

Part V:

Public Health Reviews

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- Public Health Agencies 1
- Agency for Healthcare Research and Quality 2
 - Early Implementation of Patient Safety Organizations (New) 2
- Centers for Disease Control and Prevention..... 2
 - Monitoring of Subrecipient Emergency Preparedness Expenditures 2
 - States’ 24/7 Reporting Systems 3
 - Radiological and Nuclear Preparedness: Assessing Selected Local Public Health
Emergency Response Plans 3
 - Prevention and Public Health Fund Recipient Capability Audits (New) 3
 - Grantees’ Use of Funds From the Prevention and Public Health Fund (New)..... 3
 - Internal Controls for Awarding Affordable Care Act Grants (New)..... 4
 - Payment of Invoices for Affordable Care Act Purchases (New)..... 4
 - Contracting Activities Within CDC’s Procurement and Grants Office (New) 4
 - CDC Oversight of High-Risk Grantees (New) 4
- Food and Drug Administration 5
 - Complaint Investigation Process 5
 - Oversight of Food Safety Operations..... 5
 - Oversight of State Food Facility Inspections 5
 - FDA Reportable Food Registry 5
 - FDA’s Oversight of Investigational New Drug Applications..... 6
 - FDA’s Policies and Procedures for Resolving Scientific Disputes 6
 - 510(k) Process for Device Approval 6
 - The Food and Drug Administration's Implementation of the Risk Evaluation and
Mitigation Strategies Program (New)..... 6
 - FDA Oversight of Claims Made on Dietary Supplement Labels (New)..... 7
- Health Resources and Services Administration 7
 - Ryan White CARE Act Payer of Last Resort Provision 7
 - Human Immunodeficiency Virus Testing in Health Centers 7

Community Health Centers’ Compliance With Affordable Care Act Grant Requirements (New).....	7
Community Health Center Limited-Scope Capability Audits (New)	8
HRSA’s Monitoring of Recipients’ Fulfillment of National Health Services Corps’s Obligations (New)	8
HRSA Oversight of High Risk Grantees (New).....	8
Indian Health Service.....	8
IHS Medicaid Reimbursements.....	8
Background Investigations To Protect Indian Children.....	9
National Institutes of Health.....	9
Superfund Financial Activities for Fiscal Year 2010	9
Colleges’ and Universities’ Compliance With Cost Principles.....	9
Review of Extra Service Compensation Payments Made by Educational Institutions.....	9
Recharge Centers at Colleges and Universities	10
Informed Consent and Privacy Protection Procedures for NIH Grantees Conducting Genetic Research (New)	10
Use of Data and Safety Monitoring Boards in Clinical Trials	10
NIH Oversight of Grants Management Policy Implementation.....	10
National Center for Research Resources’ Oversight of Clinical and Translational Science Awards.....	11
Inappropriate Salary Draws From Multiple Universities (New).....	11
Cost Sharing Claimed by Universities (New).....	11
Awardee Eligibility for Small Business Innovation Research Awards (New)	11
Substance Abuse and Mental Health Services Administration.....	12
Progress in Meeting Performance Goals for the Substance Abuse Treatment Block Grant Program.....	12
SAMHSA Oversight of Grantees	12
SAMHSA Grantees’ Use of Funds From the Prevention and Public Health Fund (New).....	12
Cross-Cutting and Other Public-Health-Related Reviews.....	12
Use of Public Health Preparedness and Response for Bioterrorism Program Funds for Employee Compensation.....	12
HHS’ Federal Response Capabilities for Public Health and Medical Services Emergency Support (New).....	13
Pandemic Influenza Planning.....	13

Public Health Legal Activities 13

Public Health Investigations 13

 Violations of Select Agent Requirements 13

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ACRONYMS AND ABBREVIATIONS FOR SELECTED ORGANIZATIONS AND TERMS USED IN PART V:

AHRQ—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY	IHS—INDIAN HEALTH SERVICE
AIDS—ACQUIRED IMMUNODEFICIENCY SYNDROME	IND— INVESTIGATIONAL NEW DRUG
ASPR—ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE	NIH—NATIONAL INSTITUTES OF HEALTH
CDC—CENTERS FOR DISEASE CONTROL AND PREVENTION	OASH—OFFICE OF THE ASSISTANT SECRETARY OF HEALTH
CFR—CODE OF FEDERAL REGULATIONS	OMB—OFFICE OF MANAGEMENT AND BUDGET
FAR—FEDERAL ACQUISITION REGULATION	PHEP—PUBLIC HEALTH EMERGENCY PREPAREDNESS
FDA—FOOD AND DRUG ADMINISTRATION	PSO—PATIENT SAFETY ORGANIZATIONS
HIV—HUMAN IMMUNODEFICIENCY VIRUS	RN—RADIOLOGICAL AND NUCLEAR [INCIDENTS]
HRSA—HEALTH RESOURCES AND SERVICES ADMINISTRATION	SAMHSA—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

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. Our reviews of public health agencies within the Department of Health & Human Services (HHS) generally 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 health surveillance system 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 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 functions of the Office of the Assistant Secretary for Health include overseeing the protection of volunteers involved in research.

Descriptions of the Office of Inspector General's (OIG) work in progress and work planned for fiscal year (FY) 2012 follow.

Agency for Healthcare Research and Quality

Early Implementation of Patient Safety Organizations (New)

We will review the policies and activities of Patient Safety Organizations (PSO) to determine the extent of participation among hospitals, their practices in receiving and analyzing adverse event reports, and the extent to which they provide information to providers and the Network of Patient Safety Databases maintained by AHRQ. We will evaluate PSOs' efforts to identify and resolve patient safety problems in hospitals and identify any barriers to the full and effective implementation of the PSO program. In a 2009 report, OIG found that hospitals did not identify all serious adverse events, suggesting that hospital incident-reporting systems may be an unreliable source of information for PSOs. Federal law established a national network of PSOs, nongovernmental entities certified by HHS to collect and analyze reports of adverse events from hospitals and other health care settings. (Patient Safety and Quality Improvement Act of 2005.) The Secretary delegated responsibility for establishing and operating the PSO program to AHRQ. PSOs must meet certain criteria, establish a database to analyze patient safety information submitted by providers, and provide technical assistance to providers. AHRQ may also provide technical assistance to PSOs on matters such as methodology, communication, data collection, or privacy concerns. PSOs began operating in late 2008, with more than 90 in existence. (OEI; 00-00-00000; expected issue date: FY 2013; 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. We will determine whether salary charges have been made at the subrecipient level and assess the adequacy of the State's subrecipient expenditure-monitoring process. 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. 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) and Federal regulations require State grantees of the PHEP program to provide time and effort certifications for employees who are expected to work solely on the PHEP Federal award. (OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, App. B, § h(3), and 2 CFR pt. 225.) Regulations require grantees to manage and monitor day-to-day operations of subgrantees to ensure compliance with Federal requirements. (45 CFR § 92.40.) (OAS; W-00-12-58140; expected issue date: FY 2012; 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. We will evaluate States' 24/7 systems to assess State preparedness for receiving urgent reports and the functionality of the systems. Pursuant to Federal law, 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. (Public Health Service Act (PHS Act), § 319C-1, and 42 U.S.C. §§ 247d-3a.) 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 State or local health department staff at any time about suspected or confirmed diseases that require urgent reporting. (OEI; 00-00-00000; expected issue date: FY 2013; new start)

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

We will determine whether and how selected localities identified radiological and nuclear (RN) incidents to be high-risk threats and have engaged in public health planning to prepare for RN incidents. We will also determine whether and how selected localities used HHS guidance. According to CDC and Department of Homeland Security guidance documents, localities will be the first to respond to an RN incident. HHS provides guidance to States and localities on how to develop RN preparedness plans. (OEI; 04-10-00250; expected issue date: FY 2012; work in progress)

Prevention and Public Health Fund Recipient Capability Audits (New)

We will perform limited-scope reviews to determine whether CDC's grantees have the capability to manage and account for Federal funds, including Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) funds, in accordance with Federal regulations. We will also determine whether Prevention and Public Health Fund grantees are able to fulfill program requirements. Federal law authorized \$500 million for FY 2010, of which \$191.8 million was appropriated to CDC, with increasing amounts up to \$2 billion for FY 2015, to support the Prevention and Public Health Fund. (Affordable Care Act § 4002.) Pursuant to Federal regulations, grantees receiving Federal funds must ensure that they are used for authorized purposes. (45 CFR §§ 74.21(b)(3) and 92.20(b)(3).) (OAS; W-00-12-59003; expected issue date: FY 2012; work in progress and new start; Affordable Care Act)

Grantees' Use of Funds From the Prevention and Public Health Fund (New)

We will determine whether CDC grantees' use of funds from the Prevention and Public Health Fund were properly used for the purposes outlined in Federal laws and directives. Federal law authorized \$500 million for FY 2010, of which \$191.8 million was appropriated to CDC, with increasing amounts up to \$2 billion for FY 2015, to support the Prevention and Public Health Fund. (Affordable Care Act § 4002.) Pursuant to Federal regulations, grantees receiving Federal funds must ensure that the funds are used for authorized purposes. (45 CFR §§ 74.21(b)(3) and 92.20(b)(3).) The use of funds from the Prevention and Public Health Fund is governed by Federal award letters; program requirements; the Affordable Care Act; and OMB Circular A-133, *Audits of States, Local Governments, and Non-Profit Organizations*. (OAS; W-00-12-59014; expected issue date: FY 2012; work in progress and new start; Affordable Care Act)

Internal Controls for Awarding Affordable Care Act Grants (New)

We will review and test CDC's internal controls for awarding Affordable Care Act grants. We will also determine whether selected CDC Affordable Care Act grantees complied with grants administration requirements and terms and conditions of the funding opportunity announcements. Federal law authorized \$500 million for FY 2010, of which \$191.8 million was appropriated to CDC, with increasing amounts up to \$2 billion for FY 2015. (Affordable Care Act, § 4002.) CDC awarded grants for prevention activities to States, local governments, and community-based organizations. (OAS; W-00-11-59000; expected issue date: FY 2012; work in progress; Affordable Care Act)

Payment of Invoices for Affordable Care Act Purchases (New)

We will review and test CDC's controls over payments for goods and services, including purchases made with Affordable Care Act, § 4002, funds. We will determine whether CDC's Financial Management Office obtains proper validation that goods or services were received before payment of invoices. We will determine whether a previously identified control deficiency has been corrected. A previous internal CDC risk assessment found that receiving validations were not obtained for 9 of 10 invoices over \$2,500 during 4th quarter FY 2009. The Financial Management Office attributed this deficiency to the high volume of bills received and processed and stated that it had added additional controls to correct the problem. (OAS; W-00-12-59015; expected issue date: FY 2012; work in progress and new start; Affordable Care Act)

Contracting Activities Within CDC's Procurement and Grants Office (New)

We will review CDC's compliance with Federal laws and regulations in the use of service contracts awarded to assist its Procurement and Grants Office (PGO). We will focus on whether PGO contracts avoided functions that were inherently governmental in nature and whether contracts were issued and administered in a manner that did not create personal services contracts. We will also determine whether CDC funded these service contracts in accordance with requirements of the bona fide needs statute. In prior audits, OIG found that CDC employees had, in some cases, directed or controlled contractor employees' daily activities and had performed supervisory activities, such as reviewing contractor employee time cards and approving leave requests. The relationship between CDC employees and contractor personnel created a personal services contract. CDC's PGO is responsible for administering CDC grants and contracts for activities identified in the Federal Acquisition Regulation (FAR) as inherently governmental in nature. Contractors make up a significant portion of employees at CDC offices and often work side by side with CDC personnel. The FAR prohibits service contracts that are for inherently governmental functions and contracts that are for personal services. (FAR 7.503(a) and FAR 37.104(b).) In addition, the bona fide needs statute requires agencies to fund severable service contracts with funds that are current and available for the year in which performance takes place. (31 U.S.C. § 1502.) (OAS; W-00-12-58202; expected issue date: FY 2012; new start)

CDC Oversight of High-Risk Grantees (New)

We will examine current CDC processes for designating and monitoring high-risk grantees. We will determine the extent to which CDC designates its National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) grantees as high risk, whether CDC includes special conditions and restrictions in high-risk grantees' contracts, and the extent to which CDC high-risk grantees comply with special conditions and restrictions in their contracts. Increased funding through the American Recovery and Reinvestment Act of 2009 (Recovery Act) for CDC's NCCDPHP increases potential vulnerabilities in CDC's oversight of grantees to prevent fraud and abuse. Pursuant to Federal

regulations, operating divisions are allowed to include special conditions and restrictions in the contracts of grantees designated as high risk if the grantees meet certain criteria (e.g., history of poor performance, financial instability). (42 CFR § 74.14 and 45 CFR § 92.12.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

Food and Drug Administration

Complaint Investigation Process

We will determine the adequacy of FDA's complaint investigation process. We will determine whether complaints are properly recorded in the Consumer Complaint System and investigated expeditiously. We will also review FDA's processes for categorizing and using complaints to identify potentially significant trends or patterns in reported illnesses or injuries. FDA relies on its complaint investigation process in its efforts to protect the public against injury and illness from contaminated or harmful foods, feed, drugs, cosmetics, medical devices, and biological products. Guidelines for investigations are in FDA's *Investigations Operation Manual*, ch. 8, § 8.2. (OAS; W-00-12-51010; expected issue date: FY 2012; 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-00-12-51002; expected issue date: FY 2012; 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. We will also determine the extent to which FDA is meeting its program guidelines and the extent to which deficiencies are identified and corrected. 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 oversight system. 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 that deficiencies are corrected. (OEI; 02-09-00430; expected issue date: FY 2012; work in progress)

FDA Reportable Food Registry

We will determine the extent to which food facilities comply with key requirements of FDA's Reportable Food Registry. We will also determine whether there are any known instances of reportable foods that facilities did not report to FDA, as required. Beginning in September 2009, FDA began requiring 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 facility discovers that it has a reportable food, the facility must

report the adulteration in FDA's reportable food registry within 24 hours and submit supplemental information as required by FDA, investigate the cause of the adulteration if the adulteration originated with the facility, and work with FDA to follow up as needed. Federal law required FDA to create the registry to provide a reliable mechanism to track outbreaks of foodborne illness. (Food and Drug Administration Amendments Act of 2007, § 1005.) (OEI; 00-00-00000; expected issue date: FY 2013; new start)

FDA's Oversight of Investigational New Drug Applications

We will review FDA's process for evaluating investigational new drug (IND) applications. We will assess FDA's timeliness and identify challenges in the IND review process. 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. Federal law governs FDA's authority to oversee INDs used in clinical trials to assess their safety and effectiveness. (Food, Drug, and Cosmetic Act (FDCA) of 1938, § 505(i).) (OEI; 00-00-00000; expected issue date: FY 2013; new start)

FDA's Policies and Procedures for Resolving Scientific Disputes

We will describe the extent and nature of formal internal scientific disputes that occurred during the approval of medical devices at the FDA Center for Devices and Radiological Health's (CDRH). We will assess the extent to which regulations, policies, and procedures were followed during the dispute resolution process. We will also assess CDRH's implementation of its new policies and procedures for addressing scientific disputes. Such disputes may arise between FDA and industry or within the FDA (e.g., reviewer and management). Federal regulations require FDA reviewers to maintain an administrative file documenting their product recommendations and decisions, including significant controversies or differences of opinion and the resolution. (21 CFR § 10.70.) Regulations provide for supervisory review of a decision if requested by the FDA reviewer or an outside stakeholder or if initiated by the supervisor, using information in the administrative file. (21 CFR § 10.75(a).) In October 2009, CDRH issued new policies and procedures for addressing internal disputes related to regulatory decisions. (OEI; 01-10-00470; expected issue date: FY 2012; work in progress)

510(k) Process for Device Approval

We will review documentation of devices that FDA cleared using the Premarket Notification process, known as the 510(k) process, and describe characteristics of the cleared devices. Certain devices may be approved under the 510(k) process. (FDCA, §§ 510(k) and 513(f), and 21 CFR § 807.92.) The 510(k) process is a faster and less expensive method to market lower-risk medical devices than the more stringent Premarket Approval process. We will conduct our review pursuant to documentation requirements at 21 CFR § 10.70. (OEI; 04-10-00480; expected issue date: FY 2012; work in progress)

The Food and Drug Administration's Implementation of the Risk Evaluation and Mitigation Strategies Program (New)

We will examine the extent to which FDA ensures drug manufacturer compliance with the requirements of the Risk Evaluation and Mitigation Strategies (REMS) program. We will also review drug manufacturer assessments of the REMS program's efficacy in minimizing risk to consumers. Ensuring the effectiveness of REMS plans is an important component of drug safety oversight, which is one of the Top Management and Performance Challenges that OIG identified for HHS. FDA may require a REMS plan for a high-risk drug, the safety of which depends on successful communication of risks and benefits. Drug manufacturers are required to submit assessments of the effectiveness

of the REMS plan at scheduled intervals. (OEI; 04-11-00510; expected issue date: FY 2013; work in progress)

FDA Oversight of Claims Made on Dietary Supplement Labels (New)

We will review a sample of dietary supplements to determine the extent to which their labeling complies with FDA regulations regarding structure function claims. Structure function claims describe the role of a dietary supplement on the structure and function of human bodies. We will also determine the extent to which manufacturers of supplements are listed in FDA's Food Facility Registry as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). We will review the accuracy of the information in the FDA's registry of manufacturers of supplements and determine how FDA monitors and responds to claims that do not comply with the regulations. FDA regulates claims made on the labels of dietary supplements but relies on manufacturers to substantiate these claims and does not require approval before marketing. Manufacturers must also register with FDA under the Bioterrorism Act. (OEI; 01-11-00210; expected issue date: FY 2012; work in progress)

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. 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. FY 2006, ADAP grant awards totaled more than \$750 million. Federal law stipulates that these 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. (Title II of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990.) This requirement, commonly referred to as the payer-of-last-resort provision, is outlined in the Public Health Service Act of 1944 (PHS Act), § 2617(b)(7)(F). (OAS; W-00-10-54260; various reviews; expected issue date: FY 2012; work in progress)

Human Immunodeficiency Virus Testing in Health Centers

We will describe HIV testing practices of HRSA-funded health centers. We will review health center service sites to determine their HIV testing practices and the factors that influence health center staff decisions. 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 5.8 percent of health center patients were tested in 2010, and little information exists regarding health center HIV testing practices. (OEI; 06-10-00290; expected issue date: FY 2012; work in progress)

Community Health Centers' Compliance With Affordable Care Act Grant Requirements (New)

We will determine whether community health centers that received Affordable Care Act, § 10503, funds are complying with Federal laws and regulations. The review will include determining the allowability of expenditures and the adequacy of accounting systems and assessing the accounting

for program income. The review is based in part on requirements of the Public Health Service Act, § 330, and Federal regulations. (OAS; W-00-12-58303; various reviews, expected issue dates: FYs 2012-13; new start; Affordable Care Act)

Community Health Center Limited-Scope Capability Audits (New)

We will determine the capacity of community health centers receiving Affordable Care Act, § 10503, funds to manage and account for Federal funds and to operate community health service delivery sites in accordance with Federal requirements. Funding provided to community health centers has increased under the Affordable Care Act. Community health service delivery sites are operated in accordance with the PHS Act, § 330, and Federal regulations. (OAS; W-00-12-58204; various reviews, expected issue dates: FYs 2012-14; new start; Affordable Care Act)

HRSA's Monitoring of Recipients' Fulfillment of National Health Services Corps's Obligations (New)

We will determine the effectiveness of National Health Service Corps (NHSC) monitoring of recipients to ensure timely fulfillment of their contract obligations or timely recognition and referral of defaults to a Treasury-designated Debt Collection Center (HHS Program Support Center) when recipients breach their obligations. We will assess the accuracy of HRSA's default rate (2 percent) and the adequacy of its followup with health care professionals who default on their service commitments. Under the PHS Act, NHSC provides loan repayments and scholarships for health professionals who agree to work for a specified period in Health Professional Shortage Areas. In FY 2010, NHSC received \$141 million in funding. The Affordable Care Act, § 5207, and the Recovery Act provided increased funding for the NHSC Loan and Scholarship Programs. (OAS; W-00-12-58205; expected issue date: FY 2012; new start; Affordable Care Act)

HRSA Oversight of High Risk Grantees (New)

We will examine HRSA processes for designating and monitoring high-risk grantees. We will determine the extent to which HRSA designates Bureau of Primary Health Care (BPHC) grantees as high risk, whether BPHC includes special conditions and restrictions in high-risk grantees' contracts, and the extent to which HRSA high-risk grantees comply with the special conditions and restrictions in their contracts. The Increased funding that BPHC receives through the Recovery Act and the Affordable Care Act increases vulnerabilities in BPHC's oversight of grantees to prevent fraud and abuse. Pursuant to Federal regulations, HHS operating divisions are allowed to include special conditions and restrictions in the contracts of grantees designated as high risk if the grantees meet certain criteria, e.g., a history of poor performance or financial instability. (42 CFR § 74.14 and 45 CFR § 92.12.) (OEI; 00-00-00000; expected issue date: FY 2012; new start)

Indian Health Service

IHS Medicaid Reimbursements

We will review IHS's expenditure of Medicaid reimbursements. Federal law allows IHS and tribal facilities to bill State Medicaid programs for services provided to Indian beneficiaries enrolled in Medicaid. (Social Security Act, § 1911.) Tribal 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 Federal Government reimburses 100 percent of the services provided to Indian beneficiaries who are

enrolled in Medicaid. (Social Security Act, § 1905(b).) States may lack incentive to require accountability for expenditures of Medicaid reimbursements that, according to law, must be used exclusively to make improvements in IHS and tribal health care facilities. (OAS; W-00-12-55065; expected issue date: FY 2012; 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, which 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. We will determine whether IHS and tribal organizations have completed required background investigations. Previous OIG work found inconsistent practices in staff background investigations. (OAS; W-00-12-50020; various reviews; expected issue date: FY 2012; new start)

National Institutes of Health

Superfund Financial Activities for Fiscal Year 2010

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

(OAS; W-00-12-56030; expected issue date: FY 2012; new start)

Colleges' and Universities' Compliance With Cost Principles

We will assess 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 on the basis of the dollar value of Federal grants received and on input from HHS operating divisions and the offices of the Assistant Secretary for Financial Resources and the Assistant Secretary for Administration. (OAS; W-00-11-50037; various reviews; expected issue date: FY 2012; work in progress)

Review of Extra Service Compensation Payments Made by Educational Institutions

We will determine whether payments for extra compensation charged to federally sponsored grants, contracts, and cooperative agreements by educational institutions complied with Federal regulations. We will determine whether extra compensation payments were properly calculated and approved by the sponsoring agency. Recent OIG work has identified problems with extra compensation payments charged to federally sponsored agreements at several colleges and universities. Pursuant to OMB requirements, charges for work performed on sponsored agreements by an individual faculty member will be based on the faculty member's regular compensation. (OMB Circular A-21, *Cost Principles for Education Institutions*, Att., § J.8.d(1).) 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. (OAS; W-00-12-50040; expected issue date: FY 2012; new start)

Recharge Centers at Colleges and Universities

We will determine whether specialized service facilities (called recharge centers) at colleges and universities have rate schedules that ensure that amounts charged are reasonable and consistent and comply with the standards for such facilities. We will also determine the necessity for and reasonableness of the recharge centers' expenses. Recent OIG work identified problems in this area. 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. Standards for specialized service facilities are found in OMB Circular A-21, *Cost Principles for Educational Institutions*, Att., § J.44. (OAS; W-00-11-50041; expected issue date: FY 2012; work in progress)

Informed Consent and Privacy Protection Procedures for NIH Grantees Conducting Genetic Research (New)

We will determine the extent to which NIH grantees conducting genetic research comply with regulations and guidance on informed consent procedures. We will also assess the informed consent and privacy protection procedures used by these grantees and determine the extent to which they ensure that human subjects' private information stored in biobanks is protected in future research. Regulations at 45 CFR part 46 address human subject protections, including informed consent, for HHS-funded research. The growth of genetic research involving human subjects has raised many ethical questions surrounding privacy, confidentiality, and unintended harms. Regulations at 45 CFR part 160 and 45 CFR part 164, subparts A and E, address privacy protections. (OEI; 01-11-00520; expected issue date: FY 2012; work in progress)

Use of Data and Safety Monitoring Boards in Clinical Trials

We will determine the extent to which Data and Safety Monitoring Boards (DSMB) monitor data in clinical trials. 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. A DSMB is made up of individuals who have pertinent expertise and who regularly review accumulated data from one or more clinical trials to ensure the safety of participants and the validity and integrity of the scientific data generated. A variety of types of monitoring, including DSMBs, are used depending on the risk, nature, size, and complexity of the clinical trial. NIH requires that all NIH-funded clinical trials establish data- and safety-monitoring plans. (NIH's "Policy for Data and Safety Monitoring," June 1998.) This requirement sets minimum responsibilities that sponsoring Institutes and centers must meet to ensure and oversee data and safety monitoring. (OEI; 12-11-00070; expected issue date: FY 2013; work in progress)

NIH Oversight of Grants Management Policy Implementation

We will examine the NIH Office of Extramural Research's (OER) oversight of the grants administration processes implemented by the 24 Institutes and Centers (IC) that award extramural grants. We will also examine OER's oversight of each IC's compliance with regulations, department directives, and agency policies. NIH is the largest Federal funder of health research and development, having awarded \$22.2 billion in FY 2010 for extramural research awards. Regulations at 45 CFR Parts 74 and 92 establish uniform administrative requirements governing HHS grants. The HHS Grants Policy Directives and the NIH Grants Policy Statement provide guidance on implementing these regulations. OER issues grants administration policy to the ICs and has oversight responsibility for ICs' compliance with both Federal regulations and departmental guidance. Each IC maintains a Grants Administration Office that is responsible for implementing its own procedures. (OEI; 07-11-00190; expected issue date: FY 2012; work in progress)

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. We will also examine NCRR's monitoring of programmatic involvement with CTSA, particularly awardee-generated goals and milestones. 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. The CTSA program began in 2006 to encourage intellectual discussion and dissemination of clinical research results and technologies among scientific investigators at 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 regulations at 45 CFR pt. 74. (OEI; 07-09-00300; expected issue date: FY 2012; work in progress)

Inappropriate Salary Draws From Multiple Universities (New)

We will determine whether faculty members working on NIH grants were inappropriately drawing salaries from multiple universities. A recent indictment alleged that two professors were inappropriately drawing salaries from two universities. Extensive and swift funding under the Recovery Act may have provided an opportunity for similar actions by other researchers. The Recovery Act provided \$10.4 billion in new funding for NIH. (OAS; W-00-12-58206; expected issue date: FY 2012; new start)

Cost Sharing Claimed by Universities (New)

We will determine how universities are meeting cost-sharing requirements. During a recent audit, we noted that to meet cost-sharing requirements, a university waived its claim for Facilities and Administrative (F&A) costs. The university then relied on a Cost Accounting Standards (CAS) exemption to directly claim costs that are normally treated as F&A costs. A CAS exemption allows, in exceptional circumstances, normally indirect costs, such as clerical salaries, postage, memberships, subscriptions, telephone charges, and office supplies, to be charged as direct costs. However, by waiving F&A costs to meet cost-sharing requirements and claiming the costs directly, the university is not complying with the intent of cost sharing. Indirect costs may be claimed in matching or cost-sharing instances only with the prior approval of the Federal awarding agency. (OMB Circular A-110, *Uniform Administrative Requirements for Grants and Other Agreements with Institutions of Higher Education, Hospitals and Non-Profit Organizations*, subpart C, section .23(b).) (OAS; W-00-12-58207; expected issue date: FY 2012; new start)

Awardee Eligibility for Small Business Innovation Research Awards (New)

We will determine the extent to which HHS improperly funds ineligible Small Business Innovation Research (SBIR) awardees. We will also determine the extent to which HHS uses a required Governmentwide database and other management controls to prevent the funding of ineligible awardees. Within HHS, NIH manages SBIR applications for awards from NIH, CDC, FDA, and the Administration for Children and Families. The SBIR Program, created by the Small Business Innovation Development Act of 1982, is a highly competitive, three-phase award system providing qualified small businesses with opportunities to propose innovative ideas that meet the specific research and development needs of the Federal Government. Eligible awardees must meet the definition of a small business and not already receive Federal funding for the proposed research.

The Small Business Innovation Research Program Reauthorization Act of 2000 required creation of a Governmentwide database to assist with monitoring of SBIR awards across Departments. (OEI; 04-11-00530; expected issue date: FY 2013; work in progress)

Substance Abuse and Mental Health Services Administration

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. We will also assess the extent to which States are reporting and meeting performance goals for this program. The program's goal is to improve access, reduce barriers, and promote effective treatment and recovery services for people who have alcohol and drug abuse problems. Federal law requires Federal agencies to develop long-term strategic plans defining goals and objectives for their programs. (Government Performance and Results Act of 1993 (GPRA).) (OEI; 00-00-00000; expected issue date: FY 2013; new start)

SAMHSA Oversight of Grantees

We will determine the extent to which SAMHSA maintains grant files in accordance with Federal regulations. We will also identify characteristics of SAMSHA's interactions (e.g., frequency and types of communication) with grantees. A number of regulations and policies govern how HHS administers grants. Federal regulations, departmental directives, and agency policies govern the administration of discretionary grants at SAMHSA. (45 CFR pts. 74 and 92.) (OEI; 07-10-00220; expected issue date: FY 2012; work in progress)

SAMHSA Grantees' Use of Funds From the Prevention and Public Health Fund (New)

We will review grantees' use of Prevention and Public Health Fund awards to determine whether the funds were properly used for the purposes outlined in Federal award letters, program requirements, and Affordable Care Act regulations. The Affordable Care Act, § 4002, authorized funds for the Prevention and Public Health Fund. From these funds, SAMHSA awarded, in FY 2010, \$20.9 million to help 43 community behavioral health agencies integrate primary care into their services. Up to \$500,000 per year will be available for 4 years to each grantee, depending on the availability of funds, need, and the progress achieved by the grantee. Pursuant to 45 CFR §§ 74.21(b)(3) and 92.20(b)(3), grantees receiving Affordable Care Act funds must ensure that the funds are used for authorized purposes. (OAS; W-00-11-59005; W-00-12-59005; expected issue date: FY 2012; work in progress and new start; Affordable Care Act)

Cross-Cutting and Other Public-Health-Related Reviews

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

We will review States' use of Public Health Preparedness and Response for Bioterrorism program funding as it relates to employee compensation. We will determine whether States have inappropriately used program funding to compensate State employees. This review cross-cuts the

bioterrorism program funding and oversight of CDC and ASPR. The program provides funding to improve State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies. (PHS Act, §§ 301(a), 317(k)(1)(2), 319, 319C-1, and 319C-2.) States may not use Federal funds to compensate State employees for non-Federal services that States have provided in the immediately prior years. (OAS; W-00-12-57228; various reviews; expected issue date: FY 2012; new start)

HHS' Federal Response Capabilities for Public Health and Medical Services Emergency Support (New)

We will determine the extent to which HHS has participated in preparedness activities to fulfill its public health and medical services emergency support responsibilities. The National Response Framework's (NRF) Emergency Support Functions (ESF) establishes a comprehensive approach that can be adapted for a variety of disasters and emergencies (i.e., incidents). NRF is used by the Federal Government to coordinate designated agencies' response efforts when an incident occurs. Fifteen ESFs are outlined in the NRF, and agencies are assigned to fulfill responsibilities as the Coordinator, Primary, or Support agency for each ESF. The Secretary of HHS, through ASPR, coordinates HHS's Federal response for ESF #8, public health and medical services. (OEI; 04-11-00260; expected issue date: FY 2012; work in progress)

Pandemic Influenza Planning

We will review HHS's implementation of high-risk areas of its pandemic influenza plan. We will also determine the extent to which States are reporting and meeting performance goals and determine how CDC's Division of Strategic National Stockpile provides countermeasures to the States. We will review areas pertaining to appropriate supplies of prepandemic vaccines, postpandemic vaccines, and antivirals and vaccine and antiviral distribution. HHS's pandemic-related activities are coordinated by CDC and ASPR. HHS's pandemic influenza plan is the blueprint for responding to the next pandemic, which has the potential to overwhelm current public health and medical care capabilities. In the 2009-H1N1 pandemic, during which 11 million doses of antivirals were released, many doses of antivirals remained unused because they were released without regard to the sufficiency of existing State stockpiles. (OAS; W-00-12-57229; expected issue date: FY 2012; new start)

Public Health Legal Activities

We assist the Department of Justice (DOJ) in resolving civil and administrative fraud cases and promoting compliance of HHS grantees. We assist DOJ in developing and pursuing Federal False Claims Act cases against institutions that receive grants from NIH and other public health service agencies. We also assist DOJ prosecutors in litigation and in settlement negotiations.

Public Health Investigations

Violations of Select Agent Requirements

We are continuing to coordinate efforts with CDC, the Federal Bureau of Investigation, and the Department of Agriculture to investigate violations of the Bioterrorism Act, which governs the registration, storage, and transfer of select agents and toxins. Federal regulations authorize OIG to

conduct investigations and impose civil monetary penalties against individuals or entities for violations of select agent requirements. (42 CFR pt. 73.) The regulations apply to the possession, use, and transfer of select (biological) agents and toxins by academic institutions and biomedical centers; commercial manufacturing facilities; and Federal, State, and local laboratories.

The [Work Plan](#) is one of OIG's three core publications. OIG's [Semiannual Report to Congress](#) summarizes OIG's most significant findings, recommendations, investigative outcomes, and outreach activities in 6-month increments. OIG's annual [Compendium of Unimplemented Recommendations](#) (Compendium) describes open recommendations that when implemented will save tax dollars and improve programs.