
Work Plan Part V: Public Health Reviews

Table of Contents

Public Health Agencies	1
Agency for Healthcare Research and Quality	2
Bioterrorism Epidemic Outbreak Response Model.....	2
Centers for Disease Control and Prevention.....	2
Monitoring of Subrecipient Emergency Preparedness Expenditures.....	2
States' 24/7 Reporting Systems	2
Radiological and Nuclear Preparedness: Assessing Selected State and Local Public Health Emergency Response Plans.....	3
Shelf Life Extension Program.....	3
Vaccines For Children Program: Storage and Management of Vaccines	3
Food and Drug Administration	4
Complaint Investigation Process	4
Oversight of Food Safety Operations.....	4
Oversight of State Food Facility Inspections.....	4
FDA Reportable Food Registry	5
FDA's Oversight of Investigational New Drug Applications.....	5
FDA's Policies and Procedures for Resolving Scientific Disputes	5
510(k) Process for Device Approval	5
FDA's Oversight of Postmarketing Surveillance Studies of Medical Devices.....	6
Submission of Electronic Drug Labels	6
Health Resources and Services Administration	7
Ryan White CARE Act Payer of Last Resort Provision	7
Human Immunodeficiency Virus (HIV) Testing in Health Centers	7
Indian Health Service.....	7
Accounting for Medication Inventory	7
IHS Medicaid Reimbursements	8
Background Investigations To Protect Indian Children	8
Mental Health and Dialysis Services at Indian Health Service and Tribal Facilities	8
National Institutes of Health	8
Superfund Financial Activities for Fiscal Year 2009.....	8
National Institute of Environmental Health Science's Grant Process.....	9
Colleges' and Universities' Compliance With Cost Principles.....	9
Review of Extra Service Compensation Payments Made By Education Institutions	9
Recharge Centers at Colleges and Universities	9
Use of Data and Safety Monitoring Boards in Clinical Trials	10
National Institute of Allergy and Infectious Diseases' Oversight of Project BioShield Grants	10
National Center for Research Resources' Oversight of Clinical and Translational Science Awards.....	10
Substance Abuse and Mental Health Services Administration	11

Substance Abuse Prevention and Treatment Block Grants.....	11
Progress in Meeting Performance Goals for the Substance Abuse Treatment Block Grant Program	11
SAMHSA Oversight of High-Risk Grantees	11
Cross-Cutting Public Health Activities.....	12
Conflict of Interest Waivers at the Department of Health & Human Services	12
Use of Public Health Preparedness and Response for Bioterrorism Program Funds for Employee Compensation	12
Pandemic Influenza Planning	12
Public Health Investigations.....	13
Violations of Select Agent Requirements	13
Public Health Legal Activities	13

Note: selected acronyms and abbreviations of terms, titles, organizations, and laws used in the Work Plan are spelled out in Appendix B.

Public Health Reviews

Public Health Agencies

Public health activities and programs represent the country's primary defense against acute and chronic diseases and disabilities and provide the foundation for the Nation's efforts to promote and enhance the health of the American people. Public health agencies within the Department of Health & Human Services (HHS) include the following:

- Agency for Healthcare Research and Quality (AHRQ). AHRQ sponsors and conducts research that provides evidence-based information on health care outcomes, quality, costs, use, and access.
- Centers for Disease Control and Prevention (CDC). CDC operates a system of health surveillance to monitor and prevent disease outbreaks, including bioterrorism; implements disease prevention strategies; and maintains national health statistics.
- Food and Drug Administration (FDA). FDA is responsible for ensuring the safety of the Nation's food, drugs, medical devices, biologics, cosmetics, and animal food and drugs.
- Health Resources and Services Administration (HRSA). HRSA maintains a safety net of health services for people who are low income or uninsured or who live in rural areas or urban neighborhoods where health care is scarce.
- Indian Health Service (IHS). IHS provides or funds health care services for American Indians and Alaska Natives.
- National Institutes of Health (NIH). NIH supports medical and scientific research examining the causes of and treatments for diseases, such as cancer, human immunodeficiency virus (HIV), and acquired immunodeficiency syndrome (AIDS).
- Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA funds services to improve the lives of people who have or are at risk for mental and substance abuse disorders.

Issues related to public health are also addressed by several offices within the Office of the Secretary. For example, the Office of the Assistant Secretary for Preparedness and Response (ASPR) serves as the Secretary's principal advisor on matters related to Federal public health preparedness and response to public health emergencies. The Office of Human Research Protections oversees the protection of volunteers involved in research.

Descriptions of work in progress and work planned for fiscal year (FY) 2011 follow.

Agency for Healthcare Research and Quality

Bioterrorism Epidemic Outbreak Response Model

We will survey and review State and local governments to determine the extent to which they are aware of and use the Bioterrorism Epidemic Outbreak Response Model (BERM) and “Community-Based Mass Prophylaxis: A Planning Guide for Public Health Preparedness” (the planning guide). The Pandemic and All-Hazards Preparedness Act of 2006 established ASPR within HHS and provided new authorities for a number of preparedness and response activities, including the development of guidance for States and localities to use when preparing for large-scale public health emergencies. In 2001, AHRQ developed the BERM Model, and at the request of the Office of Public Health Emergency Preparedness (OPHEP), BERM model 2.0 was released in 2005. OPHEP was ASPR’s predecessor and funded the planning guide in 2004. We will also determine whether BERM and the planning guide meet States’ and localities’ needs for planning for medical surge (medical evaluation and care during events that exceed the limits of the normal medical infrastructure of an affected community) and community-based mass prophylaxis (measures designed to preserve health or prevent the spread of disease).

(OEI; 00-00-00000; expected issue date: FY 2012; new start)

Centers for Disease Control and Prevention

Monitoring of Subrecipient Emergency Preparedness Expenditures

We will review the adequacy of one State’s monitoring of subrecipient expenditures charged to the Public Health Emergency Preparedness (PHEP) program. The purpose of the program is to upgrade and integrate State and local public health jurisdictions’ preparedness for and response to terrorism and other public health emergencies. The Office of Management and Budget (OMB) Circular A-87, *Cost Principles for State, Local, and Indian Tribal Governments*, App. B, § h(3) and the Code of Federal Regulations (CFR) at 2 CFR pt. 225, require State grantees of the PHEP program to provide time and effort certifications for employees who are expected to work solely on that Federal award. Regulations at 45 CFR § 92.40, require grantees to also manage and monitor day-to-day operations of subgrantees to ensure compliance with Federal requirements. A prior review disclosed that one State was not able to provide the required certifications for its employees who charged 100 percent of their time and effort to the PHEP program. We will determine whether similar salary charges have been made at the subrecipient level and assess the adequacy of the State’s subrecipient expenditure-monitoring process.

(OAS; W-00-11-58140; expected issue date: FY 2011; new start)

States’ 24/7 Reporting Systems

We will review the status of States’ systems for receiving urgent reports of bioterrorism agents and other public health emergencies. Pursuant to the Public Health Service Act (PHS Act), § 319C-1 (42 U.S.C. §§ 247d-3a), CDC funds PHEP Cooperative Agreements that include critical

tasks that States must accomplish to improve the timeliness and accuracy of communications about threats to the public's health and to decrease the time needed to classify health events, such as terrorism or naturally occurring disasters. The State must operate urgent disease and public health emergency reporting systems 24 hours per day, 7 days per week (24/7 systems). The 24/7 systems enable health care providers to report to or consult with State or local health department staff at any time about suspected or confirmed diseases that require urgent reporting. We will evaluate States' 24/7 systems to assess State preparedness for receiving urgent reports and the functionality of the systems.

(OEI; 00-00-00000; expected issue date: FY 2012; new start)

Radiological and Nuclear Preparedness: Assessing Selected State and Local Public Health Emergency Response Plans

We will review the extent to which selected States and/or localities have developed and exercised radiological and nuclear (RN) public health emergency response plans. According to CDC and Department of Homeland Security (DHS) guidance documents, States and localities will be the first to respond to an RN incident. To respond to such incidents, CDC provides guidance to States and localities on how to develop RN preparedness plans. We will also determine the extent to which selected States and/or localities are prepared to respond to the public health needs of the population in the event of an RN incident.

(OEI; 04-10-00250; expected issue date: FY 2011; work in progress)

Shelf Life Extension Program

We will determine whether CDC is utilizing the Shelf Life Extension Program (SLEP), managed by FDA, to extend the expiration dates on Strategic National Stockpile (SNS) drugs in lieu of destroying expired drugs and replacing them. In 2002, the CDC entered into a memorandum of agreement for SLEP to reduce the cost of replacing SNS inventory. The SNS maintains significant amounts of pre-positioned drugs to prepare for emergencies. While all drugs have an expiration date set by the manufacturer, the actual shelf life of certain drugs, if stored properly, can be much longer. We will verify the data SNS used to report the dollars saved through SLEP and will examine inventory records and SLEP records to verify the extent to which CDC is submitting drugs for SLEP.

(OAS; W-00-11-52320; expected issue date: FY 2011; new start)

Vaccines For Children Program: Storage and Management of Vaccines

We will review the extent to which Vaccines for Children (VFC) providers are storing and managing vaccines according to CDC's VFC Operations Guide. The VFC program was created by the Omnibus Budget Reconciliation Act of 1993 (BBRA) as an entitlement program to be a required part of each State's Medicaid plan. The VFC program is funded by CMS and implemented by CDC. The VFC Operations Guide contains requirements and procedures for all States and immunization grantees that receive VFC-funded vaccines, as well as minimum requirements that providers must meet, including requirements relating to storage of vaccines, to participate in the VFC program. The VFC program cost \$3.4 billion in 2009. In examining

VFC providers' qualifications pursuant to the VFC Operations Guide, we will also determine whether vaccines were stored within temperature ranges required by FDA.
(OEI; 04-10-00430; expected issue date: FY 2011; work in progress)

Food and Drug Administration

Complaint Investigation Process

We will review the adequacy of FDA's complaint investigation process, upon which the agency relies in its efforts to protect the public against injury and illness from contaminated or harmful foods, feed, drugs, cosmetics, medical devices, and biological products. We will determine whether complaints are properly recorded in the Consumer Complaint System and investigated in an expeditious manner as required by FDA's *Investigations Operation Manual*, ch. 8, § 8.2. We will also review FDA's processes for categorizing and using complaints to identify potentially significant trends or patterns in reported illnesses or injuries.

(OAS; W-00-11-51010; expected issue date: FY 2011; new start)

Oversight of Food Safety Operations

We will review FDA's oversight and operations related to imported pet food and feed products, including the extent of FDA's enforcement authorities, its procedures to implement those authorities, how FDA is carrying out the activities called for in its procedures, and the sufficiency of the authorities. We will review FDA's policies to determine whether it requires imported pet food and feed to be produced under the same safety standards as those that apply in the United States. We will also determine whether FDA samples imported pet food and feed for chemicals and microbial pathogens. If FDA is not sampling food and feed products, we will determine why.

(OAS; W-00-11-51002; expected issue date: FY 2011; new start)

Oversight of State Food Facility Inspections

We will review FDA's oversight of food facility inspections conducted by States under contract with FDA. FDA created the Contract Inspection Audit Program in 2006, in response to an OIG report recommending that FDA take steps to address shortcomings in its system of oversight. Under this program, 7 percent of each State's inspectors are audited by FDA or the State each year to ensure that the State's contract inspections are adequate and that the State is complying with contract requirements. When audits identify deficiencies in the State inspector's performance or systemic deficiencies in the State's inspection program, FDA and the State take action to ensure deficiencies are corrected. We will determine the extent to which FDA is meeting its program guidelines, and the extent to which deficiencies are identified and corrected.

(OEI; 02-09-00430; expected issue date: FY 2011; work in progress)

FDA Reportable Food Registry

We will determine the extent to which food facilities comply with key requirements of the FDA's Reportable Food Registry. Pursuant to the Food and Drug Administration Amendments Act of 2007, § 1005, FDA created the reportable food registry to provide a reliable mechanism to track outbreaks of foodborne illness. Beginning in September 2009, FDA began requiring food facilities to report all instances in which there is a reasonable probability that the use of, or exposure to, an article of food will cause severe health problems or death. FDA refers to such foods as "reportable foods." When a food facility discovers that it is in possession of a reportable food, the facility must (1) report the adulteration in FDA's reportable food registry within 24 hours and submit supplemental information as required by FDA, (2) investigate the cause of the adulteration if the adulteration originated with the facility, and (3) work with FDA authorities to follow up as needed. We will also determine whether there are any known instances of reportable foods that facilities did not report to FDA as required.

(OEI; 00-00-00000; expected issue date: FY 2012; new start)

FDA's Oversight of Investigational New Drug Applications

We will review FDA's process for evaluating investigational new drug (IND) applications. The Food, Drug, and Cosmetic Act of 1938 (FDCA), § 505(i), governs FDA's authority to oversee INDs used in clinical trials to assess their safety and effectiveness. Drug sponsors submit IND applications to FDA for review, and the agency has 30 days from receipt of the applications to review them, after which the sponsors may start clinical trials without FDA's approval. We will assess FDA's timeliness and identify challenges to the IND review process.

(OEI; 00-00-00000; expected issue date: FY 2011; new start)

FDA's Policies and Procedures for Resolving Scientific Disputes

We will review the FDA Center for Devices and Radiological Health's (CDRH) policies and procedures for resolving scientific disputes about approval of devices. Such disputes may arise between FDA and industry or within the FDA (e.g., reviewer and management). Federal regulations at 21 CFR § 10.70 require FDA reviewers to maintain an administrative file documenting their product recommendations and decisions, including significant controversies or differences of opinion and the resolution. The regulation at 21 CFR § 10.75(a) provides for supervisory review of a decision if requested by the FDA reviewer or an outside stakeholder, or initiated by the supervisor, using information in the administrative file. We will review a sample of administrative files for disputed device decisions and assess the extent to which regulations, policies, and procedures were followed during the dispute resolution process. We will also assess whether CDRH managers and staff are aware of and trained on policies and procedures for resolving scientific disputes.

(OEI; 01-10-00470; expected issue date: FY 2011; work in progress)

510(k) Process for Device Approval

We will review FDA's internal controls and quality review procedures for the 510(k) device approval process. Pursuant to sections 510(k) and 513(f) of the FDCA (implemented

by regulations at 21 CFR 807.92), certain devices may be approved under a simplified “510(k) process,” in which an entity must demonstrate that the device is as safe and effective as a device already approved (“substantial equivalence”). This is a faster process, and there are concerns that manufacturers may stretch the evidence to claim that the device is substantially equivalent to an already-approved device. We will also examine the extent to which manufacturers submit data on long-term safety under the 510(k) process and FDA’s post-marketing surveillance of such medical devices.

(OEI; 04-10-00480; expected issue date: FY 2011; work in progress)

FDA’s Oversight of Postmarketing Surveillance Studies of Medical Devices

We will review FDA’s oversight of medical device postmarketing surveillance studies. Under section 522 of the FDCA, FDA may require manufacturers of medical devices to complete postmarketing surveillance for any moderate- to high-risk medical device (Class II or III) that, if it failed, has a reasonable likelihood of serious adverse health outcomes. A 2006 OIG study of FDA’s oversight of postmarketing study commitments for drugs found that FDA could not readily determine whether or how expeditiously such postmarketing study commitments were progressing toward completion, in part because some information submitted by drug applicants was incomplete and because information was missing from some applications. We will examine the extent to which FDA has required postmarketing studies of medical devices, the level of compliance among sponsors that have been required to perform such studies, and FDA’s oversight of sponsors’ study commitments. We will also identify trends and challenges associated with postmarketing surveillance studies.

(OEI; 00-00-00000; expected issue date: FY 2012; new start)

Submission of Electronic Drug Labels

We will review FDA’s oversight of drug manufacturers’ compliance with the requirement to electronically submit to FDA complete and accurate drug labels for currently marketed prescription drugs. In December 2003, FDA published final regulations at 21 CFR §§ 314.50(l), 314.94(d), 601.14(b), and 314.81(b), requiring drug manufacturers to submit electronically to FDA specific labeling content for new drug applications, abbreviated new drug applications, and certain biologics license applications and annual reports. In November 2005, drug manufacturers were required to begin electronic submission of prescribing and product information for prescription drug labels in a structured product-labeling format. The format is intended to give health care providers accurate, up-to-date drug information using standardized medical terminology in a readable, accessible format. We will examine the accuracy and completeness of electronic labels submitted to FDA. We will also identify any factors that result in inaccurate or missing information.

(OEI; 00-00-00000; expected issue date: FY 2012; new start)

Health Resources and Services Administration

Ryan White CARE Act Payer of Last Resort Provision

We will review States' compliance with the payer of last resort requirement in their administration of the AIDS Drugs Assistance Program (ADAP) funds. Title II of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (CARE Act) stipulates that grant funds not be used to make payments for items or services eligible for coverage by any other Federal or State program or by any health insurance policy. This requirement, commonly referred to as the payer of last resort provision, is outlined in section 2617(b)(7)(F) of the PHS Act. In FY 2006, ADAP grant awards totaled more than \$750 million. A previous OIG report indicated that a significant percentage of payments made for ADAP medications in one State should have been paid by parties other than the ADAP.

(OAS; W-00-08-54260; various reviews; expected issue date: FY 2011; work in progress)

Human Immunodeficiency Virus (HIV) Testing in Health Centers

We will describe HIV testing practices of Health Resources and Services Administration (HRSA) funded health centers, and the factors that health centers staff report influence their decisions regarding HIV testing practices. The Centers for Disease Control and Prevention (CDC) estimates that 56,300 new HIV infections occurred in the United States in 2006. In an effort to reduce this number, CDC issued new recommendations to make HIV testing a routine part of medical care. Health centers are critical to this effort because they provide health services to populations that are disproportionately affected by HIV. However, HRSA estimates that only 3.5 percent of health center patients were tested in 2007 and little information exists regarding health center HIV testing practices. We will describe the extent to which health centers do or do not provide HIV testing. For health centers that provide HIV testing, we will describe their practices and the factors that influence them.

(OEI; 06-10-00290; expected issue date: FY 2011; work in progress)

Indian Health Service

Accounting for Medication Inventory

We will review IHS's accounting for medication inventory. Office of Management and Budget (OMB) Circular A-123, *Management's Responsibility for Internal Control*, section II, requires Federal managers to implement controls to provide reasonable assurance that assets are safeguarded against waste, loss, unauthorized use, or misappropriation. Although IHS is required to implement inventory procedures for drugs controlled by the Drug Enforcement Administration (DEA), there is no commensurate Federal requirement for inventories of non-DEA-controlled drug products, which account for most of the drugs on hand. We will determine whether pharmacies in IHS facilities have implemented controls to ensure accountability for medication inventories.

(OAS; W-00-08-55060; various reviews; expected issue date: FY 2011; work in progress)

IHS Medicaid Reimbursements

We will review IHS's expenditure of Medicaid reimbursements. The Social Security Act, § 1911, allows IHS and tribal facilities to bill State Medicaid programs for services provided to Indian beneficiaries also enrolled in Medicaid. The facilities bill for services using OMB encounter rates, which are set payment amounts for inpatient and outpatient services (visitations). Unlike the Medicaid program whereby the States provide some of the funds for Medicaid services, the Social Security Act, § 1905(b), permits the Federal Government to reimburse 100 percent of the services provided to Indian beneficiaries also enrolled in Medicaid. Accordingly, States may lack incentive to require accountability for expenditures of Medicaid reimbursements that, according to law, must be used exclusively for the purpose of making improvements to IHS and tribal health care facilities.

(OAS; W-00-11-55065; expected issue date: FY 2011; new start)

Background Investigations To Protect Indian Children

We will review the handling of background investigations required by the Indian Child Protection and Family Violence Prevention Act. This law requires that all IHS employees and contractors who have regular contact with, or control over, Indian children be investigated for any history of certain criminal acts. Previous OIG work found inconsistent practices in staff background investigations. We will determine whether IHS and tribal organizations have completed required background investigations.

(OAS; W-00-11-50020; various reviews; expected issue date: FY 2011; new start)

Mental Health and Dialysis Services at Indian Health Service and Tribal Facilities

We will review the availability of mental health and dialysis services at Indian Health Service and tribal facilities. Funding for such services is provided under the Indian Health Care Improvement Act that was reauthorized in the Health Care and Education Reconciliation Act of 2010. Mortality resulting from alcoholism, diabetes, and suicide is significantly higher among American Indians and Alaska Natives (AI/AN) than among other Americans. Dialysis and mental health services pose particular challenges because of limited access to specialized equipment and/or staff. We will evaluate barriers to access.

(OEI; 09-08-00580 and 09-08-00581; expected issue date: FY 2011; work in progress)

National Institutes of Health

Superfund Financial Activities for Fiscal Year 2009

We will review the payments, obligations, reimbursements, and other uses of Superfund amounts by NIH's National Institute of Environmental Health Sciences (NIEHS). A provision of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), codified at 42 U.S.C. § 9611(k), requires that OIG conduct an annual audit of the Institute's Superfund activities.

(OAS; W-00-11-56030; expected issue date: FY 2011; new start)

National Institute of Environmental Health Science's Grant Process

We will review issues related to grants made by NIEHS to determine whether it complied with the HHS *Grants Administration Manual* and whether FY 2005 to 2007 expenses incurred by its Director's office were in accordance with NIH policies.

(OAS; W-00-11-50036; expected issue date: FY 2011; new start)

Colleges' and Universities' Compliance With Cost Principles

We will review colleges' and universities' compliance with selected cost principles issued by OMB Circular A-21, *Cost Principles for Educational Institutions*. We will conduct reviews at selected schools based on the dollar value of Federal grants received and on input from HHS operating divisions and the offices of the Assistant Secretary for Financial Resources (ASFR) and the Assistant Secretary for Administration (ASA).

(OAS; W-00-11-50037; various reviews; expected issue date: FY 2011; new start)

Review of Extra Service Compensation Payments Made By Education Institutions

We will review payments for extra compensation charged to Federally sponsored grants, contracts, and cooperative agreements by education institutions to determine whether the payments were in accordance with Federal regulations. Pursuant to OMB Circular A-21, *Cost Principles for Education Institutions*, Att., § J.8.d(1), charges for work performed on sponsored agreements by faculty members will be based on the individual faculty member's regular compensation. Any charges for work representing "extra compensation" above the faculty member's base salary are allowable provided that arrangements are specifically provided for in the agreement or are approved in writing by the sponsoring agency. We will determine whether extra compensation payments were properly calculated and approved by the sponsoring agency. Recent OIG work has indicated problems with extra compensation payments charged to Federally sponsored agreements at several colleges and universities.

(OAS; W-00-11-50040; expected issue date: FY 2011; new start)

Recharge Centers at Colleges and Universities

We will determine whether recharge centers at colleges and universities have a reasonable and consistent rate schedule and comply with the standards set forth in OMB Circular A-21, *Cost Principles for Educational Institutions*, Att., § J.44 for specialized service facilities.

Specialized service funds (recharge centers) at universities operate as in-house enterprises and are used to finance, account for, and report on the provision of goods and services to other university operating units. Recent OIG work identified problems in this area. We will review the rate schedules of various recharge centers at colleges and universities to ensure that the amounts charged are reasonable and consistent. We will also review the recharge centers' expenses to determine reasonableness and necessity.

(OAS; W-00-11-50041; expected issue date: FY 2011; new start)

Use of Data and Safety Monitoring Boards in Clinical Trials

We will review the extent to which Data and Safety Monitoring Boards (DSMB) monitor data in clinical trials. A DSMB is a group of individuals who have pertinent expertise that regularly reviews accumulated data from one or more ongoing clinical trials to ensure the safety of participants in the trials and the validity and integrity of the scientific data generated. The NIH “Policy for Data and Safety Monitoring,” set forth in June 1998, requires that all NIH-funded clinical trials establish data- and safety-monitoring plans. A variety of types of monitoring, including DSMBs, are used depending on the risk, nature, size, and complexity of the clinical trial. This requirement sets minimum responsibilities that sponsoring Institutes and Centers must meet to ensure and oversee data and safety monitoring. We will also determine how and to what extent NIH is ensuring that grantees comply with the NIH policy for DSMBs in multisite clinical trials.

(OEI; 00-00-00000; expected issue date: FY 2012; new start)

National Institute of Allergy and Infectious Diseases’ Oversight of Project BioShield Grants

We will review the processes that the National Institute of Allergy and Infectious Diseases (NIAID) uses to monitor Project BioShield grantees’ compliance with Federal laws, regulations, and policies. Project BioShield, created by the Project BioShield Act of 2004, authorizes the Federal Government to research, develop, and procure medical countermeasures, such as vaccines, therapeutics, and diagnostics. It has primary responsibility for research and development of such medical countermeasures. From FY 2005 to FY 2010, NIAID awarded approximately \$100 million in grants for Project BioShield-related medical countermeasure research and development. NIAID is required to follow HHS rules for grants oversight and monitoring, including periodic review and approval of progress and financial reports. We will review NIAID’s oversight of grantees that have received awards under NIAID’s Project BioShield funding. We will also examine how NIAID ensures that grantees are aware of required security measures as well as the consequences of noncompliance with the requirements during the research and development of Project BioShield products.

(OEI; 00-00-00000; expected issue date: FY 2012; new start)

National Center for Research Resources’ Oversight of Clinical and Translational Science Awards

We will review the National Center for Research Resources (NCRR) process for overseeing Clinical and Translational Science Award (CTSA) grantees. The CTSA program began in 2006 to encourage intellectual discussion and dissemination of clinical research results and technologies among scientific investigators at various medical colleges and universities. The CTSA program awards 5-year grants to 12 academic health centers annually. When fully implemented in 2012, the CTSA program will consist of a consortium of 60 institutions that facilitates the creation of translational science networks and biomedical informatics tools. NCRR oversees this program and its milestones for compliance with CTSA program objectives and HHS grant administration requirements in regulations at 45 CFR pt. 74. Congress awarded

over \$300 million during the first 2 years of this program, with funding of the full CTSA initiative expected to exceed \$500 million annually by 2012. We will also examine NCR's monitoring of programmatic involvement with CTAs, particularly awardee-generated goals and milestones.

(OEI; 07-09-00300; expected issue date: FY 2011; work in progress)

Substance Abuse and Mental Health Services Administration

Substance Abuse Prevention and Treatment Block Grants

We will review one State's expenditures of SAMHSA-funded Prevention and Treatment Block Grants (SAPTBG) for State FYs 2003 through 2007. The State has reported expenditures that exceeded its awards for at least one previous year. SAMHSA requested that OIG perform this review to determine whether the State had adequate controls over its expenditure of SAPTBG funds and can meet applicable Federal requirements specified in 42 U.S.C. § 300x-30 and regulations at 45 CFR § 96.134.

(OAS; W-00-09-57205; A-04-09-03526; expected issue date: FY 2011; work in progress)

Progress in Meeting Performance Goals for the Substance Abuse Treatment Block Grant Program

We will review SAMHSA's progress in identifying performance goals for the Substance Abuse Treatment Block Grant program. The goal of the block grant program is to improve access, reduce barriers, and promote effective treatment and recovery services for people who have alcohol and drug abuse problems. The Government Performance and Results Act of 1993 (GPRA) requires Federal agencies to develop long-term strategic plans defining goals and objectives for their programs. We will also assess the extent to which States are reporting and meeting performance goals for this program.

(OEI; 00-00-00000; expected issue date: FY 2012; new start)

SAMHSA Oversight of High-Risk Grantees

We will review the extent to which SAMHSA monitors high-risk grantees in accordance with Federal regulations at 45 CFR pt. 74 and pt. 92, departmental directives, and agency policies. As part of grant applications, States must outline a plan for sustaining the program and services after Federal funds expire. We will determine the extent to which SAMHSA is reviewing sustainability plans and whether SAMHSA project officers and financial managers are communicating with high-risk grantees to identify opportunities for improvement.

(OEI; 07-10-00220; expected issue date: FY 2011; work in progress)

Cross-Cutting Public Health Activities

Conflict of Interest Waivers at the Department of Health & Human Services

We will review the extent to which waivers for HHS employees who had conflicts of interest were documented in accordance with Office of Government Ethics (OGE) requirements. Federal statutes, including 18 U.S.C. § 208, and OGE regulations, including at 5 CFR § 2635, address conflicts of interest. Conflict of interest waivers must be adequately documented pursuant to requirements set forth in regulations at 5 CFR §§ 2640.301 and 302. The Secretary issued a memorandum that provided further instructions for issuing adequately documented waivers to HHS employees in accordance with Federal statutes and OGE regulations. Prior OIG work found vulnerabilities in waivers for special Government employees on Federal advisory committees at CDC. We will also determine whether employees signed waivers in accordance with Federal ethics requirements.

(OEI; 04-10-00010; expected issue date: FY 2011; work in progress)

Use of Public Health Preparedness and Response for Bioterrorism Program Funds for Employee Compensation

We will review States' use of the Public Health Preparedness and Response for Bioterrorism program funding as it relates to employee compensation. The program, authorized under sections 301(a), 317(k)(1)(2), 319, 319C-1, and 319C-2 of the PHS Act, provides funding to improve State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies. States may not use Federal funds to compensate State employees for non-Federal services that States have provided in the immediately prior years. We will determine whether States have inappropriately used program funding to compensate State employees.

(OAS; W-00-11-57228; various reviews; expected issue date: FY 2011; new start)

Pandemic Influenza Planning

We will review HHS's implementation of high-risk areas of its pandemic influenza plan. The plan is HHS's blueprint for responding to the next pandemic that has the potential to overwhelm current public health and medical care capabilities. We will review areas pertaining to appropriate supplies of pre-pandemic vaccines, post-pandemic vaccines, and antivirals; and vaccine and antiviral distribution. We will also determine the extent to which States are reporting and meeting performance goals. This will include an assessment of how the SNS provides countermeasures to the States in light of the 2009-H1N1 pandemic, during which 11 million doses of anti-virals were released. Many of these remained unused because they were released without regard to the sufficiency of existing State stockpiles.

(OAS; W-00-11-57229; expected issue date: FY 2011; new start)

Public Health Investigations

Violations of Select Agent Requirements

On March 18, 2005, HHS issued a final regulation at 42 CFR pt. 73 on possession, use, and transfer of select (biological) agents and toxins, which applies to academic institutions; commercial manufacturing facilities; and Federal, State, and local laboratories. The rule authorizes OIG to conduct investigations and to impose civil monetary penalties (CMP) against individuals or entities for violations of these requirements. As of May 2010, OIG had settled 14 cases involving violations of the select-agent regulations and had collected nearly \$2 million in CMPs. We are continuing to coordinate efforts with CDC, the Federal Bureau of Investigation (FBI), and the Department of Agriculture (USDA) to investigate violations of the statute governing the registration, storage, and transfer of select agents and toxins.

Public Health Legal Activities

OIG assists the Department of Justice (DOJ) in the resolution of civil and administrative fraud cases and promotes compliance of recipients of HHS grant funding. In the public health area, OIG assists DOJ to develop and pursue Federal False Claims Act (FCA) cases against institutions that receive grants from NIH and other public health service agencies. We assist DOJ prosecutors in litigation and in settlement negotiations.