Public Health Reviews

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 incomes 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 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.

Effective management of public health programs is essential to ensure that they achieve their goals and best serve the programs' intended beneficiaries. In its work planning activities in fiscal year (FY) 2015 and beyond, OIG will consider key risk areas, such as the adequacy of CDC and its public health partners' preparedness to respond to public health emergencies, including disease outbreaks. Future work planning efforts will also include examinations of access to quality services and health and safety protections, including the integrity of the food, drug, and medical supply chain.

Acronyms and Abbreviations for Selected Terms:

AHRQ—Agency for Healthcare Research and Quality
AIDS—acquired immunodeficiency syndrome
CDC—Centers for Disease Control and Prevention
CoP—conditions of participation
DHS—Department of Homeland Security
FDA—Food and Drug Administration
FDAA—Food and Drug Amendments Act of 2007
HCP— Health Center Program
HIPAA—Health Insurance Portability and Accountability Act
HRSA—Health Resources and Services Administration
IC— institute/center (NIH)
IHS—Indian Health Service
MCO— managed care organization
MRC— Medical Reserve Corps
OMB—Office of Management and Budget
NIH—National Institutes of Health
NOM— national outcome measure
PMR— postmarketing requirement
PPHF—Prevention and Public Health Fund
PSO—Patient Safety Organization
SAMHSA—Substance Abuse and Mental Health Services Administration
SAPTBG—Substance Abuse Prevention and Treatment Block Grant
SSBG—Social Services Block Grant
WTCHP—World Trade Center Health Program

Agency for Healthcare Research and Quality

➢ AHRQ—Early implementation of patient safety organizations

We will review the policies and activities of Patient Safety Organizations (PSOs) to determine the extent of hospitals' participation in such activities, identify PSOs' practices for receiving and analyzing adverse event reports, and determine 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. 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. 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, such as infections or injury, caused to patients during medical care. (OEI; 06-14-00080; expected issue date: FY 2015)

Centers for Disease Control and Prevention

➢ CDC—World Trade Center Health Program: Review of medical claims

We will review World Trade Center Health Program (WTCHP) expenditures to assess whether internal controls have been established in the WTCHP in accordance with Office of Management and Budget (OMB) Circular A-123, *Management's Responsibility for Internal Control*. As part of our review, we will determine whether the internal controls are adequate to (1) detect and prevent fraudulent or duplicate billing and payment for inappropriate medical services and (2) prevent excessive administrative payments in accordance with OMB Circular A-122, *Cost Principle for Non-Profit Organizations*. Prior Federal audits found that CDC did not reliably estimate costs for monitoring and treating program beneficiaries. Pursuant to the legislative requirements, medical

services are provided to eligible responders and survivors with health conditions related to the September 11, 2001, terrorist attacks on the World Trade Center through contracted facilities known as Clinical Centers of Excellence. The WTCHP was established in January 2011 and is administered by CDC. (James Zadroga 9/11 Health and Compensation Act of 2010 and Public Health Service Act, § 3301(d).) (OAS; W-00-14-59040; expected issue date: FY 2015)

➢ CDC—Award process for the President's Emergency Plan for AIDS Relief cooperative agreements

We will review CDC's award process for the cooperative agreements it has 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 foreign and domestic recipients. During previous reviews of CDC's award monitoring process, we noted possible deficiencies, such as conflicting, missing, or inaccurate information in the Funding Opportunity Announcement and the Notice of Award. The *Grants Policy Directive*, Part 2, § 04, specifies the process for competitive review, ranking applications, approval of applications, and award policy. (OAS; W-00-13-58311; expected issue date: FY 2015)

➢ Prevention and Public Health Fund grants—CDC Oversight

We will assess the effectiveness of CDC's management of the Prevention and Public Health Fund (PPHF) program. We will also determine selected grantees' compliance with grant requirements. Section 4002 of the Patient Protection and Affordable Care Act (ACA) established the PPHF program to provide expanded and sustained national investments in prevention and public health, to improve health outcomes, and to enhance health care quality. CDC received appropriations totaling $2.2 billion during FYs 2010–2013, representing 66 percent of total PPHF dollars. Recent legislation may change CDC's PPHF allotment. (OAS; W-00-14-59027; expected issue date: FY 2015; ACA)

➢ CDC—Accountability for property

We will determine whether CDC implemented recommendations that OIG previously made on the basis of an audit of CDC's property system. CDC maintains various types of accountable property in the United States and overseas. In a previous report, we recommended that CDC improve its controls over property. Specifically, we recommended that CDC adjust the property system to reflect the results of the annual physical inventory, remove from the property system any lost or missing property, ensure that all newly acquired property items are barcoded and correctly added to the property system, and reconcile the general ledger to the property system to identify and resolve discrepancies. As of January 2013, CDC had 60,820 items of accountable property in its inventory, representing an original purchase cost of about $455 million. (OAS; W 00-14-59025; expected issue date: FY 2015)

➢ CDC—Oversight of security of the strategic national stockpiles of pharmaceuticals

We will review CDC's efforts to ensure that pharmaceutical stockpiles are secure from theft, tampering, or other loss. We will use guidelines established in the Department of Homeland Security's (DHS) *Physical Security Manual* to assess security risks at selected stockpiles. The Strategic National Stockpile program, for which CDC and 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. The stockpiles are stored at strategic locations for the most rapid distribution possible. 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 2015)

Food and Drug Administration

➢ FDA—Inspection of generic drug manufacturers

We will determine the extent to which FDA conducts inspections of generic drug manufacturers. We will also describe the results of such inspections and the enforcement actions taken by FDA in response to shortcomings or deficiencies. FDA typically inspects drug manufacturing facilities before generic drug approval and conducts routine inspections of foreign and domestic manufacturers to monitor compliance with good manufacturing practices. Generic drugs are copies of FDA-approved brand-name drugs that must be equivalent to the original drugs with respect to conditions of use, active ingredient(s), route of administration, dosage form, strength, labeling, and performance characteristics. Pharmaceutical companies must receive FDA approval before marketing and manufacturing a new generic drug. (OEI; 01-13-00600; expected issue date: FY 2015)

➢ FDA—Oversight of postmarketing studies of approved drugs

We will determine the extent to which FDA requires postmarketing studies and clinical trials (referred to as postmarketing requirements, or PMRs) for new drug applications. We will also assess how FDA monitors PMRs and takes enforcement action against applicants that do not comply with them. Section 505(o)(3) of the Food and Drug Administration Amendments Act of 2007 (FDAAA) provides FDA new authority to require additional testing of an approved prescription drug or biological product to assess serious risk related to its use. Under this authority, FDA may require an applicant to conduct PMRs at the time of approval or after approval if FDA becomes aware of new safety information or an unexpected serious risk associated with the use of the drug. (OEI; 01-13-00390; expected issue date: FY 2015)

➢ FDA—FDA inspections of high-risk food facilities

We will assess FDA's designation and inspection of high-risk food facilities. FDA is responsible for safeguarding the Nation's food supply by ensuring that all food ingredients are safe and that food is free of disease-causing organisms, chemicals, or other harmful substances. To carry out this responsibility, FDA inspects food facilities to ensure food safety and compliance with regulations. The Food Safety Modernization Act mandated that FDA increase the frequency of its inspections of domestic food facilities and inspect facilities on the basis of risk; it also indicated the criteria for designating a facility as high risk. (OEI; 02-14-00420; expected issue date: FY 2015)

➢ FDA—Review of information exchange in the drug supply chain

We will review drug supply chain trading partners' (e.g., drug manufacturers, wholesale distributors, dispensers) early experiences in exchanging transaction information and transaction history as required by section 202 of the Drug Supply Chain Security Act. Transaction information includes basic information about the drug (e.g., the strength and dosage form of the product, the National

Drug Code, etc.), and the transaction history includes transaction information for every prior transaction for that drug back to the manufacturer. Together, this information forms the foundation of drug traceability and the security of the drug supply chain. Except for dispensers, trading partners must comply with the new exchange requirements by January 1, 2015, (dispensers have until July 1, 2015, to comply). We will interview trading partners about how they have successfully exchanged this information and what, if any, obstacles they have faced. (OEI; 05-14-00640; expected issue date: FY 2015)

➢ FDA—Drug sponsors' compliance with clinical trial reporting requirements

In 2007, Congress passed the FDAAA (42 U.S.C. § 282(j)) which mandated that certain clinical trials be registered and their results be reported in the clinical trial registry and reporting data bank known as ClinicalTrials.gov. These reporting requirements are an important tool that enhances FDA's ability to assess and monitor a drug's safety and efficacy. We will determine the extent to which clinical trials comply with the reporting requirements set forth by the FDAAA and the way in which FDA is ensuring that these requirements are met. (OEI; 02-14-00610; expected issue date: FY 2015)

Health Resources and Services Administration

➢ HRSA-Community health centers' compliance with grant requirements of the Affordable Care Act (new)

We will determine whether community health centers that received funds pursuant to the ACA, § 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-00-14-5928; various reviews; expected issue dates: FY 2015; ACA)

➢ HRSA—Duplicate discounts for 340B purchased drugs (new)

We will assess the risk of duplicate discounts for 340B-purchased drugs paid through Medicaid managed care organizations (MCOs) and describe States' efforts to prevent them. The ACA § 2501 required States to begin collecting rebates for drugs paid through Medicaid MCOs and prohibited duplicate discounts under the 340B Program for such drugs. However, existing tools and processes used to prevent duplicate discounts in fee-for-service Medicaid may not be sufficient for drugs paid through Medicaid MCOs. (OEI; 05-14-00430; expected issue date: FY 2015; ACA)

➢ HRSA—Oversight of vulnerable health center grantees (new)

We will determine the extent to which HRSA awards grant money to Health Center Program (HCP) grantees that have documented compliance or performance issues. HRSA has a variety of processes in place to monitor HCP grantees on program compliance, clinical performance, and financial health. However, even with all of these data available, HRSA may still continue to fund grantees with serious, ongoing compliance or performance issues. (OEI; 05-14-00470; expected issue date: FY 2015)

Indian Health Service

➢ IHS—Hospital oversight

We will examine IHS's efforts to ensure that its hospitals provide quality inpatient care. We will examine IHS's efforts to monitor each hospital's ability to provide quality care and maintain compliance with Medicare conditions of participation (CoP) and will identify which quality or compliance problems are most common. IHS operates 28 acute care hospitals that provide inpatient care to eligible American Indians and Alaska Natives. IHS hospitals are monitored through periodic onsite surveys by CMS-approved accrediting organizations that assess compliance with Medicare CoPs. (OEI; 09-13-00280; 06-14-00010; expected issue date: FY 2015)

National Institutes of Health

➢ NIH—Superfund financial activities for fiscal year 2014

We will review payments, obligations, reimbursements, and other uses of Superfund money 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-00-15-59050; expected issue date: FY 2015)

➢ NIH—Extramural construction grants

We will perform reviews at facilities that received extramural construction grants to determine whether funds were spent in accordance with Federal requirements. We will determine whether appropriate bidding procedures were followed and whether expenditures were allowable under the terms of the grants and applicable Federal requirements. Extramural construction grants are awarded to build, renovate, or repair non-Federal biomedical and behavioral research facilities. The intended recipients of these awards are institutions of higher education as well as nonprofit and regional organizations across the country. (42 CFR Part 52b, 45 CFR Part 74, 2 CFR Part 215, 2 CFR Part 220, and 2 CFR Part 225.) (OAS; W-00-13-50042; various reviews; expected issue date: FY 2015)

➢ NIH—Colleges' and universities' compliance with cost principles

We will assess colleges' and universities' compliance with selected cost principles issued by OMB in Circular A-21, *Cost Principles for Educational Institutions*. We will conduct reviews at selected colleges and universities 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 2015)

➢ NIH—Oversight of grants management policy implementation

We will examine NIH's oversight of three basic requirements for postaward grants administration among the 24 institutes and centers (ICs) that award extramural grants. We will also examine NIH's

oversight of each IC's compliance with regulations, HHS directives, and agency policies. NIH issues grants administration policy to the ICs and oversees ICs' compliance with Federal regulations and HHS guidance. Each IC maintains a Grants Administration Office that implements its own procedures. Federal regulations establish uniform administrative requirements governing HHS grants. (45 CFR Parts 74 and 92.) The HHS *Grants Policy Directives* and the NIH *Grants Policy Statement* provide guidance on implementing the regulations. (OEI; 07-11-00190; expected issue date: FY 2015)

➢ NIH—Use of appropriated funds for contracting

We will review the appropriateness of NIH's obligation of appropriated funds for the services it obtains through contracts to ensure that appropriated funds were used only during their period of availability in accordance with the Anti-Deficiency Act of 1950 (Anti-Deficiency Act) and were used only for a bona fide need arising in the fiscal year for which the appropriation was made. We will review contracts and contract modifications to quantify any errors. Prior reviews identified problems in the use of appropriated funds for various NIH contracts. Key provisions of the Anti-Deficiency Act prohibit the Government from obligating or expending funds in advance of an appropriation unless authorized by law. (31 U.S.C § 1341(a)(1).) Also, appropriations may be used only for bona fide needs arising in the fiscal year for which the appropriation was made. (31 U.S.C. § 1502.) We will issue a summary report of corrective actions taken to address weaknesses identified in our reports. (OAS; W-00-10-52314; various reviews; expected issue date: FY 2015)

Substance Abuse and Mental Health Services Administration

➢ SAMHSA—Reporting and oversight of the Substance Abuse Prevention and Treatment Block Grant program performance

We will assess the data collection methods used by States to report on national outcome measures (NOMs) for the Substance Abuse Prevention and Treatment Block Grant (SAPTBG) program. We will also determine the extent to which SAMHSA oversees States' reporting of NOMs. SAMHSA is required to collect performance data and analyze the effectiveness of its programs, including the SAPTBG program. To do so, SAMHSA developed NOMs that aim to measure performance and improve accountability. However, SAMHSA has acknowledged a lack of specificity, uniformity, and quality in its data collection and reporting procedures. (OEI; 04-12-00160; expected issue date: FY 2015)

Other Public-Health-Related Reviews

➢ Audits of Hurricane Sandy Disaster Relief Act (new)

The Disaster Relief Appropriations Act, 2013, P.L. No. 113-2 (Disaster Relief Act), provided funding to HHS for use in aiding Hurricane Sandy disaster victims and their communities. After sequestration, HHS received $759.5 million in Disaster Relief Act funding. Of this amount, $733.6 million was allocated to three operating divisions: the Administration for Children and Families, NIH, and

SAMHSA. We plan to perform audits of grantees that have received Disaster Relief Act grant funding through one of the above-mentioned HHS operating divisions. We will review grantees' internal controls related to the oversight of Disaster Relief Act funds. Additionally, we plan to review the allowability of costs claimed and the appropriateness of costs that were budgeted but not yet expended. (OAS; W-00-15-59052; various reviews; expected issue date: FY 2015)

➢ Hurricane Sandy—HHS use of volunteer medical personnel to respond

We will describe the use of Medical Reserve Corps (MRC) volunteers in New Jersey and New York during the Hurricane Sandy response. We will also describe any challenges and successes encountered while using MRC volunteers. MRC is a national network of volunteers that is organized and managed at the local level. These volunteers provide various services, such as supporting local public health activities and assisting in emergency preparedness response and recovery. More than 2,000 volunteers were deployed in New York and New Jersey during the Hurricane Sandy response. (OEI; 04-13-00350; expected issue date: FY 2015)

➢ Hurricane Sandy—Social Services Block Grant guidance, disbursement, and reporting summary

We will assess guidance, disbursement, and reporting related to the $500 million in Hurricane Sandy disaster funding transferred to the Social Services Block Grant (SSBG). We will determine when HHS and States provided guidance to grantees regarding the expenditure of the funds, determine the timeliness with which HHS and States disbursed awards, and identify what reporting requirements were put in place. We will also describe challenges that States and their subgrantees encountered in accessing and using disaster funding. The Disaster Relief Act provided additional funds to the SSBG program to address necessary expenses resulting from Hurricane Sandy, including social, health, and mental health services for individuals and for repair, renovation, and rebuilding of health care facilities, child care facilities, and other social services facilities. (OEI; 00-00-00000; expected issue date: FY 2015)

➢ Hospitals' electronic health record system contingency plans (new)

We will determine the extent to which hospitals comply with contingency planning requirements of the Health Insurance Portability and Accountability Act (HIPAA). We will also compare hospitals' contingency plans with government- and industry-recommended practices. The HIPAA Security Rule requires covered entities to have a contingency plan that establishes policies and procedures for responding to an emergency or other occurrence that damages systems that contain protected health information (45 CFR, Part 164 § 308(7)(i)). (OEI; 01-14-00570; expected issue date: FY 2015)

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.

➢ 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 against individuals or entities for violations of these requirements. We are continuing to coordinate efforts with CDC, the Federal Bureau of Investigation, and the Department of Agriculture to investigate violations of Federal requirements for the registration, storage, and transfer of select agents and toxins.