

Part IV:

Public Health, Human Services, and Departmentwide Issues

Part IV:

Public Health, Human Services, and Departmentwide Issues

Public Health Programs.....	1
Improve States' and Localities' Medical Surge Preparedness for Pandemics	1
Ensure That State Public Health Laboratories Meet Cooperative Agreement Requirements on Biological Threats	3
Improve Oversight of the Ethics Program for Special Government Employees on Federal Advisory Committees at CDC (New).....	5
Update and Maintain an Accurate National Drug Code Directory	7
Improve and Strengthen Food Facilities' Compliance With Records Requirements for Traceability of Food Products	9
Ensure That Clinical Investigators Disclose All Financial Interests	11
Minimize Financial Risk in the Food and Drug Administration's Information Technology Contracts	13
Use Adverse Event Reports to Detect and Address Safety Concerns About Medical Devices (New)	15
Ensure That Food Facility Registry Provides Complete and Accurate Information (New) ...	17
Improve Monitoring of Foreign Clinical Trials (New).....	19
Strengthen Inspections of Domestic Food Facilities to Ensure Food Safety and Compliance (New)	21
Eliminate Excessive Costs in the 340B Drug Pricing Program.....	23
Improve Monitoring of Ryan White CARE Act Grantees and Subgrantees	25
Increase Reporting of Medical Malpractice Cases to the National Practitioner Data Bank....	27

Collect Health Education Assistance Loan Debts (New).....	29
Reduce Overpayments for Contract Health Services Hospital Claims and Cap Payments for Nonhospital Services at the Medicare Rate for Those Services	31
Increase Oversight of Grantees’ Management of Financial Conflicts of Interest in Research (New)	33
Increase Oversight of Grantee Institutions To Ensure Compliance With Federal Financial Conflict-of-Interest Regulations	37
Human Services Programs	39
Use Voluntary Contributions To Expand Services for the Elderly	39
Ensure That States’ Cost-Sharing Practices Comply With Requirements and Improve Data Quality	41
Delineate Roles and Enforce Unaccompanied Children’s Services Requirements	43
Departmentwide Issues	45
Strengthen State Protections for Persons With Disabilities in Residential Settings	45
Improve Financial Analysis and Reporting Processes	47

Public Health Programs

Public Health > Assistant Secretary for Preparedness and Response

Improve States' and Localities' Medical Surge Preparedness for Pandemics

Background: A pandemic would affect much of the country at the same time, so medical resources—such as hospital beds, medical equipment, and personnel—likely would be scarce. The ability to rapidly respond to an increased demand for medical resources is often referred to as a “medical surge.” The public health emergency caused by an outbreak of human cases of H1N1 influenza has highlighted the need for States and localities to be prepared for a medical surge.

We assessed the extent to which selected States and localities have prepared for a medical surge in response to an influenza pandemic and have conducted and documented exercises that test their medical surge preparedness. This review is based on a sample of 5 States and 10 localities and presents a snapshot of these States' and localities' preparedness for an influenza pandemic as of late summer 2008. The review is based on a review of documentation from the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), and the selected States and localities, as well as structured in-person interviews with key officials in each of the selected States and localities.

Findings: We found that all of the 10 localities that we reviewed had established partnerships to prepare for a medical surge; however, the degree to which coordination occurred varied. We also found that fewer than half of the localities had started to recruit medical volunteers, and none of the five States that we reviewed had implemented an electronic system to manage the volunteers. Similarly, the 10 localities had acquired limited medical equipment for a pandemic, but only 3 of the 5 States had electronic systems to track available beds and equipment. As of late summer 2008, most of the localities were in the early stages of planning for alternate care sites, and most had not identified guidelines for altering triage, admission, and patient care during a pandemic. Finally, although the localities conducted medical surge exercises, none consistently documented the lessons learned.

Recommendation: We recommend that ASPR, in collaboration with CDC, work with States and localities to improve their efforts within each of the five components of medical surge that we reviewed: coordinating with and involving a wide array of stakeholders in medical surge and pandemic planning; recruiting, registering, and training medical volunteers for use in a pandemic; managing medical equipment currently being stockpiled for a public health emergency, such as a pandemic; planning for alternate care sites for use during a pandemic; and identifying and adopting guidelines for altering triage, admission, and patient care during a pandemic.

Management Response Summary: ASPR concurred with our recommendation. In October 2009, ASPR stated that it had updated its *Medical Surge Capacity and Capability Handbook* and added hospital reporting requirements to aid State health care system planning. In December 2010, ASPR stated that it was engaging with other agencies and Departments administering health-related preparedness grants as a primary partner in a “grant alignment” project designed to streamline all Federal grant mechanisms and to maximize the efficiency of grant management processes to improve preparedness and response outcomes.

Status: We continue to monitor ASPR’s progress in implementing our recommendations.

Related Report:

2009 SEP *State and Local Pandemic Influenza Preparedness: Medical Surge.*
OEI-02-08-00210 [Report](#)

Public Health > Centers for Disease Control and Prevention

Ensure That State Public Health Laboratories Meet Cooperative Agreement Requirements on Biological Threats

Background: In 2006, through its Cooperative Agreement, CDC allocated about \$766 million to 62 awardees to meet 9 preparedness goals. Preparedness Goal 3, Detect and Report, is the only goal that focuses on public health laboratory testing and reporting biological threats. This goal contains 2 required critical tasks with 11 requirements. These requirements contain multiple elements that State public health laboratories must meet to decrease the time needed to detect and report biological public health threats. For most of the Preparedness Goal 3 requirements, State public health laboratories must coordinate with private clinical laboratories, known as sentinel laboratories, that perform preliminary testing and ship specimens to the State.

Findings: We surveyed public health laboratory officials in 50 States and 3 metropolitan areas to assess the extent to which they have made progress toward meeting 9 of the 11 Cooperative Agreement requirements for State public health laboratory testing and reporting. We found that every State reported meeting at least three of the requirements that we reviewed, but no State met all nine. At least 87 percent of States reported meeting all of the elements in four of the nine requirements. Less than 65 percent of States reported meeting all the elements in 5 of the 9 testing and reporting requirements we reviewed, and less than 10 percent of States reported meeting all elements in two of these five requirements.

Recommendations: CDC should continue to assist States in meeting Cooperative Agreement requirements intended to decrease the time needed to detect and report biological public health threats. CDC should place special emphasis on improving performance for the 2 requirements met by less than 10 percent of States by (1) determining why less than 10 percent of States conducted tests of their sentinel laboratories' ability to ship outside regular business hours and providing assistance to States on how to increase the number of tests conducted and (2) ensuring that States use a consistent method to identify sentinel laboratories to be included in their databases and that the databases include all the required elements.

Management Response Summary: CDC concurred with our overall recommendation that it continue to assist States in meeting the Cooperative Agreement requirements to decrease the time needed to detect and report biological public health threats. CDC concurred that it should determine how sentinel laboratories are identified and noted that States should have flexibility in determining the functional criteria for a

facility to be considered a sentinel laboratory. CDC noted at that time that States had until 2010 to meet all the required critical tasks stipulated.

In October 2010, CDC informed the Office of Inspector General (OIG) that it continues to provide guidance to States on how to decrease the time needed to detect and report biological public health threats. CDC also noted that, due to a 12-month extension granted in 2009 by the Department of Health & Human Services (HHS), awardees now have until August 2011 to complete the critical tasks stipulated under the current Cooperative Agreement and subsequent continuation guidance, including the requirement to decrease the time needed to detect and report biological public health threats.

Status: We continue to monitor CDC's progress in implementing our recommendations.

Related Report:

2008 OCT *Public Health Laboratory Testing To Detect and Report Biological Threats.*
OEI-04-07-00750 [Report](#)

Public Health > Centers for Disease Control and Prevention

Improve Oversight of the Ethics Program for Special Government Employees on Federal Advisory Committees at CDC (New)

Background: Federal Advisory Committees (committees) play an influential role in decisionmaking for the Federal Government. Special Government employees (SGE) are individuals who are not regularly employed by the Government and typically have other employment. On these committees, SGEs serve as subject-matter experts. To protect the committees' integrity and credibility, SGEs with conflicts of interest must not inappropriately influence their committees' work. Before permitting SGEs to participate in committee meetings, CDC must ensure that SGEs disclose complete financial information on a Confidential Financial Disclosure Report and identify and resolve all SGEs' conflicts of interest. Finally, CDC must provide ethics training to SGEs and monitor their compliance with ethics requirements during committee meetings. We reviewed Confidential Financial Disclosure Reports and related documents for 246 SGEs serving on 17 CDC committees in 2007.

Findings: We found that CDC and its SGEs on committees did not comply with a number of ethics requirements in 2007. That is, for almost all SGEs, CDC did not ensure that Confidential Financial Disclosure Reports were complete in 2007, and most of these forms contained multiple omissions. In addition, CDC did not identify or resolve conflicts of interest for 64 percent of SGEs in 2007. Over one-fourth of SGEs had both unidentified and unresolved potential conflicts of interest on file. CDC also did not ensure that 41 percent of SGEs received required ethics training in 2007. Finally, 15 percent of SGEs did not comply with ethics requirements during committee meetings in 2007. These SGEs either participated in meetings without having a current, certified Confidential Financial Disclosure Report on file, or they voted on committee matters in which they were prohibited from participating because of a documented conflict of interest.

Recommendations: CDC should (1) ensure SGEs' Confidential Financial Disclosure Reports are complete; (2) require SGEs to disclose their involvement in grants and other relevant interests that could pose conflicts which are not disclosed on the Confidential Financial Disclosure Report; (3) identify and resolve all SGEs' conflicts of interest before permitting them to participate in committee meetings; and (4) track SGE compliance with ethics requirements.

Management Response Summary: In its response to our draft report, CDC concurred with all of our recommendations. Since the time of our review, CDC

indicated that it has begun or plans to implement improvements that coincide with our recommendations.

Status: We will continue to monitor CDC's implementation of our recommendations.

Related Report:

2009 DEC *CDC's Ethics Program for Special Government Employees on Federal Advisory Committees.* OEI-04-07-00260 [Report](#)

Public Health > Food and Drug Administration

Update and Maintain an Accurate National Drug Code Directory

Background: The Drug Listing Act of 1972, § 3, amended the Food, Drug, and Cosmetic Act (FDCA) to require drug firms that are engaged in manufacturing, preparing, propagating, compounding, or processing drugs to report all drug products to the Food and Drug Administration (FDA). Drug products are uniquely identified and reported using a three-segment number, called the National Drug Code (NDC), which is a universal product identifier for human drugs. FDA assigns the first segment and drug firms assign the other two segments. FDA enters the full NDC number and information submitted as part of the listing process into a database known as the Drug Registration and Listing System. FDA extracts information from the database several times a year and publishes that information in the *NDC Directory* (the directory). When drug firms introduce a new drug product or discontinue a product, they must report the complete NDC and associated information to FDA as part of the drug-product listing process.

Findings: We found that the directory was neither complete nor accurate. An estimated 9,187 prescription drug products were missing from the list, while another 5,150 had not cleared the listing process. An estimated 34,257 drug products listed were no longer on the market or were listed in error. Problems with the directory resulted primarily from drug firms' failure to report instances when drugs are placed on or taken off the market and the firms' failure to provide sufficient and accurate information to complete the listing process.

Recommendations: FDA should (1) provide greater control over the assignment of NDCs, (2) implement a mechanism to routinely identify drug product omissions and inaccuracies, and (3) identify and take appropriate action against drug firms that consistently fail to list drug products and update information.

Management Response Summary: FDA concurred with our recommendations and requested access to our data files to follow up on identified problems. In comments on our draft report, FDA delineated a number of initiatives to improve the directory's completeness and accuracy, such as conversion to an electronic listing system for use by drug firms.

FDA said in its response to the report that it was preparing a proposed rule to clarify listing requirements, enhance control of the drug establishment registration and drug-listing process, and improve data accuracy and completeness. This proposed rule was published on August 29, 2006 (71 Fed. Reg. 51276). Subsequent to the publication of our report, FDA told us that in December 2006, it held a public hearing on this proposed

rule. In its 2011 update of its response to our recommendations, FDA said that it was in the process of finalizing this rule.

In a step toward implementation of our second recommendation, FDA has begun implementing an electronic system for firms to submit drug product listing data using the structured product label submission process. In a step toward implementation of our third recommendation, FDA has collaborated with The Centers for Medicare & Medicaid (CMS) to develop a Non-Matched NDC List that, among other things, helps FDA identify drug products that are not properly listed, as required. The development and posting of this list has prompted firms to address previously incorrect or incomplete listing data, including discontinued products that are no longer marketed.

Status: We continue to monitor FDA's progress in implementing our recommendations.

Related Report:

2006 AUG *The Food and Drug Administration's National Drug Code Directory.*
OEI-06-05-00060 [Report](#)

Public Health > Food and Drug Administration

Improve and Strengthen Food Facilities' Compliance With Records Requirements for Traceability of Food Products

Background: Beginning in 2005, FDA required certain food facilities to maintain records identifying the sources, recipients, and transporters of food products. These records enable FDA to trace articles of food through each stage of the supply chain—from retail outlets back to farms—if FDA has a reasonable belief that a food product is adulterated and presents a serious health threat. Traceability is the ability to follow the movement of food products through the stages of production, processing, and distribution. Traceability is often needed to identify the sources of food contamination and the recipients of contaminated food in product recalls and seizures. We used two primary data sources for our review: a traceability exercise of 40 selected food products and structured interviews with the managers of the food facilities that handled the selected food products to determine the extent of the information that facilities kept about their sources, recipients, and transporters, which we used to trace the products.

Findings: We were able to trace 5 of the 40 products through each stage of the food supply chain. For 31 of the 40 products, we were able to identify facilities that likely handled the products. Most facilities did not maintain lot-specific information in their records and could estimate only a range of deliveries (from one or more facilities) that may have included the products we purchased. Several factors prevented us from tracing the specific products through the food supply chain: facilities did not always maintain lot-specific information; products were not labeled with required information; and products from a number of farms were mixed. We found that 59 percent of the facilities did not meet FDA's record requirements about sources, recipients, and transporters. This meant that 70 of the 118 facilities in our sample did not provide required information. We also found that one-quarter of the food facilities were not aware of FDA's records requirements. Others described practices designed to improve traceability.

Recommendations: We recommend that FDA (1) work with the food industry to develop additional guidance to strengthen traceability; (2) address issues related to mixing raw food products from a large number of farms; (3) seek statutory authority to ensure that facilities are complying with record requirements; and (4) conduct education and outreach to inform the food industry about its records requirements.

Management Response Summary: In its comments on our report, FDA said that it would consider our recommendation regarding seeking statutory authority, and it

described its efforts in response to our recommendation to work with the food industry to conduct education and outreach. FDA did not say whether it concurred with the other recommendations but noted that it continues to work closely with its food-safety partners to strengthen its ability to protect Americans from foodborne illness, which includes determining whether additional statutory authority is needed to better protect public health.

In its February 2011 update of its response to our recommendations, FDA said that it has taken several steps to improve recordkeeping and food tracing. For example, FDA completed a pilot study on tracing in the tomato industry and is planning several other pilot studies to assess the feasibility of different tracing systems and technologies. FDA described its efforts in response to our recommendation to work with the food industry to conduct education and outreach.

Status: We acknowledge the efforts FDA has taken and continue to monitor its progress in implementing our recommendations. Although the FDA Food Safety Modernization Act implemented several of the report's recommendations, we continue to emphasize the need for FDA to seek statutory authority to ensure that facilities are complying with the record requirements related to food traceability. FDA does not currently have the authority to request facilities' records regarding traceability during routine inspections.

Related Report:

2009 MAR *Traceability in the Food Supply Chain*. OEI-02-06-00210 [Report](#)

See Also:

2009 MAR OIG Testimony Before the House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies: "Traceability in the Food Supply Chain." [Testimony](#)

Public Health > Food and Drug Administration

Ensure That Clinical Investigators Disclose All Financial Interests

Background: Most new drugs, biological products, and medical devices undergo clinical trials on human subjects before they are marketed in the United States. Sponsors, generally pharmaceutical or device companies, oversee trials conducted by clinical investigators. Sponsors must collect financial information from clinical investigators before the trials. However, sponsors submit financial information to FDA only when they submit their marketing applications after clinical trials end. For each clinical investigator, sponsors submit a financial form either certifying that the investigator does not have a financial interest regarding the outcome of the trial or disclosing such a financial interest.

Findings: We found that clinical investigators might not be disclosing all their financial interests. One percent of clinical investigators disclosed a financial interest during the period reviewed. FDA cannot determine whether sponsors have submitted financial interest information for all their clinical investigators. We also found that almost half of marketing applications were missing financial interest information. In almost one-third of marketing applications, FDA reviewers did not document a review of financial interest information, and neither FDA nor sponsors took action for 20 percent of marketing applications with disclosed financial interests.

Recommendations: FDA should (1) ensure that sponsors submit complete financial information for all their clinical investigators, (2) ensure that FDA reviewers consistently review financial information and take action in response to disclosed financial interests by using a review template and providing guidance and training to reviewers, and (3) require that sponsors submit financial information as part of the pretrial application process.

Management Response Summary: FDA generally agreed with our recommendations. However, the agency did not agree with our final recommendation that FDA require sponsors to submit financial information for clinical investigators during the pretrial application process. FDA emphasized that collecting financial information before clinical trials is the sponsors' responsibility. As of February 2009, FDA required entities submitting marketing applications to include a complete list of clinical investigators and either certify to the absence of reportable financial arrangements or disclose the nature of the financial arrangements. FDA also updated the *Compliance Program Guidance Manual* chapter entitled "Clinical Investigator Inspections."

Currently, FDA is revising its *Guidance for Industry: Financial Disclosure by Clinical Investigators*. The proposed revisions are aimed at ensuring that all required information is included in the application to FDA. FDA plans to issue the revised guidance in draft; as of January 2011, the document was in agency clearance.

Status: We continue to monitor FDA's implementation of our recommendations.

Related Report:

2009 JAN *The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information*. OEI-05-07-00730 [Report](#)

Public Health > Food and Drug Administration

Minimize Financial Risk in the Food and Drug Administration's Information Technology Contracts

Background: Pursuant to the Federal Acquisition Regulation (FAR), agencies must establish procedures to select qualified contractors while protecting the Government from unnecessary financial risk. Agencies must perform acquisition planning, clearly define what they are buying in the requirements section of a statement of work (SOW), and select an appropriate contract type and method. Agencies must also monitor contractors to ensure quality results.

Findings: We found that FDA's Center for Drug Evaluation and Research (CDER) relied primarily on acquisition methods that emphasize speed and flexibility over planning. CDER also relied on time-and-materials contract actions that increase risk for the Government. Because CDER did not clearly define its requirements or performance measures, it also did not apply quality assurance (QA) plans consistently.

Recommendations: We recommend that FDA minimize its contract risk by (1) defining information technology (IT) requirements more clearly, (2) converting ongoing time-and-materials contract actions to fixed-price contract actions when appropriate, (3) using performance incentive plans when appropriate, and (4) using documented QA plans.

Management Response Summary: FDA neither agreed nor disagreed with our recommendation to define its IT requirements more clearly. However, it did identify actions that it is taking that support that recommendation, such as implementing a formal business process model. FDA agreed with our other recommendations to convert time-and-materials contracts to fixed-price contracts when appropriate and to use performance incentives and QA plans, saying that it will use these methods in future contracts when applicable. In its January 2011 update to its response to our recommendations, FDA stated that it has developed and initiated standard operating procedures as part of its information technology information management process.

Status: We continue to monitor FDA's implementation of our recommendations.

Related Report:

2009 JAN *Management of Information Technology Contracts at the Food and Drug Administration's Center for Drug Evaluation and Research.*
OEI-01-07-00450 [Report](#)

Public Health > Food and Drug Administration

Use Adverse Event Reports to Detect and Address Safety Concerns About Medical Devices (New)

Background: The adverse event reporting system provides both the Center for Devices and Radiological Health (CDRH) and manufacturers with a means to identify and monitor significant adverse events involving medical devices. Adverse events include deaths, serious injuries, malfunctions, and events that require remedial action to prevent an unreasonable risk of substantial harm to the public. Regulations require that manufacturers of medical devices and facilities that use these devices (hereinafter referred to as user facilities) submit reports to FDA within specific timeframes ranging from 5 days to 1 year following the occurrence of an adverse event.

Findings: We found that CDRH has not documented followup on adverse events, nor does it consistently perform its first-time reading of adverse event reports in a timely manner. In addition, CDRH rarely acts when manufacturers and user facilities submit reports late. We also found that the inability to obtain complete and usable information in adverse event reports hinders analysts' review of the reports, and that CDRH makes limited use of annual reports. Overall, FDA received twice as many adverse event reports for medical devices in 2007 as in 2003; however, the number of some types of reports, such as 5-day reports, decreased. We also found that although manufacturers submitted most adverse event reports on time, many 5-day manufacturer reports and 5-day user facility reports were late.

Recommendations: FDA should (1) develop a clear protocol for reviewing adverse event reports that specifically addresses the following needs: (a) documenting followup on adverse events, (b) ensuring and documenting that CDRH is meeting its own guidelines for reviewing high-priority adverse event reports, (c) following up with manufacturers who routinely submit reports late or with incomplete information, and (d) enhancing outreach strategies to reduce user facility underreporting; and (2) seek legislative authority to eliminate the regulation for user facilities to submit annual reports.

Management Response Summary: FDA agreed with both of our recommendations. In its comments, FDA said that CDRH would develop a clear review protocol that addresses the needs that our report identified. FDA stated that it is developing a new database that should allow for more extensive documentation and followup on adverse events and permit FDA to more readily identify late and incomplete reports. FDA also stated that CDRH has developed a tracking system that facilitates referrals to its Office of Compliance and follows up on them.

Status: We will continue to monitor FDA's progress in addressing our recommendations.

Related Report:

2009 OCT *Adverse Event Reporting for Medical Devices.* OEI-01-08-00110 [Report](#)

Public Health > Food and Drug Administration

Ensure That Food Facility Registry Provides Complete and Accurate Information (New)

Background: Section 305(a) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires certain food facilities to register with FDA. As of December 2003, FDA began requiring food facilities that manufacture, process, pack, or hold food for consumption in the United States to register their facilities with FDA. The purpose of this registration is to provide FDA with sufficient and reliable information about food facilities so that it can quickly locate facilities during an outbreak of foodborne illness. It also allows FDA to locate these facilities for inspection. Our review was based on a purposive sample of 130 selected domestic food facilities. Our analysis compared information about the selected facilities in the registry with information obtained during structured interviews with the facility managers.

Findings: Our review raised questions about the accuracy and utility of the registry. We found that 7 percent of selected facilities either failed to register or failed to cancel their registrations with FDA, as required. Additionally, we found that 48 percent of selected facilities either failed to provide accurate information when they first registered or failed to provide accurate information after changes in the facility's information, as required. For each of these facilities, FDA was missing information or had inaccurate information, which could hinder FDA's ability to identify food facilities that may be linked to an outbreak of foodborne illness. We also found that FDA's regulations do not ensure that the registry contains certain information that may be needed in an emergency. In many cases, we found that because providing certain information in the registry is optional, facilities failed to provide information that may be useful to FDA in an emergency. Finally, we found that 52 percent of the facility managers at the selected facilities reported that they were unaware of FDA's registry requirements.

Recommendations: FDA should (1) consider seeking statutory authority to impose civil penalties through administrative proceedings against facilities that either fail to register or fail to provide accurate information for the registry; (2) consider making some of the optional fields within the registry mandatory; and (3) work with the food industry to conduct additional education and outreach activities to inform food facilities about the registry requirements.

Management Response Summary: FDA generally agreed with our recommendations. FDA noted that the study confirms problems that the agency has encountered as well as the need for additional statutory authority.

Status: We will continue to monitor FDA's progress in addressing our recommendations. Although the FDA Food Safety Modernization Act implemented one of the report's recommendations (that facilities be required to reregister on a routine basis), we continue to emphasize the need for FDA to have additional authority to penalize noncompliant facilities.

Related Report:

2009 DEC *FDA's Food Facility Registry*. OEI-02-08-00060 [Report](#)

Public Health > Food and Drug Administration

Improve Monitoring of Foreign Clinical Trials (New)

Background: The FDCA requires all new investigational drugs and biologics to undergo clinical trials on human subjects to demonstrate the safety and efficacy of these products prior to approval for sale in the United States. FDA ensures the rights, safety, and well-being of subjects who participate in these trials and verifies that the clinical trial data collected are both accurate and reliable. Sponsors may submit data from foreign and domestic clinical trials to support marketing applications. For data from foreign clinical trials, often the first time that FDA has the opportunity to review the safety and accuracy of those trials is when the sponsor is seeking permission to market the drug in the United States, which may be years after the clinical trials have concluded. Sponsors may realize benefits from conducting research abroad, such as lower costs in some countries or the ability to conduct larger trials in less time. However, medical ethicists have raised concerns about the increased prevalence of foreign clinical trials. These concerns include the ability of local regulatory bodies and institutional review boards to adequately monitor clinical trials to protect the rights and welfare of subjects and to ensure data integrity.

Findings: We found that in fiscal year (FY) 2008, sponsors relied heavily on data from foreign clinical trials to support their marketing applications for drugs and biologics. We found that 80 percent of approved marketing applications for drugs and biologics contained data from foreign clinical trials. Further, over half of clinical trial subjects and sites were located outside the United States. Although FDA inspected clinical investigators at few clinical trial sites overall, FDA inspected clinical investigators at foreign sites at an even lower rate—less than 1 percent of foreign sites. Challenges in conducting foreign inspections and data limitations inhibit FDA's ability to monitor foreign clinical trials. For example, if a sponsor has not submitted an Investigational New Drug (IND) application or consulted with FDA in some other way about its foreign clinical trials prior to seeking FDA marketing approval, the agency has no way of knowing whether and where foreign clinical trials are taking place and therefore cannot conduct inspections while the trials are in progress. Further, despite guidelines in the Good Clinical Practice international quality standard, sponsors generally submitted data that were presented inconsistently, making it difficult to locate clinical trial information, particularly site locations and subject enrollment.

Recommendations: FDA should (1) require standardized electronic clinical trial data and create an internal database of clinical trial data; (2) monitor trends in foreign clinical trials not conducted under INDs and, if necessary, take steps to

encourage sponsors to file INDs; and (3) continue to explore ways to expand its oversight of foreign clinical trials.

Management Response Summary: FDA agreed with all of our recommendations. With regard to the first recommendation, FDA is piloting a site selection tool to standardize clinical trial data and may expand use of the tool within the agency. FDA added that the data captured by the site selection tool represent a partial solution and that it is considering long-term solutions. With regard to the second recommendation, FDA said that it will continue to assess trends in foreign clinical trials through inspection data and will explore whether tracking the number of applications with clinical trial data not collected under INDs is feasible. With regard to the third recommendation, FDA plans to leverage its partnership with the European Medicines Agency to work with other regulatory bodies. FDA is also expanding worldwide outreach and training in concepts of Good Clinical Practice.

Status: We will continue to monitor FDA's implementation of our recommendations.

Related Reports:

- 2009 JUN *Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials.*
OEI-01-08-00510 [Report](#)
- 2007 SEPT *The Food and Drug Administration's Oversight of Clinical Trials.*
OEI-01-06-00160 [Report](#)
- 2001 SEPT *The Globalization of Clinical Trials.* OEI-01-00-00190 [Report](#)

Public Health > Food and Drug Administration

Strengthen Inspections of Domestic Food Facilities to Ensure Food Safety and Compliance (New)

Background: FDA inspects food facilities to ensure food safety and compliance with regulations. According to FDA guidance, when the agency identifies violations that are significant enough to warrant an “official action indicated” (OAI) classification, some type of regulatory action should be recommended. This action could include issuing a warning letter, holding a regulatory meeting, or initiating an enforcement action such as a seizure or an injunction.

Findings: We found that many food facilities went 5 years or longer without an FDA inspection. We also found that there was a large decline in the number of food facility inspections conducted by FDA over a 5-year period, as well as a decline in the number of violations identified by FDA inspectors. Further, when violations were identified, FDA did not routinely take swift and effective action to ensure that these violations were remedied. Specifically, we found that for 36 percent of the facilities that received OAI classifications, FDA took no additional steps to ensure that the violations were corrected.

Recommendations: To strengthen the significant weaknesses in its inspections and to ensure food safety and compliance with the regulations, FDA should (1) provide additional guidance about when it is appropriate to lower OAI classifications; (2) take appropriate actions against facilities with OAI classifications, particularly those that have histories of violations; (3) ensure that violations are corrected for all facilities that receive OAI classifications; and (4) consider seeking additional statutory authority that would allow FDA to impose civil penalties through administrative proceedings.

Management Response Summary: In its comments to our draft report, FDA supported our recommendation to seek additional statutory authority (recommendation 4) and agreed with our recommendation to provide additional guidance about when it is appropriate to lower OAI classifications (recommendation 1). FDA noted several actions it has taken, or plans to take, to address the remaining two recommendations.

Status: We will continue to monitor FDA’s implementation of our recommendations.

Related Report:

2010 APR *FDA Inspections of Domestic Food Facilities.* OEI-02-08-00080 [Report](#)

Public Health > Health Resources and Services Administration

Eliminate Excessive Costs in the 340B Drug Pricing Program

Background: The Public Health Service Act of 1944 (PHS Act), § 340B, created the 340B Drug Pricing program to lower drug prices for more than 12,300 entities, including community health centers, public hospitals, and various Federal grantees.

Pharmaceutical manufacturers calculate the 340B discount using a specified formula and must sell their products at or below this ceiling price to continue to have their products covered by the Medicaid program. The Health Resources and Services Administration's (HRSA) Pharmacy Affairs Branch administers the program for the thousands of enrolled entities nationwide, which are estimated to have spent \$3.4 billion on drugs in 2003.

Findings: Because of systemic problems with the accuracy and reliability of the Government's record of 340B ceiling prices, we found that HRSA could not adequately oversee the 340B Drug Pricing Program. HRSA lacked the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price. We found that in a single month in 2005, 14 percent of total purchases made by 340B entities exceeded 340B ceiling prices, resulting in total projected overpayments of \$3.9 million for the year.

Recommendations: HRSA should (1) improve its oversight of the 340B Drug Pricing Program to ensure that entities are charged at or below the 340B ceiling price; (2) work with CMS to ensure accurate and timely pricing data for the Government's official record of 340B ceiling prices; and (3) strengthen its administration of the 340B Drug Pricing Program by (a) establishing detailed standards for the calculation of 340B ceiling prices and (b) providing participating entities with secure access to certain pricing data to help approximate the 340B ceiling prices.

Savings: \$46.8 million by federally supported covered entities.*

**We estimated savings based on \$3.9 million in overpayments by 340B entities in 1 month in 2005, multiplied by 12 to calculate savings for 1 year. More indirect savings to HHS are likely but have not been calculated.*

Management Response Summary: HRSA concurred with our recommendations and said that it had taken steps to monitor more closely prices paid by the 340B program. In its comments on our 2005 report, HRSA said that it anticipated promulgating a price policy in conjunction with formalizing instructions for the calculation of 340B ceiling prices. HRSA indicated that in April 2007, it had implemented a 1-year 340B Drug Pricing Program pilot project requesting manufacturers to voluntarily submit their

prices for comparison with the ceiling prices. To the extent that resources permitted, HRSA would review the data that manufacturers and entities voluntarily submitted. HRSA also indicated that oversight mechanisms to validate 340B price calculations and access to certain pricing data by participating entities will be addressed through the initiatives supported by the appropriation funding.

In March 2009, HRSA informed us that it would consider seeking the authority to establish penalties for violations of the PHS Act, § 340B, and is following CMS's practices concerning detailed standards for the 340B price calculations. In a September 2009 followup review, HRSA indicated that it was drafting guidelines for 340B pricing publications; however, it lacked the resources to complete the project. In September 2009, HRSA reported that its pilot project revealed that apparent price discrepancies between the manufacturer's price and the 340B ceiling price were primarily because of differences in the package size that were being compared.

Section 7102 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) directs the Secretary of HHS to improve manufacturer compliance with 340B reporting rules, including verifying the accuracy of ceiling prices, establishing a system for manufacturers to refund overcharges, and providing 340B participating entities with limited access to ceiling prices. On September 20, 2010, HRSA published an advance notice of public rulemaking to solicit comments for the development of such regulations.

Status: We continue to monitor HRSA's efforts to develop new regulations on 340B program integrity.

Related Reports:

2006 JUL *Review of 340B Prices.* OEI-05-02-00073 [Report](#)

2005 OCT *Deficiencies in the Oversight of the 340B Drug Pricing Program.*
OEI-05-02-00072 [Report](#)

See Also:

2005 DEC *OIG Testimony Before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations: "340B Program."*
[Testimony](#)

Public Health > Health Resources and Services Administration

Improve Monitoring of Ryan White CARE Act Grantees and Subgrantees

Background: The Ryan White Comprehensive AIDS Resources Emergency Act (CARE Act) was passed in 1990 and reauthorized in 1996 and 2000. In FY 2001, Congress provided \$597.3 million under Title I and \$977.4 million under Title II of the CARE Act. In 2006, Congress enacted the Ryan White HIV/AIDS Treatment Modernization Act. Title I of the Ryan White HIV/AIDS Treatment Modernization Act provides emergency relief grants to cities disproportionately affected by human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS), and Title II provides grants to States to improve the organization of HIV/AIDS-related health and support services. States distribute Title II funds to subgrantees.

Findings: We found that in 2000, Title I and Title II project officers had not adequately monitored sampled grantees (e.g., progress reports were missing, monitoring visits were not conducted, and grantee applications were not used as management tools). HRSA provided limited support to project officers to systematically monitor grantees (e.g., little guidance and training, lack of corrective action plans, and minimal coordination). Grantees' monitoring of subgrantees was limited (75 percent of the sampled grantees did not have comprehensive documentation to demonstrate that they were monitoring subgrantees).

Recommendations: HRSA should (1) specify and enforce standards and policies about how project officers should monitor grantees, (2) address training of project officers, (3) standardize corrective actions, (4) increase the number of site visits, (5) improve project officer continuity and coordination, (6) set standards for grantees' monitoring of subgrantees, and (7) increase efforts to monitor grantees' oversight of subgrantees.

Management Response Summary: HRSA concurred with our recommendations and indicated that significant administrative changes had occurred since the studies were conducted. In May 2008, HRSA told OIG that it had taken a variety of steps to implement our recommendations. The steps include enhancing training for project officers, developing a site visit protocol for onsite monitoring, and increasing the number of grantee site visits. HRSA reported that in March 2009, it had consolidated its grants operations and project officers and its monitoring of Part A and Part B (formerly Title I and II) grantees and, through its Office of Performance Review, was receiving more information with regard to grantee performance.

Per congressional request, in June 2009, OIG reviewed HRSA's status in addressing our recommendations related to grantees' monitoring of subgrantees. In December 2010, HRSA stated that it was in the process of developing monitoring standards that may be used by CARE Act Part A and Part B programs in a comprehensive on-site review of programmatic, fiscal, and clinical quality management performance of their subgrantees. A site-visit protocol will also be developed specifically to measure compliance with legislative mandates and HRSA policies, grants management requirements, and program guidance. Full implementation of this effort is anticipated in the FY 2011 grant year.

Status: We continue to monitor HRSA's progress in implementing our recommendations.

Related Reports:

2004 MAR *Monitoring of Ryan White CARE Act Title I and Title II Grantees.*
OEI-02-01-00640 [Report](#)

2004 MAR *Ryan White CARE Act Title I and Title II Grantees' Monitoring of Subgrantees.*
OEI-02-01-00641 [Report](#)

Public Health > Health Resources and Services Administration

Increase Reporting of Medical Malpractice Cases to the National Practitioner Data Bank

Background: Pursuant to an HHS policy directive issued on October 15, 1990, all settled or adjudicated medical malpractice cases involving HHS must be reported to the National Practitioner Data Bank (NPDB).

Findings: We found that as of October 2004, HHS agencies had failed to report as many as 474 medical malpractice cases to the NPDB. Individual agency underreporting was as follows: Indian Health Service (IHS), 290 cases; HRSA, 179 cases; and the National Institutes of Health (NIH), 5 cases.

This underreporting was caused by a number of factors, including (1) lost medical malpractice files; (2) incomplete information in medical malpractice files; (3) a decision by the HHS peer review entity, the Medical Claims Review Panel, not to identify practitioners who met the standard of care (a decision that was inconsistent with policy); and (4) the failure to replace a key Program Support Center claims official or to reassign the person's reporting duties.

Recommendations: IHS, HRSA, and NIH should each (1) implement corrective action to address unreported cases, (2) improve internal controls involving file management, and (3) assign staff members to assume responsibility for addressing practitioner questions/complaints and data entry of reports to NPDB.

Management Response Summary: There was partial concurrence with our recommendations. Before OIG issued its October 2005 report, IHS started reporting cases in which standards of care were not met. HRSA started reporting such cases soon thereafter. In comments on our draft report, HRSA's Administrator indicated that HHS was developing a policy on reporting cases in which standards of care were not met.

As of April 2008, IHS had submitted 205 more reports of practitioners to NPDB, and HRSA had submitted 297 reports. As of April 2008, NIH had not submitted any reports. In March 2009, HRSA informed OIG that it had submitted 17 medical malpractice payment reports between January 1 and December 31, 2008. For the same period, IHS reported to OIG that it had submitted 33 malpractice payment reports and assigned a specific risk-management team to address complaints and questions and perform data entry of NPDB reports. IHS also told us that it had a risk management and medical liability manual and had established file management controls.

In December 2010, IHS reported that it submitted 37 medical malpractice payment reports to the NPDB in FYs 2009 and 2010, and that the agency is up to date on reporting. HRSA stated that it submitted 22 medical malpractice payment reports to NPDB in FY 2010. NIH stated that it will not submit reports to NPDB until a revised departmental policy is issued.

Status: We continue to monitor implementation of our recommendations by IHS, HRSA, and NIH.

Related Report:

2005 OCT *HHS Agencies' Compliance With the National Practitioner Data Bank Malpractice Reporting Policy.* OEI-12-04-00310 [Report](#)

Public Health > Health Resources and Services Administration

Collect Health Education Assistance Loan Debts (New)

Background: The Health Education Assistance Loan (HEAL) program began in 1978 to help eligible graduate students in health professions finance their education. Although no new HEAL loans have been issued since September 30, 1998, HRSA continues to oversee prior loans made by participating lenders, such as banks and credit unions. HHS's Program Support Center provides HRSA with debt management services that include many of the activities involved in trying to obtain payments when individuals default on HEAL loans. HHS reimburses lenders for any HEAL loans that are not repaid because of borrowers' default, bankruptcy, death, or total and permanent disability.

Findings: We found that of the 486 HEAL defaulters who earned income in FY 2008, 312 made no payments on their loans during that time. These 312 HEAL defaulters earned \$13.4 million and owed \$47.5 million on their loans in FY 2008. Ninety-eight of these defaulters (31 percent) earned \$50,000 or more and were responsible for nearly \$15 million of the \$47.5 million owed.

We also found that of the 174 HEAL defaulters who earned income and made loan payments in FY 2008, nearly half (45 percent) paid less than \$2,000 each during that time. The median income for these defaulters was \$47,331. The 174 HEAL defaulters earned \$9.6 million and owed \$22.5 million on their loans in FY 2008. The amount these defaulters paid totaled \$659,135 in FY 2008, or just 3 percent of their total loan balance during that time.

Recommendation: HRSA should work with the Program Support Center to consider obtaining wage data from Federal or State sources to enable HRSA and the Program Support Center to target future collection efforts on defaulters with income.

Management Response Summary: HRSA concurred with our recommendation. In September 2010, HRSA stated that the HEAL program might be transferred to the Department of Education (ED). However, there is currently no further information as to when this transfer might take place or how this transfer would affect the debt collection process.

Status: We will continue to monitor HRSA's implementation of our recommendations.

Related Report:

2010 FEB *Health Education Assistance Loan Defaulters With Income in Fiscal Year 2008.*
OEI-03-09-00100 [Report](#)

Public Health > Indian Health Service

Reduce Overpayments for Contract Health Services Hospital Claims and Cap Payments for Nonhospital Services at the Medicare Rate for Those Services

Background: Contract Health Services (CHS) contracts with private providers, such as hospitals and physicians, to deliver emergency or specialty services to eligible Indians when an IHS or tribal facility is unable to provide the necessary care. Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and its implementing regulations, all Medicare-participating hospitals must accept reimbursement no greater than the Medicare rate as payment in full for patients eligible for CHS. Nonhospital providers, including physicians, are not covered by the MMA provision. We reviewed the extent to which IHS and tribes paid above the Medicare rate for CHS hospital claims.

Findings: We found that IHS and tribes paid above the Medicare rate for 22 percent of hospital claims. As a result, IHS and tribes overpaid \$1 million for hospital claims between January and March 2008. We also determined that if IHS and tribal payments for nonhospital claims were capped at the Medicare rate, IHS and tribes could have saved as much as \$13 million between January and March 2008. Savings from claims over the Medicare rate could have paid for about 41,000 more nonhospital claims between January and March 2008 that might otherwise have been deferred or denied. Moreover, IHS and tribes paid above Medicare rates for 71 percent of nonhospital claims, most of which were for physician services.

Recommendation: IHS should seek legislative authority to cap payments for CHS nonhospital services at the Medicare rate for those services.

Savings: TBD*

**We estimated that if IHS and tribal payments for nonhospital claims were capped at the Medicare rate, IHS and tribes could have saved as much as \$13 million between January and March 2008.*

Management Response Summary: In its comments to our draft report, IHS concurred with our recommendation. IHS stated that it will continue to meet with tribes and tribal organizations to develop a plan to cap payments for CHS nonhospital services.

Status: We will continue to monitor IHS's implementation of our recommendations.

Related Report:

2009 SEP *IHS Contract Health Services Program: Overpayments and Potential Savings.*
OEI-05-08-00410 [Report](#)

Public Health > National Institutes of Health

Increase Oversight of Grantees' Management of Financial Conflicts of Interest in Research (New)

Background: NIH is the primary Federal agency responsible for conducting and supporting medical research. Organized into 27 Institutes and Centers, NIH receives billions of dollars annually to support its mission. In FY 2008, the total appropriation was \$29.5 billion, 80 percent of which was distributed through almost 50,000 competitive grants to more than 325,000 investigators at over 3,000 universities, medical schools, and other research institutions across the country and around the world. Pursuant to Federal regulation, each grantee institution receiving NIH funds must have a written policy for identifying financial conflicts of interest and ensuring that conflicts are managed, reduced, or eliminated. Each grantee institution must also certify that existing conflicts will be reported to NIH prior to the expenditure of any funds under that award; that these conflicts have been managed, reduced, or eliminated; and that any subsequently identified conflicts will be reported and will managed, reduced, or eliminated, at least on an interim basis, within 60 days of identification.

Findings: The most common type of financial conflict of interest among NIH-funded researchers is equity ownership. To manage financial conflicts of interest, grantee institutions often require researchers to disclose their conflicts in research publications; however, grantee institutions rarely reduce or eliminate financial conflicts of interest. There are a number of vulnerabilities in grantee institutions' identification, management, and oversight of financial conflicts of interest. We found that because nearly half of the grantee institutions do not require researchers to provide specific amounts of equity or compensation on their financial disclosure forms, specific financial interests of NIH-funded researchers are often unknown. In addition, when researchers submit information regarding their financial interests, grantee institutions do not routinely verify it.

Recommendations: NIH should (1) require grantee institutions to provide it with details regarding the nature of financial conflicts of interest and how they are managed, reduced, or eliminated at the time grant funds are issued; (2) require grantee institutions to collect all information on significant financial interests held by researchers and not just those deemed by researchers to be reasonably affected by the research; (3) require grantee institutions to collect information on specific amounts of equity and compensation from researchers; (4) develop and disseminate guidance on methods to verify researchers' financial interests; (5) ensure that grantee institutions are providing adequate oversight of subgrantee compliance with the Federal financial conflict-of-interest regulations;

(6) ensure that grantee institutions are maintaining proper documentation as outlined in the Federal financial conflict-of-interest regulations, (7) ensure that grantee institutions are taking appropriate actions against researchers who do not follow grantee institutions' financial conflict-of-interest policies and procedures; (8) increase oversight of grantee institutions to ensure that financial conflicts of interest are reported and managed appropriately; and (9) develop regulations that address financial conflicts of interest at grantee institutions.

Management Response Summary: NIH did not state in its response to our final report whether it concurs or does not concur with our recommendations. NIH stated that many of the report findings were not made within the context of the current regulation on financial conflicts of interest and therefore, many of the recommendations are difficult to assess and/or cannot be implemented because NIH is bound by the requirements of the current regulation. The current regulation permits NIH to rely on grantee institutions to monitor and enforce researcher compliance with the regulation.

Based on the public comments received in response to the advance notice of proposed rulemaking (ANPRM), and taking into consideration observations made by OIG in its reports and other related information, NIH published a notice of proposed rulemaking on May 21, 2010 (75 Fed. Reg. 28688), and a Supplemental Notice (specifically encouraging comment on whether the proposed enforcement authorities should be further revised and clarified) on July 21, 2010 (75 Fed. Reg. 42362), extending the public comment period until August 19, 2010. NIH is currently in the process of drafting a final rule that NIH believes will increase institutional and NIH oversight and broaden the scope of clinical investigator disclosure.

NIH notes that many of the observations made by the OIG in the report were included in the ANPRM and NPRM and are currently under consideration as the final rule is developed. Because the final rule has not been issued, NIH believes it is premature to take a position on the OIG recommendations at this time.

In addition to the pending regulation, NIH also reported initiating a compliance review to determine if selected NIH-supported institutions have policies and/or procedures that are consistent with the conflict-of-interest requirements set forth in 42 CFR part 50, subpart F. The program targets a review of the top 100 NIH-supported institutions that received grant funding under the American Reinvestment and Recovery Act of 2009 (Recovery Act) in FY 2009 and have not submitted a financial conflict of interest report to the NIH over the past 5 years.

Status: OIG maintains its position that increased oversight of grantee institutions is needed to ensure that conflicts of interest are reported and managed appropriately. We will continue to monitor NIH's implementation of our recommendations.

Related Report:

2009 NOV *Review of How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health.* OEI-03-07-00700 [Report](#)

Public Health > National Institutes of Health

Increase Oversight of Grantee Institutions To Ensure Compliance With Federal Financial Conflict-of-Interest Regulations

Background: Federal regulations establish standards to ensure that the design, conduct, or reporting of research funded under Public Health Service (PHS) grants is not biased by any conflicting financial interest of an investigator. The regulations require each institution that receives NIH funds to have a written policy for identifying financial conflicts of interest and ensuring that such conflicts are managed, reduced, or eliminated. Of NIH's 27 Institutes and Centers, 24 have grant-making authority and are responsible for managing and overseeing grants. NIH's Office of Extramural Research (OER) develops and implements policies and regulations governing NIH grants and develops and maintains information systems related to extramural research grants administration. Grantees must inform their respective funding institutes of any financial conflicts of interest before spending any NIH grant funds. Conflicts identified during the grant period must be reported, via conflict-of-interest reports, to the institutes within 60 days. Institutes are asked but not required to forward reports of grantee conflicts of interest to OER. We examined the extent to which NIH oversees grantee institutions' financial conflicts of interest for FY 2004 through FY 2006.

Findings: Our examination of financial conflict-of-interest reports and related documentation revealed that NIH institutes and OER could not provide an accurate count of the financial conflict-of-interest reports received from grantees because the regulations did not explicitly require reporting of the nature of the conflicts or other details; grants officials did not know what types of conflicts existed and had little information on which to follow up; and the institutes' primary method of oversight was to rely on grantees' assurances that financial conflict-of-interest regulations were being followed.

Recommendations: NIH should (1) increase oversight of grantee institutions to ensure their compliance with Federal financial conflict-of-interest regulations; (2) require grantee institutions to provide details of the nature of financial conflicts of interest and how they are managed, reduced, or eliminated, and (3) work with the Secretary of HHS to amend the regulation to require submission of such details.

Management Response Summary: NIH concurred with the first recommendation but did not concur with the second or third recommendations, saying that grantee institutions are responsible for identifying and managing financial conflicts of interest.

NIH issued an advance notice of proposed rulemaking at 74 Fed. Reg. 21610, May 8, 2009, to gain public input on whether modifications are needed to 42 CFR part 50, subpart F. NIH invited public comments on the potential regulation of this area, particularly on (1) expanding the scope of the regulation and disclosure of interests, (2) defining “significant financial interest,” (3) identifying and managing conflicts by grantee institutions, (4) ensuring grantee institution compliance, (5) requiring grantee institutions to provide more information to NIH, and (6) broadening the regulation to address institutional conflicts of interest. In response to public comments, NIH issued a notice at 75 Fed. Reg. 28688, May 21, 2010, with revisions to the ANPRM. If enacted as proposed, this regulation would implement several of OIG’s recommendations, such as requiring grantee institutions to provide detailed information on financial conflicts and how they are managed. NIH is developing a final regulation.

In addition to the pending regulation, NIH also reported initiating a compliance review to determine if selected NIH-supported institutions have policies and/or procedures that are consistent with the conflict-of-interest requirements set forth in 42 CFR part 50, subpart F. The program targets a review of the top 100 NIH-supported institutions that received grant funding under the Recovery Act in FY 2009 and have not submitted a financial conflict-of-interest report to NIH over the past 5 years.

Status: We continue to recommend that NIH collect details of the nature and management of financial conflicts of interest as part of its oversight responsibility of grantee institutions. We will continue to monitor the progress of the rulemaking. In the interim, OIG recommends that NIH use its authority pursuant to 42 CFR § 50.604(g)(3) to request details on the nature and management of financial conflicts of interest at grantee institutions.

Related Reports:

- 2009 NOV *Review of How Grantees Manage Financial Conflicts of Interest in Research Funded by the National Institutes of Health.* OEI-03-07-00700 [Report](#)
- 2008 JAN *National Institutes of Health: Conflicts of Interest in Extramural Research.* OEI-03-06-00460 [Report](#)

Human Services Programs

Human Services > Administration on Aging

Use Voluntary Contributions To Expand Services for the Elderly

Background: Administration on Aging (AoA) regulations permit States to use voluntary contributions to meet cost-sharing or matching grant requirements. However, during the audit period, this use of contributions was contrary to the Older Americans Act of 1965 (OAA), which requires that voluntary contributions be used to increase services for the elderly.

Findings: According to their financial status reports, 28 States and the District of Columbia erroneously used \$90.8 million in voluntary contributions in FY 1996 to meet cost-sharing or matching grant requirements.

Recommendations: AoA should revise its regulations in accordance with the OAA.

Savings: \$90.8 million*

**Estimated savings are based on information in FY 1996 financial status reports for all States, the District of Columbia, and Puerto Rico.*

Management Response Summary: AoA concurred with the recommendation. AoA subsequently told us that because the OAA Amendments of 2006 (OAAA) changed provisions relating to voluntary contributions, it was determining the kinds of regulatory changes needed as a result. As of October 2010, no regulatory changes had been made.

Status: We continue to monitor any regulatory changes in relation to AoA's progress on implementation of this recommendation.

Related Report:

2001 FEB *States' Use of Voluntary Contributions Under Title III of the Older Americans Act.* A-12-00-00002 [Report](#)

Human Services > Administration on Aging

Ensure That States' Cost-Sharing Practices Comply With Requirements and Improve Data Quality

Background: In 2000, amendments to the OAA allowed States to implement cost sharing for certain OAA services. The AoA defines “cost sharing” as a method of requiring a recipient to share in the cost of the service received. The amendments include a number of requirements to protect low-income older individuals’ access to services.

Findings: We found that as of March 2005, States’ implementation of cost sharing had been limited. Twelve States had implemented cost sharing for at least one OAA service in at least one part of the State. None of these States had implemented cost sharing for all allowed OAA services. AoA had provided limited guidance to States about implementing cost sharing. States had not implemented cost sharing in accordance with the OAA requirements designed to protect low-income older individuals’ access to services. Also, AoA’s participation data could not be used to determine the impact of cost sharing on participation, primarily because States reported participation data in the National Aging Program Information System/State Program Reports (NAPIS/SPR) differently.

Recommendations: AoA should (1) ensure that States’ cost-sharing practices comply with OAA requirements, (2) provide more guidance to States about cost sharing, and (3) improve the quality of its data so that any effects of cost sharing can be determined.

Management Response Summary: AoA partially concurred with our recommendations. AoA indicated that it had taken several actions, including holding senior agency staff meetings with regional administrators to review OAA cost-sharing requirements and establishing technical assistance and guidance for State Units on Aging. AoA did not concur with the recommendation to improve the NAPIS/SPR data, noting that it had made several improvements to these data, such as developing a software reporting structure and training manual. Despite these improvements, our work indicated that States varied in their reporting of data. These data are essential for cost-sharing and AoA performance measurements.

Status: We will continue to monitor AoA’s progress in implementing our recommendations.

Related Report:

2006 SEP *Cost Sharing for Older Americans Act Services.* OEI-02-04-00290 [Report](#)

Human Services > Administration for Children and Families

Delineate Roles and Enforce Unaccompanied Children's Services Requirements

Background: An unaccompanied alien child is defined in 6 U.S.C. § 279(g)(2) as a child under the age of 18 who has no lawful immigration status in the United States and who has no parent or legal guardian in the United States available to provide care and physical custody. When an unaccompanied alien child is found, the Department of Homeland Security (DHS) apprehends and detains the child and contacts the Administration for Children & Families (ACF) Office of Refugee Resettlement (ORR), which contacts a facility funded by the Division of Unaccompanied Children's Services (DUCS). Pursuant to the Homeland Security Act of 2002 (HSA), the Director of ORR is responsible for the care and custody of unaccompanied alien children, and DHS is responsible for immigration benefits and enforcement. The Flores Agreement (so named for a class-action lawsuit challenging detention policies and procedures for children in Federal custody) includes minimum standards for placement, care, and release to sponsors of alien children in Federal custody.

Findings: In our case file reviews of unaccompanied children apprehended by DHS who were in DUCS-funded facilities between April 1 and September 30, 2006, we found that most children were placed in and released from such facilities in accordance with Federal standards. However, we determined from our file reviews and facility visits that improvements were needed in case file documentation, DUCS program oversight, and the delineation of responsibilities between DHS and HHS.

Recommendations: ACF should establish a memorandum of understanding (MOU) between HHS and DHS to clearly delineate the roles and responsibilities of each Department.

Management Response Summary: ACF did not indicate whether it concurred with our recommendation. It said that ORR was drafting a *Joint Operations Manual* (JOM) with DHS, with the ultimate goal of drafting an MOU. In December 2010, ACF informed us that ORR and DHS were updating the draft version of the JOM to conform to the new statutory requirements in the Trafficking Victims Protection Reauthorization Act of 2008. DUCS and DHS are also in the process of drafting regulations outlining responsibilities that have changed due to the passage of the act.

Status: While we acknowledge the actions ACF has taken to address the other recommendations in this report, we continue to recommend that an MOU between HHS and DHS be implemented.

Related Report:

2008 MAR *Division of Unaccompanied Children's Services: Efforts To Serve Children.*
OEI-07-06-00290 [Report](#)

Departmentwide Issues

Departmentwide Issues > Interagency Coordination

Strengthen State Protections for Persons With Disabilities in Residential Settings

Background: Several HHS operating divisions fund programs or services that play a role in protecting persons with disabilities from abuse or neglect. For facilities receiving Medicare or Medicaid funds—including nursing homes, psychiatric facilities, and intermediate care facilities for persons with mental retardation—CMS has established Conditions of Participation (CoP) requiring that residents and patients be protected from abuse or neglect. ACF and the Substance Abuse and Mental Health Services Administration (SAMHSA) provide States with grants to establish protection and advocacy systems for investigating allegations of abuse or neglect. Also, FDA oversees the regulation of medical devices, including physical restraints, and receives information on deaths that occur during the use of restraints.

Findings: We found that between 1999 and 2000, about 90 percent of persons with disabilities in residential facilities were in facilities that are not subject to CMS oversight and relied solely on protections offered by State systems to identify, investigate, and resolve reports of abuse or neglect, including the misuse of restraints and seclusion. The levels of protection provided by State systems vary widely. Limited Federal standards, partly because of HHS's limited statutory authority to set requirements for many facilities and homes, have left persons with disabilities more vulnerable in residential facilities in which State systems are not well developed. Also, HHS was at a disadvantage in identifying systemic problems because it received limited information on occurrences of abuse or neglect.

Recommendations: CMS, ACF, SAMHSA, and FDA should work cooperatively to provide information and technical assistance to States to (1) improve the reporting of potential abuse or neglect of persons with disabilities across all residential settings, (2) strengthen investigation and resolution processes, (3) assist in analyzing incident data to identify trends that indicate systemic problems, and (4) identify the nature and causes of incidents to prevent future abuse.

Management Response Summary: CMS, ACF, SAMHSA, and FDA concurred with our recommendation to work cooperatively and provide information and technical assistance to States. Each agency detailed actions that it was taking or planned to take to improve safeguards. The SAMHSA grant program to support implementation of effective alternatives to restraint and seclusion was initiated in FY 2001 and concluded in FY 2010. Currently, SAMHSA is establishing a national technical assistance center for seclusion and restraint and trauma-informed care. The contract was awarded in September 2010 and the center is expected to be fully operational in January 2011. In FY 2010, ACF added tasks related to the investigation of abuse and neglect in home and community-based settings to the technical assistance contract for protection and advocacy agencies.

Status: We continue to monitor the progress made on these recommendations.

Related Report:

2001 MAY *Reporting Abuses of Persons with Disabilities.* A-01-00-02502 [Report](#)

Departmentwide > Financial Management

Improve Financial Analysis and Reporting Processes

Background: The Government Management Reform Act of 1994 (GMRA) requires that many Federal agencies, including HHS, prepare annual financial statements. The Government Accountability Office's (GAO) *Government Auditing Standards* and the Office of Management and Budget's (OMB) Bulletin 07-04, *Audit Requirements for Federal Financial Statements*, provide auditors with guidance about how to audit and report on the Federal financial statements. OMB Bulletin A-127 requires that financial statements be the culmination of a systemic accounting process. The statements are to result from an accounting system that is an integral part of a total financial management system containing sufficient structure, effective internal control, and reliable data.

Findings: The FY 2010 financial statement audit noted that internal control weaknesses continued in HHS's financial management systems and financial analyses and oversight. HHS's lack of an integrated financial management system impaired its ability to support and analyze account balances. Manual intervention was required to correct transactions that did not post in accordance with standards and to transfer information between systems that did not interface electronically.

In addition, certain reconciliations and account analyses were not adequately or promptly performed to ensure that differences were identified and resolved and that invalid or old transactions were identified and closed. Also, management has not implemented corrective action for some longstanding deficiencies in internal control. HHS's financial management systems did not substantially comply with Federal financial management systems requirements or the U.S. Government Standard General Ledger at the transaction level.

Furthermore, general control issues related to the design and operation of key controls related to security management, access controls, configuration management, segregation of duties, and contingency planning were noted. In addition, weaknesses were noted in general controls, business process controls, interface controls, and data management system controls for specific financial applications.

Recommendations: HHS should (1) continue to develop and refine its financial management systems and processes to improve its accounting, analysis, and oversight of financial management activity and (2) provide a secure computing environment for critical applications throughout all the operating divisions.

Management Response Summary: In the *FY 2010 Agency Financial Report*, issued in November 2010, HHS generally concurred with the findings in the audit report. HHS will prepare corrective action plans to address the identified findings.

Status: We continue to monitor HHS's progress in improving its financial analysis and report processes and related controls as part of the annual audit of the HHS's financial statements.

Related Report:

2010 NOV *Department of Health and Human Services Fiscal Year 2010 Agency Financial Report. Section II. Daniel R. Levinson, Inspector General, Report on the Financial Statement Audit of the Department of Health and Human Services for Fiscal Year 2010. A-17-10-00001 (pp. II-7, II-53) [Report](#)*