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Part V 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. Our reviews of public health agencies within the Department of Health and 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 have low income or are 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 (OASH) include overseeing the protection of volunteers involved in research.

Acronyms and Abbreviations for Selected Organizations and Terms Used in Part V:

AIDS—acquired immunodeficiency syndrome
 CHS—Contract Health Services (program)
 FAR—Federal Acquisition Regulation
 HIV—human immunodeficiency virus

IND—investigational new drug
 OMB—Office of Management and Budget
 PSO—Patient Safety Organizations
 SBIR—Small Business Innovation Research (program)

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

AHRQ—Early Implementation of Patient Safety Organizations

We will review the policies and activities of Patient Safety Organizations (PSO) to determine the extent of participation among hospitals, PSO's practices in receiving and analyzing adverse event reports, and the extent to which PSOs provide information to health care 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. PSOs are 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.) Adverse events are harm caused to patients during medical care, such as infections or injury. A prior OIG review 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. (OEI; 00-00-00000; expected issue date: FY 2014; new start)

Centers for Disease Control and Prevention

CDC—Oversight of Security of the Strategic National Stockpile for Pharmaceuticals (New)

We will review efforts by CDC to ensure that pharmaceutical stockpiles are secure from theft, tampering, or other loss. We will use the guidelines established in the Department of Homeland Security's *Physical Security Manual* to assess security risks at selected stockpiles. The Strategic National Stockpile Program, for which CDC and the Department of Homeland Security (DHS) 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 distribution response possible, and CDC is responsible for ensuring that the materials in these facilities are adequately protected and stored. (OAS; W-00-13-58310; expected issue date: FY 2013; new start)

CDC—Award Process for the President's Emergency Plan for AIDS Relief Cooperative Agreements (New)

We will review the award process for cooperative agreements that CDC awarded under the President's Emergency Plan for AIDS Relief (PEPFAR) program to ensure compliance with applicable laws, regulations, and departmental guidance. The review will include awards made to both foreign and domestic recipients. The *Grants Policy Directive*, Part 2, § 04, specifies the process for competitive review, ranking applications, approval of applications, and the award policy. During previous reviews of the award monitoring process, we noted possible deficiencies, such as conflicting, missing or inaccurate

information in the Funding Opportunity Announcement and the Notice of Award. (OAS; W-00-13-58311; expected issue date: FY 2013; new start)

CDC—Oversight of HIV/AIDS Prevention and Research Grants (New)

We will assess whether CDC's oversight of HIV/AIDS prevention and research grants was conducted in accordance with Federal regulations and HHS policies. During FYs 2007 through 2011, CDC used more than \$3.6 billion to award grants for HIV/AIDS prevention and research. These grants are important tools in carrying out CDC's mission of meeting the goals of the National HIV/AIDS Strategy for the United States. (OEI; 00-00-00000; expected issue date: FY 2014; new start)

CDC—Grantees' Use of Funds (New)

We will determine the allowability of costs funded with FY 2012 HHS appropriations and claimed by Centers for Disease Control and Prevention (CDC) grantees using the funds to reduce chronic disease and promote healthy lifestyles. Grantees receiving such funds must ensure that the funds are used for authorized purposes, including whether funds were spent on lobbying, and in compliance with the purposes outlined in Federal laws, Office of Management and Budget (OMB) circulars, and other directives. (OAS; W-00-13-59014; expected issue date: FY 2013; new start)

CDC—Oversight of High-Risk Grantees

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 NCCDPHP increases potential vulnerabilities in CDC's oversight of grantees to prevent fraud and abuse. Pursuant to Federal regulations, special conditions and restrictions may be included 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; 04-12-00240; expected issue date: FY 2012; work in progress)

Food and Drug Administration

FDA—Oversight of Wholesale Prescription Drug Distributors (New)

We will assess the adequacy of FDA's oversight of wholesale prescription drug distributors and determine the extent to which FDA ensures that States are licensing wholesalers according to applicable State and Federal laws. All drug wholesalers must be licensed under State licensing systems, which must in turn meet the FDA guidelines under 21 CFR Part 205. (Prescription Drug Marketing Act of 1987, § 6.) (OEI; 00-00-00000; expected issue date: FY 2014; new start)

FDA—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 to protect the public against injury and illness from contaminated or harmful foods, feed, drugs, cosmetics, medical devices, and biological products. Guidelines for such investigations are in FDA's *Investigations Operation Manual*, ch. 8, § 8.2. (OAS; W-00-13-51010; expected issue date: FY 2013; new start)

FDA—Oversight of Investigational New Drug Applications

We will review FDA's process for evaluating investigational new drug (IND) applications. To begin clinical studies on a new drug product for human use, the sponsor (usually a manufacturer or research organization) must submit to FDA an IND application with all the known information about the new drug and describe how the proposed human clinical trials will be conducted. We will assess FDA's timeliness and identify challenges in the IND review process. FDA 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 2014; new start)

FDA—Implementation of the Risk Evaluation and Mitigation Strategies Program

We will examine the extent to which FDA ensures drug manufacturer compliance with the requirements of the Risk Evaluation and Mitigation Strategies (REMS) program, designed to identify risks and benefits of drugs. FDA may require a REMS plan for a drug associated with risks that may outweigh its benefits. We will also review drug manufacturer assessments of the REMS program's efficacy in minimizing risk to consumers. Drug manufacturers are required to submit assessments of the effectiveness of the REMS plan at scheduled intervals. 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. (OEI; 04-11-00510; expected issue date: FY 2013; work in progress)

FDA—510(k) Process for Device Approval

We will determine FDA's progress in either reclassifying or requiring the more stringent "Premarket Approval" process for certain types of high-risk medical devices. FDA clears lower-risk devices through the "Premarket Notification," (510(k), process), which is a faster and less expensive method. We will determine the extent to which FDA documented its decision to clear devices through the less stringent 510(k) process in 2010 in accordance with 21 CFR § 10.70. (FDCA, §§ 510(k) and 513(f), and 21 CFR § 807.92.) (OEI; 04-10-00480; expected issue date: FY 2013; work in progress)

Health Resources and Services Administration

HRSA—Health Center Adoption of Routine Testing for Human Immunodeficiency Virus Testing

We will determine the extent to which HRSA-funded health centers have adopted CDC's recommendation for routine HIV testing. We will review health center service sites to determine their HIV testing practices. 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 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 2013; work in progress)*

HRSA—Community Health Centers' Compliance With Grant Requirements of the Affordable Care Act

We will determine whether community health centers that received funds pursuant to the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), § 10503, are complying with Federal laws and regulations. The review will include determining the allowability of expenditures and the adequacy of accounting systems that assess and account for program income. The review is based in part on requirements of the Public Health Service Act, § 330, and Federal regulations.

(OAS; W-00-13-58303; various reviews, expected issue dates: FY 2013; new start; Affordable Care Act)

HRSA—Monitoring of Recipients' Fulfillment of National Health Services Corps Obligations

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. Pursuant to 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 discretionary funding. In addition to its annual appropriation, the NHSC had received \$300 million in funding through the Recovery Act in FY 2009, of which \$160 million was available in FY 2010. The Affordable Care Act, § 10503, and the Recovery Act provided increased annual funding for the NHSC Loan Repayment and Scholarship Programs, totaling \$1.5 billion over five years (FYs 2011 – 2015).

(OAS; W-00-13-58205; expected issue date: FY 2013; new start; Affordable Care Act)

Indian Health Service

IHS—Contract Health Services Program’s Compliance With Appropriations Laws (New)

We will determine whether IHS has adequate controls in place to ensure that it is appropriately funding its Contract Health Services (CHS) program and whether the program is complying with the purpose, time, and amount requirements specified in appropriations statutes. IHS can provide health care directly or by funding tribes to independently deliver health care. When an IHS or tribal facility is not available or does not provide required emergency or specialty care, IHS and tribes rely on the CHS program to purchase services from private health care providers. (42 CFR Part 136.) The rising cost of health care services and transportation and increased need have led to greater demands for services provided by CHS. Recently, the Government Accountability Office (GAO) noted that IHS/CHS had inadequate controls and identified potential Antideficiency Act violations. If IHS and CHS do not have adequate internal controls to properly monitor the costs of CHS services, the programs may incur Antideficiency Act violations by not complying with appropriations statutes while administering the program.

(OAS; W-00-13-50041; expected issue date: FY 2013; new start)

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 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-00-13-55065; expected issue date: FY 2013; new start)

National Institutes of Health

NIH—Extramural Construction Grants at NIH Grantees (New)

We will perform reviews at facilities that received extramural construction grants to determine whether Recovery Act funds were spent in accordance with Federal requirements. (42 CFR Part 52b, 45 CFR Part 74, 2 CFR Part 215, 2 CFR Part 220, and 2 CFR Part 225.) We will determine whether appropriate bidding procedures were followed and whether expenditures were allowable under the terms of the grants and applicable Federal requirements. The Recovery Act provided \$1 billion to be invested in extramural construction projects to build, renovate, or repair non-Federal biomedical and behavioral research facilities. The intended recipients of these awards were institutions of higher education as well as nonprofit and regional organizations across the country. *(OAS; W-00-13-50042; expected issue date: FY 2013; new start)*

NIH—Equipment Claims by Grantees (New)

We will determine whether NIH grantees' claims for equipment purchases are in compliance with the special terms and conditions set forth by the Recovery Act and applicable Federal requirements. We will conduct reviews at selected schools based on the dollar value of Federal grants received and on input from NIH. Capital expenditures for special-purpose equipment are addressed by OMB Circular A-81, *Cost principles for Educational Institutions*, and at 2 CFR Part 220, App. A, § J.18(b)(2). (OAS; W-00-12-50037; various reviews; expected issue date: FY 2013; work in progress)

NIH—Human Subjects Protection Practices of National Cancer Institute Extramural Grantees Collecting Biospecimens (New)

We will determine the extent to which informed consent documents for research that includes the collection of biospecimens comply with human subjects protection regulations. Further, we will determine the extent to which Institutional Review Boards (IRB) overseeing this type of research comply with regulations. We will also determine the extent to which principal investigators and IRBs take measures to address unique risks associated with this type of research. Biospecimens are biological materials (i.e. blood, plasma, tissue) taken from clinical trial human subjects or remaining from a clinical procedure. With research involving the collection of biospecimens, informational risks, such as a breach of privacy, are magnified because of the long-term electronic storage of the subjects' personally identifiable information and the potential for the biospecimens to be used in research not specified at the time of collection. No current regulations directly address human subjects' protections in research that includes the collection of human biospecimens. Regulations at 45 CFR Part 46, subpart A address human subject protections, including informed consent, for HHS-funded research. (OEI; 01-11-00520; expected issue date: FY 2013; work in progress)

NIH—Superfund Financial Activities for Fiscal Year 2011

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, 42 U.S.C. § 9611(k).) (OAS; W-00-12-56030; W-00-13-56030; expected issue date: FY 2013; new start)

NIH—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-00-13-50037; various reviews; expected issue date: FY 2013; new start)

NIH—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-00-13-50040; expected issue date: FY 2013; new start)

NIH—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 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 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 2013; work in progress)

NIH—Inappropriate Salary Draws From Multiple Universities

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 each 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-00-13-58206; expected issue date: FY 2013; new start)

NIH—Cost Sharing Claimed by Universities

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, § 23(b).) (OAS; W-00-13-58207; expected issue date: FY 2013; new start)

NIH—Awardee Eligibility for Small Business Innovation Research Awards

We will determine the extent to which HHS ensures that Small Business Innovation Research (SBIR) awardees meet eligibility requirements and awards are not duplicative. We will also determine the extent to which SBIR award funding amounts comply with program guidance and whether HHS assesses the commercialization success of SBIR-funded projects. Within HHS, NIH manages SBIR applications for awards from NIH, CDC, FDA, and the Administration for Children and Families (ACF). 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

SAMHSA—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 and determine the extent to which States are reporting and meeting the goals. The program's purpose 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; 04-12-00160; expected issue date: FY 2013; new start)

SAMHSA—Grantees’ Use of Funds From the Prevention and Public Health Fund

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 \$20.9 million in FY 2010 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-00-12-59005; W-00-13-59005; A-07-12-04191; expected issue date: FY 2013; work in progress and new start; Affordable Care Act)

Other Public-Health-Related Reviews

Select Agent Shipments To and From Foreign Countries (New)

We will review exports and imports of select agents between U.S.-based entities and foreign countries. Select agents are biological agents and toxins that have the potential to pose a severe threat to human, animal, or plant health or to animal or plant products. Federal regulations direct entities that possess, use, or transfer HHS select agents to, among other requirements, restrict access to select agents to approved individuals; develop and implement security plans; and maintain detailed select agent inventory and access records. (42 CFR Part 73.) Prior OIG reviews of domestic select agent transfers noted deficiencies in these and other areas of select agent management. We will examine imports and exports of select agents made from October 1, 2009, through September 30, 2011, for compliance with these and related requirements. (OAS; W-00-13-50043; expected issue date: FY 2013; new start)

Protections of Human Research Subjects (New)

We will review the Office for Human Research Protections’ (OHRP) oversight of institutional compliance with Federal requirements designed to protect human research subjects. OHRP, a component of the HHS Office of the Assistant Secretary for Health, provides leadership in the protection of the rights, welfare, and well-being of subjects involved in research conducted or supported by HHS. OHRP derives compliance authority from the PHS Act, § 289, and 45 CFR part 46. At OHRP’s discretion, it evaluates written substantive indications of noncompliance with 45 CFR part 46. This review is being conducted in followup to a series of OIG reports issued in 1998 that identified vulnerabilities in Federal oversight of human research subjects. (OEI; 00-00-00000; expected issue date: FY 2014; new start)

Federal Response Capabilities for Public Health and Medical Services Emergency Support

We will determine the extent to which HHS has prepared to fulfill its public health and medical services emergency support responsibilities. The Department of Homeland Security's National Response Framework's (NRF) presents guiding principles that enable all response partners to prepare for and provide a unified national response to disasters and emergencies. The NRF is used by the Federal Government to coordinate designated agencies' response efforts when an incident occurs. The NRF established fifteen emergency support functions, and Federal agencies are assigned to fulfill responsibilities as the Coordinator, Primary, and/ or Support agency for each function. HHS serves as the Primary and Coordinator agency for public health and medical services. (OEI; 04-11-00260; expected issue date: FY 2013; work in progress)

Pandemic Influenza Response Planning

We will review HHS's implementation of key areas in 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 vaccines and antivirals to the States. We will review areas pertaining to appropriate supplies of prepandemic vaccines, postpandemic vaccines and antivirals, and distribution of vaccines and antivirals. 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 sent to areas that already had enough doses of vaccine. (OAS; W-00-13-57229; expected issue date: FY 2013; new start)

Oversight of Laboratory-Developed Tests (New)

We will determine HHS agencies' oversight of the clinical effectiveness of laboratory-developed tests (LDT). We will determine the extent and nature of LDT use for health care decisions and describe the challenges in regulating LDTs. The Medical Devices Amendments Act of 1976 provided FDA with the authority to regulate all medical devices, including in vitro diagnostics, for clinical effectiveness. LDTs, a category of in vitro diagnostics, have traditionally been used in research settings only. Because of this limited use, FDA has chosen to use regulatory discretion with respect to these tests and does not oversee them. LDTs are also subject to CMS oversight through its enforcement of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). However, CLIA addresses laboratory practices rather than the clinical effectiveness of the tests they conduct. (Clinical Laboratory Improvement Amendments of 1988 (CLIA), § 493, and Medical Device Amendments Act of 1976. (OEI; 00-00-00000; expected issue date: FY 2014; new start)

Public Health Legal Activities

OIG assists 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

In 2005, HHS issued a final regulation on possession, use, and transfer of select (biological) agents and toxins that applies to academic institutions; commercial manufacturing facilities; and Federal, State, and local laboratories. (70 Fed. Reg. 13294 (March 18, 2005), 42 CFR Part 73.) The rule authorizes OIG to conduct investigations and to impose civil monetary penalties (CMP) against individuals or entities for violations of these requirements. We are continuing to coordinate efforts with CDC, the FBI, and the Department of Agriculture (USDA) to investigate violations of Federal requirements for the registration, storage, and transfer of select agents and toxins.

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.