside NIH. In FY 2001, NIH awarded more than \$16.8 billion in extramural grants to 50,000 researchers affiliated with more than 2,500 universities, hospitals, and other research facilities.
(OEI; 01-03-00020; expected issue date: FY 2004)

Grantee Administration of Funds

We will evaluate whether selected NIH grantees have followed laws, regulations, and other Federal guidance, such as OMB 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. We will select grantees of the agency's Human Genome Research Institute, where total grant awards have increased rapidly in recent years and now approach \$500 million annually.
(OAS; W-00-04-56200; various reviews; expected issue date: FY 2005)

Safeguards Over Controlled Substances

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-00-04-56006; A-00-04-00000; expected issue date: FY 2005)

Monitoring Adverse Events in Clinical Trials

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. These boards, which are required to be used for later stage clinical trials, analyze adverse event reporting during clinical trials to determine if the trials are safe enough to continue.

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

Grantee Compliance With Invention Reporting Requirements

We will determine whether grantees and contractors have complied with Federal regulations on reporting inventions developed under NIH grants or contracts. We will also examine how and to what extent NIH tracks, monitors, and requires invention reporting by its grantees and contractors. Finally, we will determine whether NIH has received royalty-free licenses to inventions developed under its grants and contracts.

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

Royalty Income From Intramural Inventions

We will assess NIH's collection of royalty income resulting 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-03-04-00000; expected issue date: FY 2005)

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-00-04-56008; A-00-04-00000; expected issue date: FY 2004)

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 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-00-04-56009; A-00-04-00000; expected issue date: FY 2004)

Substance Abuse and Mental Health Services Administration

SAMHSA's Role in Terrorism Preparedness

We will review the extent to which the Substance Abuse and Mental Health Services Administration's (SAMHSA) grants have enabled States to prepare for and respond to the mental health and substance abuse effects of terrorism and other disasters. SAMHSA's \$4 million State Capacity for Emergency Response program awards grants to States to adopt and implement mental health and substance abuse plans addressing all hazards, including natural disasters, accidents, mass violence, terrorism, and bioterrorism. SAMHSA provides technical assistance, guidance, and support under this program.

(OEI; 00-00-00000; expected issue date: FY 2004)

Oversight of Grants

We will assess the effectiveness of SAMHSA'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 an evaluation of the process used to ensure that grants are achieving their intended purposes.

(OAS; W-00-03-57200; various reviews; expected issue date: FY 2004)

Cross-Cutting Public Health Activities

Followup on Departmental Laboratory Security

We will perform selected followup reviews at NIH, CDC, and FDA laboratories, focusing on whether these facilities have implemented our recommendations for bolstering physical security and determining if additional safeguards are necessary. Given the Nation's heightened awareness of the potential for bioterrorist attacks, it is critical that we continue to

assess the security of departmental laboratories and the select agents housed within them. (OAS; W-00-03-58100; various reviews; expected issue date: FY 2004)

Security of University Laboratories

Following our first series of reviews, which identified a pattern of weakness in select agent security, we will assess the security of 10 additional university laboratories that have select agents. Select agents are substances that could be used in bioterrorist attacks. 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, at selected universities reviewed during FY 2003, we will assess the corrective actions taken in response to our recommendations.

(OAS; W-00-03-56100; various reviews; expected issue date: FY 2004)

Implementation of Select Agent Recommendations

We will determine whether CDC, FDA, and NIH have complied with steps delineated in the Secretary's March 2002 memo and identify any areas where the agencies can improve their select agent controls. The Secretary directed the agencies to implement 12 requirements to better control and secure the select agents in their laboratories.

(OAS; W-00-04-58004; various reviews; expected issue date: FY 2004)

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 inadequate accounting controls. In FY 2003, HHS spent \$4.3 billion on bioterrorism preparedness, most of it through cooperative agreements between States and HRSA or CDC. We will determine whether States used these funds in accordance with the cooperative agreements and departmental regulations.

(OAS; W-00-04-58005; various reviews; expected issue date: FY 2004)

Reporting by Family Planning Clinics

We will determine the effectiveness of HHS efforts to ensure grantee compliance with family planning reporting requirements in cases of child abuse, child molestation, sexual abuse, rape, or incest. Title X of the Public Health Service Act authorizes grants for voluntary family planning services, primarily for low-income women. These grant funds are included in HRSA's budget. In accordance with the law, the Office of Population Affairs, which administers title X, requires grantees to comply with State reporting laws relating to the

identification of child abuse, child molestation, sexual abuse, rape, or incest. Our study will examine oversight of this reporting requirement by the Office of Population Affairs.
(*OEI; 00-00-00000; expected issue date: FY 2004*)

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 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 oversees and enforces the standards.

(*OAS; W-00-04-56005; A-00-04-00000; expected issue date: FY 2005*)

Time and Effort Reporting Requirements

We will determine how and to what extent single audits assess and document colleges' and universities' compliance with the 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 time and effort reporting systems to support the distribution of salaries and wages. However, the extent to which single audits currently assess these systems is largely unknown.

(*OEI; 05-03-00230; expected issue date: FY 2004*)

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, OIG issued an interim final rule on Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 1003). We are developing an initiative to pursue violations of these new regulations through civil monetary penalties.