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TO: The Secretary
            Through: DS _____
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FROM: Inspector General

SUBJECT: Top Management and Performance Challenges Facing the Department of
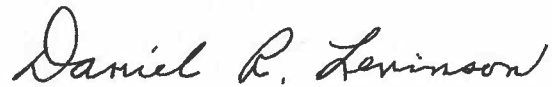   Health and Human Services in Fiscal Year 2011

This memorandum transmits the Office of Inspector General's (OIG) list of top management and performance challenges facing the Department of Health and Human Services (Department). The *Reports Consolidation Act of 2000, Public Law 106-531*, requires OIG to identify these management challenges, assess the Department's progress in addressing each challenge, and submit this statement to the Department annually.

The OIG's list of top management and performance challenges for Fiscal Year 2011 includes the following:

1) Implementing the Affordable Care Act

2) Preventing and Detecting Medicare and Medicaid Fraud

3) Identifying and Reducing Improper Payments

4) Patient Safety and Quality of Care

5) Integrity and Security of Information Systems and Data

6) Availability and Quality of Data for Effective Program Oversight

7) Oversight of CMS Program and Benefit Integrity Contractors

8) Ensuring Integrity in Medicare and Medicaid Benefits Delivered by Private Plans

9) Avoiding Waste in Health Care Pricing Methodologies

10) Grants Management and Administration of Contract Funds

11) Ensuring the Safety of the Nation's Food Supply

12) Oversight of the Approval, Safety, and Marketing of Drugs and Devices

13) Oversight and Enforcement of the Department's Ethics Programs

OIG looks forward to continuing to work with the Department to identify and implement strategies to protect the integrity of the Department's programs and the well-being of the beneficiaries of these programs. If you have any questions or comments, please contact me, or your staff may contact Erin Bliss, Director of External Affairs, at (202) 205-9523 or Erin.Bliss@oig.hhs.gov.

Daniel R. Levinson

Attachment

FY 2011 Top Management And Performance Challenges Identified By Office Of The Inspector General

Why This Is a Challenge

The Department is implementing and administering new programs under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (ACA) involving billions of dollars in grants, loans, and benefits payments. These programs include the Affordable Insurance Exchanges, the Consumer Operated and Oriented Plan Program, the Pre-Existing Condition Insurance Plan, the Early Retiree Reinsurance Program, the Prevention and Public Health Fund, the Center for Medicare and Medicaid Innovation, and others. In addition, the ACA enacted numerous changes and additions to existing Department programs, including Medicare and Medicaid. Noteworthy examples include novel programs, such as the Medicare Shared Savings Program, designed to improve quality and reduce cost through health care delivery and payment reform.

Responsibility for implementing ACA provisions, administering new and changed programs, and/or overseeing ACA funding rests with components across the Department, including the Centers for Medicare & Medicaid Services (CMS), the Office of the Secretary, the Health Resources and Services Administration (HRSA), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Administration on Aging, the Centers for Disease Control and Prevention (CDC), the Indian Health Service (IHS), the Agency for Healthcare Research and Quality, and the Office of Inspector General (OIG). Many programs require close coordination between the Department and other federal and State agencies. Additional ongoing implementation and operational challenges include the magnitude, complexity, and novelty of programs; compressed implementation timelines; and marketplace dynamics.

Focusing on integrity in these programs is essential to ensuring that they operate with economy and efficiency and are free from fraud, waste, and abuse. The Department and its partners must indentify and mitigate program vulnerabilities and prioritize oversight resources. The Department must also ensure that providers, insurers, employers, and program beneficiaries understand their rights, responsibilities, and obligations under the new law.

Progress in Addressing the Challenge

The Department and its partners have issued and are continuing to issue regulations and other guidance for ACA programs. The Department has made a range of resources available on its Web site to inform the public about these programs and is working with States and other entities to identify potential program vulnerabilities and set up guidelines and systems to mitigate risks. The Department has continued to fortify its infrastructure to support the implementation, administration, and oversight of new and expanded programs. OIG has provided technical assistance to CMS and other Department components to assist in indentifying and preventing program integrity vulnerabilities. Moreover, OIG plans to examine several ACA programs in fiscal year (FY) 2012, including the Early Retiree Reinsurance Program, the Prevention and Public Health Fund, and ACA-funded Community Health Centers. Additional progress related to the ACA is described elsewhere in these challenges.

What Needs To Be Done

The Department and its partners must be vigilant in identifying and addressing existing and emerging fraud, waste, and abuse risk areas in ACA-related programs. The Department should continue to apply lessons learned about accountability, transparency, compliance, and risk management from its American Reinvestment and Recovery Act (Recovery Act) and other program experiences to ACA implementation and oversight. The Department should also continue to train staff overseeing ACA grants and contracts on effective internal controls and best practices for preventing and detecting fraud, waste, and abuse. Data systems supporting ACA programs must be scrutinized for accuracy and completeness, as well as compliance with security and privacy rules. The Department, including OIG, should continue to implement the full complement of program integrity provisions in the ACA and

identify the most effective ways to use new oversight authorities and tools. The Department should continue its efforts to provide stakeholders with clear guidance about ACA programs.

Additional recommendations for addressing ACA-related vulnerabilities appear elsewhere in these challenges.

Key OIG Resources:

- Office of Inspector General Fiscal Year 2012 Work Plan: http://oig.hhs.gov/reports-and-publications/workplan/index.asp.

Management Issue 2: Preventing and Detecting Medicare and Medicaid Fraud

Why This Is a Challenge

Perpetrators of schemes to defraud Medicare and Medicaid range from criminals who masquerade as bona fide health care providers and suppliers but who do not provide legitimate services or products to Fortune 500 companies that pay kickbacks to physicians in return for referrals. Fraud is a crime of deception, and perpetrators design their schemes to avoid detection. The Department faces multiple challenges in preventing and detecting these frauds, including:

- effectively using CMS's provider enrollment and payment suspension authorities against those providers and suppliers that have exploited weaknesses to commit fraud rather than provide legitimate patient care,
- managing the Department's expanding use of data analysis, and
- excluding individuals and entities from federal health care programs to protect the programs and beneficiaries.

Many of CMS's essential program integrity activities are carried out by contractors. (See Challenge 7, Oversight of CMS Program and Benefit Integrity Contractors, for more information.)

Progress in Addressing the Challenge

Enrollment and Payment. The ACA addressed many program vulnerabilities by authorizing rigorous enrollment and screening processes, enrollment moratoria, and payment suspension. In February 2011, CMS published a final rule implementing the ACA provisions concerning screening of providers and suppliers based on fraud risk. CMS's enhanced payment suspension authority took effect in March 2011.

Data analysis. Enhanced data analysis made possible the impressive enforcement results of the nine Medicare Fraud Strike Forces, which are part of the Health Care Fraud Prevention and Enforcement Action Team (HEAT). The strike forces are interagency teams of prosecutors and federal and local law enforcement that focus enforcement resources on geographic areas at high risk for fraud. CMS has made claims data available more quickly and efficiently by providing limited law enforcement access to real-time data and has increased the number of trained law enforcement users on the One Program Integrity tool. In June 2011, CMS implemented the Fraud Prevention System (FPS) to risk-score Medicare Fee-for-Service (FFS) claims prepayment and awarded a contract to IBM in July 2011 to develop and test new predictive models for inclusion in the FPS.

Accountability. CMS's imposition of payment suspensions is one example of the Department's increased focus on accountability. OIG is using its permissive exclusion authority to pursue exclusion of responsible corporate officers of sanctioned providers and suppliers that may otherwise view civil penalties and fines as the cost of doing business.

What Needs To Be Done

CMS's final rule on enrollment screening takes important steps toward preventing unscrupulous providers and suppliers from obtaining Medicare billing privileges. However, there are additional opportunities for CMS to strengthen the enrollment system, including adopting a more flexible screening approach, tailoring screening measures to fraud risks, and classifying reenrolling DME and home health providers as "high risk." Moreover, the Department must ensure that its response to program vulnerabilities captures not only improper payments but also fraud; to that end, the contractors on which it relies must be carefully selected and have the tools, training, resources, and incentive to appropriately address improper payments and make appropriate fraud referrals. (See Challenge 7, Oversight of CMS Program and Benefit Integrity Contractors, for additional information.)

The Department should continue to improve law enforcement's access to data—including real-time claims data—as well as create more robust data sets, which are critical to identifying and investigating fraud. OIG must also ensure that it has the capacity to handle the volume of new fraud referrals that can be expected from CMS's expansion into predictive modeling and that CMS and OIG coordinate closely on such referrals.

The Department should continue to focus on accountability for fraud. In addition, OIG will continue to use its permissive exclusion authority for responsible individuals and entities in appropriate cases and monitor its effect on recidivism.

Key OIG Resources:

- South Florida and Los Angeles Suppliers' Compliance With Medicare Standards: Results From Unannounced Visits. OEI-03-07-00150 (South Florida) and OEI-09-07-00550 (Los Angeles)
- Questionable Billing for Brand-Name Inhalation Drugs in South Florida. OEI-03-09-00530
- Press Release: Medicare Fraud Strike Force Charges 111 Individuals for More Than $225 Million in False Billing and Expands Operations to Two Additional Cities. http://www.hhs.gov/news/press/2011pres/02/20110217a.html
- OIG Testimony for Senate Finance Committee Hearing: Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges. http://oig.hhs.gov/testimony/docs/2011/levinson_testimony_03022011.pdf

Management Issue 3: Identifying and Reducing Improper Payments

Why This Is a Challenge

Improper payments are a significant problem, costing billions of dollars annually across federal programs. In November 2009, the President signed Executive Order 13520, Reducing Improper Payments and Eliminating Waste in Federal Programs, and in July 2010, the Improper Payments Elimination and Recovery Act (IPERA) was enacted. The purpose of the Executive Order and IPERA is to reduce improper payments by intensifying efforts to eliminate payment error, waste, fraud, and abuse in the major programs administered by the federal government, including the Department's health care programs, while continuing to ensure that federal programs serve and are accessible by their intended beneficiaries.

In 2010, the Office of Management and Budget (OMB) designated 14 programs as "high error." CMS administers five of these high-error programs: Medicare FFS; Medicare Part D; Medicare Advantage; Medicaid; and the Children's Health Insurance Program (CHIP). For FY 2010, the Department reported improper payments totaling more than $70 billion in Medicare FFS, Medicare Advantage, and Medicaid. HHS's Administration for Children and Families (ACF) also administers programs susceptible to improper payments. For example, ACF estimated that its Child Care program's national error rate equaled 13 percent and ACF programs accounted for $1 billion in improper payments in 2010.

Improper payments are divided into four categories: unsupported services, medically unnecessary services, incorrect billings, and other noncovered cost or error types. These are the core payment issues within the Department. OIG has recently completed and has underway several reviews that focus on improper payments. One review identified over 700 providers that routinely had errors over a 4-year period (2005 through 2008).

Progress in Addressing the Challenge

The Department has taken actions to address some improper payment vulnerabilities. CMS uses the Comprehensive Error Rate Testing (CERT) program to measure the Medicare FFS error rate and as a guide in developing corrective actions to reduce improper payments. CMS analyzes the CERT improper payment data and uses the results to provide feedback to Medicare contractors to enhance their medical reviews, focus on high risk areas, and reduce improper payments. Also, Medicare's automated systems have edits in place to detect and reject payment for medical services that are physically impossible, such as a hysterectomy for a male beneficiary, and "medically unlikely," such as services claimed for which the quantity billed exceeds acceptable clinical limits.

CMS developed the Payment Error Rate Measurement (PERM) program to review improper payments for Medicaid and CHIP FFS claims, managed care claims, and beneficiary eligibility. Though causes of improper payments vary from State to State, PERM helps CMS identify trends and common errors

across States. Based on PERM results, States are required to submit Corrective Action Plans (CAP) 90 days after they are notified by CMS of their error rates. Many States' CAPs focus on provider education to reduce improper payment rates.

CMS contracts with Recovery Auditors to help detect and correct past improper payments so that CMS can implement actions that will prevent future improper payments. CMS has made policy and manual changes and local system edits, and CMS Medicare Administrative Contractors have conducted local provider education.

CMS has also developed a methodology to estimate an error rate for its Medicare Advantage program and implemented processes and procedures to reduce administrative and documentation errors, the two most prevalent error types in the Medicare Advantage program. Additionally, ACF has also begun to measure error rates for its Child Care, Foster Care, and Head Start programs and provided staff to serve on OMB improper payments teams.

The Department is also examining techniques used by private sector entities to reduce improper payments. CMS is conducting data analysis and predictive modeling to identify improper claims in Medicare FFS and is considering requiring prior authorizations for certain services. CMS is also exploring ways to leverage existing compliance programs within the provider community to educate providers about payment vulnerabilities.

What Needs To Be Done

The Department should continue to develop error rates for additional programs to comply with IPERA requirements. Medicare Part D and CHIP are slated to have projected error rates in the 2011 and 2012 reporting periods, respectively.

Further, the Department should use historical improper payment data to identify the root causes of improper payments and develop, implement, and track a Department CAP. In addition, for Medicare FFS claims, CMS should also continue to monitor its payment systems to identify additional edits and prepayment reviews that could identify suspicious claims and prevent improper payments. The Department should continue to identify best practices in the private sector that it can use to avoid improper payments. It should also expand its provider education efforts around program requirements and improper payment vulnerabilities. (See Challenge 10, Grants Management and Administration of Contract Funds, for additional information regarding improper payments.)

Key OIG Resources

Centers for Medicare & Medicaid Services' Use of Medicare Fee-for-Service Error Rate Data To Identify and Focus on Error-Prone Providers. A-05-08-00080

- Inappropriate Claims for Medicaid Personal Care Services. OEI-07-08-00430
- Independent Contractor's Review of Durable Medical Equipment Claims From the Fiscal Year 2008 Comprehensive Error Rate Testing Program. A-01-09-00500
- Questionable Billing for Brand-Name Inhalation Drugs in South Florida Under Medicare Part. OEI-03-09-00530

Management Issue 4: Patient Safety and Quality of Care

Why This Is a Challenge

As a purchaser of health care for over 100 million Americans, the Department faces challenges in ensuring the quality of care rendered to federal health care program beneficiaries. Despite increased attention to patient safety, quality problems persist. According to the Joint Commission, 40 wrong-site surgeries are performed in U.S. hospitals and surgicenters every week. OIG has found that 13.5 percent of hospitalized Medicare beneficiaries suffered harm from adverse events during their hospital stays. Forty-four percent of these adverse events were preventable and were caused by care failures, such as medical error, substandard care, or inadequate monitoring. Other OIG work has raised concerns about overmedication of beneficiaries with antipsychotic drugs in nursing homes; more than 20 percent of antipsychotic drugs claims for Medicare patients in nursing homes exceeded Medicare limits on dose or duration. OIG has also identified concerns with the licensure and qualifications of

health care providers across all settings of care. In addition, for more than 60 percent of claims, hospices did not meet federal requirements for establishing adequate plans of care.

OIG investigations have uncovered instances and systemic patterns of substandard care in nursing homes. Problems often include inadequate staffing resulting in substandard care, failure to provide adequate nutrition and hydration, patients' developing preventable or untreated pressure wounds (bedsores), and other serious deficiencies.

Progress in Addressing the Challenge

The Department has taken steps to improve quality of care and promote patient safety. These includes targeting specific populations, such as improving coordination of care for Medicare beneficiaries with multiple chronic conditions, as well as improving care for all beneficiaries. The Department has committed up to $1 billion in ACA funding to the Partnership for Patients Initiative, a public-private partnership designed to keep patients from becoming injured or sicker and to help patients heal without complication. Members of the partnership will identify specific steps they will take to reduce preventable injuries and complications in patient care. Two specific goals set by the partnership are to reduce hospital readmissions by 20 percent and reduce preventable harm to hospital patients by 40 percent.

The Department is implementing value-based purchasing (VBP) payment policies required by the ACA, such as the policy establishing the new VBP program for hospitals that will include quality metrics, as well as other payment policies targeting improved quality, such as the hospital-acquired conditions policy. These policies provide incentives to deliver better care. The Department continues to promote the adoption of electronic health records (EHR) and electronic prescribing, which should improve quality of care, reduce medication errors, and otherwise promote patient safety. It established tools to help beneficiaries compare facility-specific quality indicators and inform their decisions regarding where to seek treatment. CMS is developing new programs, such as the Medicare Shared Savings Program, as well as demonstration programs sponsored by the new Center for Medicare and Medicaid Innovation, with potential to enhance provider accountability for quality of care and improve coordination of care and care transitions.

OIG has entered into corporate integrity agreements with several nursing homes and other health care providers, including hospitals, assisted-living facilities, and dental clinics, which include quality-monitoring provisions. CMS and OIG continue to work closely with law enforcement partners at the Department of Justice and through the Federal Elder Justice Interagency Working Group to pursue providers that subject elderly persons to abuse or neglect, to exchange ideas, and to promote policies advancing better care for the elderly.

What Needs To Be Done

The Department should continue to prioritize quality of care and patient safety and build upon its past efforts, including implementing the quality improvement provisions of the ACA and achieving the goals set by the Partnership for Patients. OIG has offered recommendations to assist the Department in this mission. For example, OIG suggested enhancements to nursing home oversight to ensure that Medicare does not pay nursing homes to overmedicate or otherwise inappropriately medicate beneficiaries. OIG also suggested enhancements to outpatient prescription drug claims that could help the Department ensure that Medicare and Medicaid beneficiaries receive only the drugs that are appropriate for their medical indications.

Further work also needs to be done to improve the quality of care rendered to patients in hospitals. For example, the Department could strengthen its hospital-acquired conditions policy, such as by improving compliance with present-on-admission coding rules and, if supported by evidence of effectiveness, expanding the list of hospital-acquired conditions. It should also continue denying payments for services of such low quality that they are virtually worthless and exclude providers that have rendered grossly substandard care, thereby preventing harm to additional beneficiaries. The Department must also ensure that health care professionals working in all sites of service, such as hospitals, nursing homes, school-based facilities, and even the beneficiaries' own homes, meet qualification and licensure requirements before they treat federal health care program beneficiaries.

Key OIG Resources

- Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. OEI-06-09-00090
- Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents. OEI-07-08-00150
- Quality Improvement Organizations' Final Responses to Beneficiary Complaints. OEI-01-09-00620

Management Issue 5: Integrity and Security of Information Systems and Data

Why This Is a Challenge

As health care providers modernize their medical recordkeeping and billing systems, the adoption of EHRs and other innovations offers tremendous opportunity for improved patient care and more efficient practice management. However, as growing quantities of personal medical information are stored in electronic format, protecting the privacy and security of these data should be prioritized. A series of OIG audits revealed that some hospitals lack sufficient security features, potentially exposing patients' electronic protected health information to unauthorized access. Vulnerabilities included unsecured wireless access, inadequate encryption, authentication failures, and other access control vulnerabilities.

Protecting beneficiaries' and providers' identifying information is critical because fraud perpetrators often use stolen beneficiary and/or physician identities to submit false claims to the programs. In one recent example, OIG investigated fraudulent medical clinics in California that used provider numbers of unaffiliated physicians to submit false claims to Medicare for medical equipment that the physicians did not order and for services that the physicians did not render. The perpetrators pleaded guilty to defrauding Medicare and the operation has been shut down.

Additionally, the Department must ensure the integrity of incentive payments to encourage providers to adopt electronic prescribing and EHRs. In particular, the Department must ensure that recipients of Medicare and Medicaid EHR incentives truly qualify for these payments and that these payment policies effectively promote adoption of desirable technological practices. OIG found that the lack of sufficient data limits State Medicaid agencies' ability to verify both eligibility requirements prior to payment and the completeness of those verifications. Between 2009 and 2021, the federal government will spend an estimated $20.6 billion on the Medicare and Medicaid EHR incentive programs.

Finally, EHRs should facilitate more accurate billing and support better quality of care, but when misused may promote fraudulent billing or wasteful or inappropriate care. For example, cut-and-paste features and auto-fill templates can reduce paperwork burdens, but can also be misused to fabricate information, which results in improper payments and leaves inaccurate and potentially dangerous information in the patient record. Similarly, well-designed decision support tools can help physicians select the best care for their patients, but inappropriately designed decision support tools can drive overutilization of services and lower the quality of care.

Progress in Addressing the Challenge

The Department has promulgated various rules that address privacy and security of patient information, encourage health care providers to use EHRs, and ensure that record systems are interoperable and facilitate accurate and secure exchange of information between authorized users. The Department has provided guidance to help covered entities comply with privacy and security rules mandated by the Health Insurance Portability and Accountability Act of 1996 and pursued enforcement actions against entities that have failed to do so. The Department has also addressed, in limited ways, privacy and security matters in its regulations governing Medicare and Medicaid EHR incentive payments. The Department has implemented numerous recommendations to make its own electronic data more secure.

In addition, OIG has undertaken educational initiatives, including direct outreach by special agents and distribution of an identity theft brochure, to help beneficiaries and providers protect themselves from medical identity theft.

What Needs To Be Done

The Department needs to heighten its focus on oversight and enforcement of privacy and security protections to ensure that hospitals and other health care providers, as well as the Department's own contractors, effectively safeguard individuals' protected health information when stored in electronic formats. This should entail continued compliance reviews to ensure adoption of adequate privacy and security standards. The Department should also provide additional guidance on general information technology security standards and best practices the health care industry should adopt for EHRs. As providers begin claiming financial incentives for adoption of electronic record and prescribing technologies, strict oversight, including prepayment verification and postpayment auditing, will be essential.

Key OIG Resources

- Early Review of States' Planned Medicaid Electronic Health Record Incentive Program Oversight. OEI-05-10-00080
- Nationwide Rollup Review of the Centers for Medicare & Medicaid Services Health Insurance Portability and Accountability Act of 1996 Oversight. A-10-08-5069
- Audit of Information Technology Security Included in Health Information Technology Standards. A-18-09-30160

Management Issue 6: Availability and Quality of Data for Effective Program Oversight

Why This Is a Challenge

The Department and OIG rely heavily on the availability and completeness of data to ensure that the over 300 departmental programs are operating as intended and to help identify instances of fraud, waste, and abuse. The Department's programs compile an enormous amount of data on beneficiaries, providers, drugs, equipment and supplies, the delivery of services, and the quality of care. When these data are unavailable, are incomplete, or contain inaccuracies, program oversight and monitoring activities are hindered. OIG work has shown challenges in the following areas:

Medicaid program data are not current, available, complete, and accurate. The Medicaid Statistical Information System (MSIS) is the only national database of Medicaid claims and beneficiary eligibility information. In a 2009 report, OIG found that MSIS data were an average of 1.5 years old when released to users for data analysis. Moreover, CMS does not enforce certain MSIS data requirements, such as the submission of managed care encounter data. To conduct necessary Medicaid oversight, OIG must sometimes request data directly from each State.

Medicare program data are not complete and accurate. CMS compiles voluminous amounts of data on, among other things, provider enrollment and ownership, medical care encounters, prescription drugs, claims and payment, and adverse actions taken against providers. OIG has found that while Medicare data are largely available for analysis and review, databases such as the Provider, Enrollment, Chain and Ownership System (PECOS); the Prescription Drug Event Database; and the Healthcare Integrity and Protection Data Bank are missing data and/or contain inaccurate information, resulting in limited usefulness for oversight purposes.

Public health and human services programs data are not timely, complete, accurate, and available for oversight purposes. The Department is responsible for ensuring that required entities report timely and accurate data on public health and human services programs to ensure that programs operate as intended and use data to help combat acute and chronic diseases and disabilities. However, OIG work has shown that databases such as ACFs Program Information Report, FDA's Food Facility Registry and its National Drug Code Directory, HRSAs 340B covered-entity database, and IHS's Health Service Directory contain incomplete and inaccurate data.

Improved quality of data received through exchanges with other Departments is needed. OIG work has found that external databases have quality issues similar to those found in Department databases. For example, a recent audit report found that the Social Security Administration (SSA) does not always verify the day of death, which impedes the usefulness of data matches between the SSA Master Death File and the Department's National Claims History File. Addressing concerns about the quality of data received from other agencies will be increasingly important as the Department expands

CMS's Integrated Data Repository the ACA to include claims and payment data from other agencies, such as SSA, the Department of Veterans Affairs, and the Department of Defense.

Progress in Addressing the Challenge

The Operating Divisions (OPDIVs) have taken or planned some steps to address data-related vulnerabilities identified by OIG. For instance, in response to OIG recommendations regarding FDA's National Drug Code Directory, FDA has implemented an electronic reporting system for drug product information that may encourage manufacturers to update their listings more frequently. In response to ACA requirements, CMS is revalidating all enrollment information for the approximately 1.5 million providers and suppliers currently in PECOS and plans to cross-check enrollment data to other referential sources to better ensure accuracy. CMS also intends to increase efforts to consistently enforce the federal reporting requirements for managed care encounter data and has committed to conducting a review of laws and regulations to identify areas in which it can strengthen reporting. CMS has acknowledged problems related to the availability, completeness, accuracy and timeliness of State Medicaid data and has launched various projects aimed at improvement.

What Needs To Be Done

To formulate a plan and take corrective action, the Department will need to review the vulnerabilities specific to each database. Until the Department makes all necessary data available and corrects specific instances of incomplete or inaccurate data, program oversight will be hindered. As the Department integrates other agencies' data, it will need to examine their validity before relying on them for oversight purposes.

Key OIG Resources

- MSIS Data Usefulness for Detecting Fraud, Waste, and Abuse. OEI-04-07-00240
- Medicaid Managed Care Encounter Data. OEI-07-06-00540
- Inaccurate Data in the Provider Enrollment, Chain, and Ownership System Individual Global Extract File. OEI-07-08-00181
- Invalid Prescriber Identifiers on Medicare Part D Drug Claims. OEI-03-09-00140

Management Issue 7: Oversight of CMS Program and Benefit Integrity Contractors

Why This Is a Challenge

With an ever-growing reliance on contractors to identify, prevent, and respond to fraud, abuse, and improper payments in the Medicare and Medicaid programs, CMS must conduct adequate oversight and monitoring. CMS contracts with several entities, including Program Safeguard Contractors (PSC), Medicare Drug Integrity Contractors (MEDIC), Zone Program Integrity Contractors (ZPIC), and Recovery Audit Contractors (RAC), to perform many Medicare integrity functions. For Medicaid integrity, CMS relies largely on State-based programs, but also contracts with Medicaid Integrity Contractors. OIG work has revealed persistent problems with CMS's program and benefit integrity contractors and ongoing vulnerabilities in CMS's oversight. These challenges include:

Inadequate contracts. The Department must ensure that CMS's contracts, statements of work, and task orders contain adequate controls, including clear roles and responsibilities and performance measures. Without these, programs are at heightened risk of poor contractor performance and ineffectiveness. Contracts should also ensure that performance incentives align with the objectives to reduce fraud, waste, and abuse. OIG has found that RACs have disincentives for referring instances of suspected fraud because even though RACs are paid through contingency fees based on the amount of overpayments collected, in cases of suspected fraud, overpayments may not be collected while the cases are being investigated. Between 2005 and 2008, RACs identified more than $1.03 billion in Medicare improper payments; however, the RACs referred only two cases of potential fraud to CMS.

Questionable contractor performance. OIG work has documented poor and/or inconsistent performance among contractors. For example, OIG found that PSCs differed substantially in the number of new investigations and case referrals to law enforcement; some had only minimal activity in these primary workload categories. Also, most PSCs had minimal results from proactive data analysis. OIG also found that PSCs referred $835 million in overpayments to claims processors for collection in 2007; however, 2 of 18 PSCs accounted for 62 percent of this amount. OIG is examining

PSCs' efforts to match Medicare and Medicaid data (known as the Medi-Medi project) to identify trends and refer suspected fraud for investigation.

Insufficient CMS Oversight. CMS must collect sufficient information to monitor contractor activities and conduct regular and meaningful reviews of contractor performance. In examining early stages of the transfer of program integrity functions from PSCs and MEDICs to ZPICs, OIG found that workload data used by CMS to oversee ZPICs were not accurate or uniform. OIG has also found problems in CMS's efforts to evaluate contractor performance. CMS evaluations of PSCs' performance did not include sufficient information and were not completed in time for the results to be used during contract renewal determinations. (For related information, please see Challenge 2, Preventing and Detecting Medicare and Medicaid Fraud, and Challenge 6, Availability and Quality of Data for Effective Program Oversight.)

Progress in Addressing the Challenge

CMS has made some progress toward addressing these challenges, including providing additional training to RACs on the identification and referral of potential fraud and developing electronic systems to monitor fraud referrals. In September 2011, CMS published its final rule implementing section 6411 of the ACA and providing guidance to the States related to the funding, operation, and maintenance costs of Medicaid RACs. Effective January 1, 2012, States are required to contract with Medicaid RACs to audit Medicaid claims to identify underpayments and overpayments and to collect overpayments. The rule requires States to make referrals of suspected fraud and/or abuse to appropriate agencies. CMS anticipates working with States to develop metrics to measure the Medicaid RACs' performance. CMS is transitioning program integrity functions from PSCs and MEDICs to the ZPICs. The ZPICs will be responsible for ensuring the integrity of all Medicare-related claims under Parts A, B, C, and D and for coordinating the Medi-Medi data match program. CMS expects that the ZPIC contracting strategy will allow for the review of claims across all benefit categories and across geographic locations, which should result in improved contractor performance. In FY 2011, CMS began conducting quarterly onsite visits to the PSCs and ZPICs.

What Needs To Be Done

The ACA expanded the RAC program to encompass improper payments in Medicaid and Medicare Parts C and D. As CMS expands its use of contractors and as contractors' responsibilities grow, CMS must make continued improvements to address the above challenges. CMS should also monitor the extent to which contractor-led program and benefit integrity activities have brought about improvements and appropriate metrics exist to assess performance.

Key OIG Resources

- Recovery Audit Contractors' Fraud Referrals. OEI-03-09-00130
- Medicare Overpayments Identified by Program Safeguard Contractors. OEI-03-08-00031
  Medicare's Program Safeguard Contractors: Activities to Detect and Deter Fraud and Abuse. OEI-03-06-00010
- Zone Program Integrity Contractors' Data Issues Hinder Effective Oversight. OEI-03-09-00520
- Medicare's Program Safeguard Contractors: Performance Evaluation Reports. OEI-03-04-00050

Management Issue 8: Ensuring Integrity in Medicare and Medicaid Benefits Delivered by Private Plans

Why This Is a Challenge

Medicare Advantage, the Part D Prescription Drug Benefit, and Medicaid Managed Care are administered by private health care plans, operating within parameters established by the federal government (and, for Medicaid, the State governments). Most Medicare beneficiaries are enrolled in Part D plans, and as of December 2009, 24 percent of beneficiaries were enrolled in Medicare Advantage. Major enrollment growth for Medicare Parts C and D is anticipated in the years following FY 2012 as the baby boomer generation becomes eligible for Medicare. As of June 2008, 72 percent of all Medicaid beneficiaries were enrolled in some type of managed care delivery system. Effective administration and oversight of these programs require extensive coordination and information sharing between the federal and State governments, private health care plans, subcontractors, health care providers, and third-party payers. The Department must ensure the accuracy of payments to

private plans, the plans' implementation of effective program integrity safeguards, and their implementation of adequate consumer protections.

Medicare and Medicaid make capitated payments to private health care plans to deliver a specified set of benefits to qualified beneficiaries. Although specific payment methodologies vary by program, in general, private plans submit bids to CMS or the States related to their expected costs for the upcoming plan year. The standard per beneficiary payment rate is usually risk-adjusted (increased or decreased) based on the health characteristics of individual enrolled beneficiaries. However, OIG has found that some Part D plans have submitted inaccurate and incomplete information in their bids and that CMS's review of Part D bids has been inadequate. As a result, Medicare has made higher payments to plans and beneficiaries have paid higher premiums than they would have if plans' bids had been more accurate. In addition, some Medicare Advantage plans have submitted inaccurate beneficiary health data used to calculate risk-adjustment payments, resulting in inflated Medicare payments.

In some States, Medicaid managed care plans are subject to limits on their administrative costs relative to their direct costs. OIG investigations have revealed that some Medicaid managed care plans have manipulated their finances and inflated their direct health care costs to circumvent these limits.

CMS and the States must also monitor private plans to ensure that they have implemented effective program safeguards. Private plans share risk with the Government and have incentives to detect and prevent fraud; however, not all plans have done so effectively. For example, we have found deficiencies in Part D plans' compliance with program requirements, including maintaining adequate compliance plans, monitoring to prevent payments on behalf of deceased beneficiaries, and paying claims with invalid prescriber numbers.

Finally, the Department must ensure that beneficiaries have sufficient access to the services that plans have agreed to provide, have accurate information about coverage and costs to make informed choices, and are protected from illegal or coercive marketing tactics and other inappropriate activities.

Progress in Addressing the Challenge

CMS has strengthened its oversight of Part D plans' compliance with program requirements and implementation of compliance plans by conducting audits and promoting effective compliance programs. It has also issued guidance to plans to identify and review drug claims with invalid prescriber identification numbers. CMS has also issued guidance and clarification regarding Medicare Advantage and Part D plans' responsibility to train all providers on ways to avoid fraud, waste, and abuse. In August 2011, CMS hosted its first annual program integrity conference and plans to deploy fraud, waste, and abuse training for Part C and Part D.

In 2010, CMS began implementing a broad set of Medicaid initiatives focused on assessing and improving States' performance in meeting regulatory requirements and ensuring that managed care systems deliver accessible, available and appropriate services to Medicaid beneficiaries. These initiatives include updating regulatory compliance checklists, developing new tools to assess the readiness of States to implement managed care, and disseminate written policy guidance to States and health plans.

What Needs To Be Done

Ensuring the accuracy of payments to private plans remains a challenge, and CMS should strengthen its oversight of bids and risk adjustment payments. CMS must also continue to monitor plans' implementation of integrity safeguards, provision of covered services to all eligible beneficiaries, and compliance with marketing rules. CMS will also need to oversee plans' compliance with medical loss ratios and ensure that plans are not inflating their direct health care costs.

Key OIG Resources:
- Concerns With Rebates in the Medicare Part D Program. OEI-02-08-00050
- Invalid Prescriber Identifiers on Medicare Part D Drug Claims. OEI-03-09-00140
- Medicare Prescription Drug Sponsors' Training on Fraud, Waste, and Abuse. OEI-01-10-00060
- Review of Florida's Children's Health Insurance Program Experience Adjustment and Refund Submission Reports. A-04-10-06123

Why This Is a Challenge

The federal government must act as a prudent purchaser of health care to ensure access to quality care without wasteful spending. Payment methodologies must be designed to reimburse providers and suppliers fairly for appropriate care and to respond to changes in the health care marketplace. However, certain Medicare and Medicaid payment methodologies are misaligned with the current health care market.

Medicare and Medicaid prescription drug payments raise such concerns. State Medicaid agencies lack accurate information about pharmacies' costs to purchase drugs, typically relying upon inaccurate and unreliable published prices to estimate pharmacy costs. As a result, Medicaid payments to pharmacies for drugs often significantly exceed pharmacies' costs for those drugs. Although drug manufacturer rebates to State Medicaid agencies present opportunities for savings, these savings are not always realized. For example, OIG found that manufacturers avoided paying billions of dollars in rebates related to increases in their drug prices by modifying existing drugs and treating them as new drugs. Further, for brand-name drugs, Medicaid is entitled to an additional rebate when the price of a drug rises faster than the rate of inflation. However, generic drugs are not subject to these additional rebates, a missed savings opportunity. Finally, beneficiaries who are eligible for both Medicaid and Medicare Part D (dual eligibles) receive their drug benefits through Medicare Part D. This shift may result in higher net costs for dual eligibles' drugs because the rebates that Part D plans have negotiated with drug manufacturers are lower than those mandated for Medicaid.

Like Medicaid drug reimbursement, Medicare fee-schedule payments for certain types of durable medical equipment (DME) bear little resemblance to market prices. For example, Medicare reimbursed suppliers approximately $17,000 for individual wound therapy pumps that suppliers, on average, purchased for $3,600. The Medicare payment rate had not been lowered as more wound pump models and manufacturers entered the market and competition drove prices down.

OIG also reviewed the effects of a regulatory change in how Medicare pays skilled nursing facilities (SNF) for certain types of therapy in 2011. CMS intended the change to be budget neutral; however, we indentified a $2.1 billion increase in payments to SNFs because SNFs changed their billing patterns in unexpected ways.

Failure to monitor and update eligibility for enhanced payments under the Medically Underserved/Health Professional Shortage Areas program (MUA/HPSA) also results in waste. This program provides enhanced Medicare payments, among other incentives, to attract providers to medically underserved areas to improve health care access. However, HRSA has not updated the criteria for qualifying as an MUA or a HPSA and does not systematically redetermine whether the shortages have been alleviated in designated areas. Thus, some locations receive enhanced funding despite no longer meeting the criteria.

The challenges and opportunities in meeting the objective of better price alignment and waste reduction are complex and are evolving, particularly as the Department is moving to paying for health care based on value rather than volume of care delivered and to linking payment to quality and health outcomes. (See Challenge 1, Implementing the Affordable Care Act, for additional information.)

Progress in Addressing the Challenge

With respect to prescription drugs, provisions of the ACA increased Medicaid drug rebates and are intended to prevent manufacturers of brand-name drugs from circumventing payment of additional rebates on alternate versions of existing drugs. CMS is also developing alternative drug price benchmarks through a monthly retail price survey so that States will have more accurate estimates of drug costs to use for their pharmacy reimbursement.

With respect to DME, the Department has implemented the Competitive Bidding Program for certain DME, which is intended to achieve savings by better aligning reimbursement with market prices. OIG has identified excessive fee-schedule payments for oxygen concentrators and power wheelchairs, whose prices are now subject to competitive bidding. We will monitor competitive bidding to determine whether it addresses our pricing concerns. The Department is also moving forward with several value-based purchasing initiatives.

In July 2011, CMS announced a final rule reducing Medicare SNF payments in FY 2012 to correct for the unintended spike in payment levels and better align Medicare payments with costs.

What Needs To Be Done

Overall, the Department must take steps to better ensure that Medicare and Medicaid payments are economical and respond timely to changes in the marketplace, including seeking new authority where needed to implement pricing changes.

Other specific actions include CMS's continuing to work with States to more accurately reimburse pharmacies for drugs, ensuring that drug manufacturers are meeting their Medicaid rebate obligations, and monitoring the Competitive Bidding Program and updating it as needed. Also, HRSA should update the HPSA and MUA criteria, as needed; review designations periodically; and remove the designations from locations that no longer face health care shortages. Finally, the Department must be vigilant in the implementation and oversight of its new VBP programs.

Key OIG Resources

- Medicaid Brand-Name Drugs: Rising Prices Are Offset by Manufacturer Rebates. OEI-03-10-00260
- Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicare Part D. OEI-03-10-00320
- Medicare Payments for Newly Available Generic Drugs. OEI-03-09-00510
- Review of Generic Drug Price Increases. A-06-07-00042
- Status of the Rural Health Clinic Program, OEI-05-03-00170
- Review of Additional Rebates for Brand-Name Drugs With Multiple Versions, A-06-09-00033

Management Issue 10: Grants Management and Administration of Contract Funds

Why This Is a Challenge

HHS is the largest grant-making organization in the federal government, and its funding of health and human services programs touches the lives of almost all Americans. In FY 2010, the Department awarded approximately $370 billion in grants, approximately 30 percent of which funded programs other than Medicaid and CHIP. The Recovery Act provided an additional $31.8 billion for the temporary expansion of these (non-Medicaid/CHIP) programs for FYs 2009 and 2010. Finally, the ACA appropriated billions in additional grant funding. HHS is also the third largest contracting agency in the federal government; in 2010, HHS awarded $19.1 billion in contracts.

Oversight and management of both new and continuing grant programs is crucial to the Department's mission and to the health and well-being of the public. However, our audits of grantees have found internal control deficiencies, problems with financial stability, inadequate organizational structures, inadequate procurement and property management policies, and inadequate personnel policies and procedures. Additionally, in recent reviews of Head Start grantees, we found significant health and safety violations.

Increased concerns by Congress and the Administration regarding transparency of and accountability for agency expenditures is creating heightened scrutiny over the administration of grant and contract dollars. Ongoing oversight by the Recovery and Accountability Transparency Board (RATB) and the results of a recent survey by the Council of the Inspectors General on Integrity and Efficiency on the use of suspension and debarment at federal agencies underscore the importance of vigorous oversight. For example, the Government Accountability Office found that the Department views suspension and debarment as an underused tool and is committed to instituting a more vigorous process, which includes training and sharing best practices.

With respect to contracts, we have focused on NIH's use of appropriations to fund 21 longer term contracts. We found a number of instances of improper funding of these contracts that have resulted in potential and actual violations of the Antideficiency Act.

Progress in Addressing the Challenge

To conduct Recovery Act oversight, OIG worked closely with OPDIVs to perform risk analyses of grantees eligible for Recovery Act funding. In most cases, our recommendations were adopted and high risk grantees did not receive funding or were subject to heightened scrutiny. Additionally, the

Department's grant recipients are nearly 100 percent compliant in required reporting to the RATB. With respect to grants oversight, HHS continues to make progress in educating grants management officials. The Department hosted a 2-day symposium in April 2011 for all of its acquisition and grants officers. OIG has also been hosting grant training focused on fraud, waste, and abuse for Department grants officers. With respect to systemic contract funding problems, the Department, as required by law, reported multiple violations of the Antideficiency Act; issued detailed policy guidance; and developed and mandated a Department-wide appropriations law training course for all budget, finance, program, and contracting officials.

What Needs To Be Done

The OPDIVs need to continue to be vigilant in monitoring the ACA, the Recovery Act, and other grant awards. Additionally, through our grants management training efforts, we have found that each OPDIV has a great deal of autonomy over how it oversees its grants and that processes for taking grant actions differ. The processes across the Department should be more consistent. With respect to contract funding, the Department has advised that "[w]e are heavily focused on preventing new violations, but in terms of old contracts that are on-going, we're taking legally appropriate actions to ensure that there are no further violations of the Antideficiency Act." OIG continues to recommend that the Department correct the improper funding of contracts that resulted in appropriations violations and continue to ensure that appropriate officials attend mandated training, that future contracts are funded properly, and that policy guidance is consistently followed.

Key OIG Resources

- Most Early Head Start Teachers Have the Required Credentials, But Challenges Exist. OEI-05-10-00240
- Review of the District of Columbia Department of Parks and Recreation's Compliance with Health and Safety Regulations for Head Start Programs. A-03-09-00363
- Appropriations Funding of National Institute of Allergy and Infectious Diseases Contract N01-AI-15416 with the University of California at San Francisco. A-03-10-03120

Management Issue 11: Ensuring the Safety of the Nation's Food Supply

Why This Is a Challenge

CDC estimates that each year roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of food-borne diseases. FDA is responsible for ensuring the safety of much of the Nation's food supply. During a food emergency, FDA is responsible for finding the contamination source and overseeing the removal by manufacturers of these products from the market. Yet, recent OIG reports found that food recall inefficiencies, inadequate food facility inspections, and recordkeeping issues impair FDA's ability to effectively resolve food emergencies. These challenges may be exacerbated in the case of imported foods, which have increased significantly in volume and variety in recent years.

In reviews of food safety recalls, we found that FDA often did not follow its own procedures for ensuring that the recall process operated efficiently and effectively. Further, FDA's procedures for monitoring recalls were not always adequate.

Our work has also found that FDA conducts food facility inspections infrequently - many food facilities went 5 years or longer without an FDA inspection. Furthermore, FDA took action against less than half of food facilities after the agency found conditions that warranted its most severe inspection classification. FDA relies increasingly upon States to conduct food facility inspections under contract; OIG is examining the effectiveness of FDA's oversight of these inspections.

Food facilities' failure to comply with FDA's recordkeeping requirements impedes the Department's ability to ensure the safety of the Nation's food supply. We found that 59 percent of selected food facilities did not comply with FDA's recordkeeping requirements. We also found that 5 percent failed to register with FDA as required. Of those that did register, almost half failed to provide accurate and complete information.

The Food Safety Modernization Act (FSMA), signed into law in January 2011, provides FDA important new authorities to better protect the Nation's food supply. However, challenges exist in implementing these new authorities.

Progress in Addressing the Challenge

The Department has made progress in addressing the safety of imported food. FDA opened field offices in China, India, and Costa Rica to conduct more inspections and work with local officials to improve the safety of foods exported to the United States. FDA expanded its inspections capacity by increasing its staff by more than 700 investigators between FY 2007 and FY 2009 and by an additional 274 staff in FY 2010. FDA also deployed the PREDICT system, which is a risk-based screening tool for imported foods. As of August 23, 2011, 11 of 16 import districts were using the PREDICT screening tool. In September 2009, FDA required food facilities to report to a new registry all instances in which a food might cause serious health consequences and to investigate the causes of any adulteration reported. FDA has implemented www.foodsafety.gov, which provides food safety information for consumers. FDA is also developing the Petnet system, which will provide information on pet item recalls.

FDA has also made progress streamlining its jurisdiction by increasing its interagency coordination. For example, FDA partners with the National Oceanic and Atmospheric Administration to develop, validate, and use new chemical tests to detect oil residues and dispersants in seafood. Additionally, FDA partnered with the U.S. Department of Agriculture, States, and localities to improve the food safety system, including implementing a national egg inspection plan, which has a goal of inspecting 600 of the Nation's largest egg facilities by the end of calendar year 2011.

What Needs To Be Done

The Department and FDA should act quickly to implement FSMA to better protect the Nation's food supply. FSMA addresses many of OIG's recommendations; however we continue to recommend that FDA vigorously use its new authorities to remedy identified weaknesses in its inspections and recall procedures. FDA should also ensure that States properly conduct contracted food facility inspections.

OIG will continue to oversee the Department's management of food safety issues. In ongoing work, OIG is examining food facility compliance with requirements of FDA's Reportable Food Registry, FDA oversight and operations related to imported pet food and feed products, and the extent of FDA's testing of human food for contamination.

Key OIG Resources

- Review of the Food and Drug Administration's Monitoring of Imported Food Recalls. A-01-09-01500

- FDA Inspections of Domestic Food Facilities.OEI-02-08-00080

- FDA's Food Facility Registry. OEI-02-08-00060

- Traceability in the Food Supply Chain. OEI-02-06-00210

- OIG Testimony on the Safety of the Nation's Food Supply. http://oig.hhs.gov/testimony/docs/2010/FDA_inspections_testimony5-6-10.pdf

Why This Is a Challenge

The Department, through FDA, is responsible for ensuring that all drugs, biologics, and medical devices are safe and effective. The Department must also ensure that once a drug, biologic, or device has been approved for use, it is marketed appropriately. However, OIG work has revealed weaknesses in FDA's ability to adequately oversee the safety of drugs, biologics, and medical devices. In particular, we have found vulnerabilities in FDA's ability to ensure the timeliness of drug application reviews; the adequate monitoring of adverse-event reporting for medical devices; and the prevention of off-label marketing of drugs, biologics, and medical devices. In addition, as a result of expanded authorities under the ACA to approve biosimilars (generic biologics), FDA will need to develop a plan to implement these new authorities without exacerbating its backlog for drug approvals. Ensuring that participants in clinical trials are protected from significant risk presents an additional challenge to the Department both during the initial approval process and after drugs, devices, and biologics are approved by FDA when post-marketing trials are conducted.

Progress in Addressing the Challenge

FDA has taken actions to address some of the vulnerabilities related to timely review of generic drug applications, including issuing a final rule and providing guidance on what to include in generic drug applications. FDA also developed a new database to more effectively review and follow up on adverse-event reports for medical devices.

FDA has an ongoing Human Subject Protection/Bioresearch Monitoring Initiative tasked with modernizing the regulation of clinical trials across the spectrum of a product's lifecycle. FDA also has a Good Clinical Practice (GCP) Initiative with the European Medicines Agency underway that will permit the use of limited resources through joint inspections. The goal of this effort is to establish a mechanism for sharing information regarding applications and inspections while providing FDA with an enhanced understanding of health systems, medical practice, and regulatory requirements in foreign countries.

OIG is also working with law enforcement partners to investigate and prosecute drug and device manufacturers that engage in illegal marketing or conduct unauthorized clinical trials. For example, in November 2010, Synthes, Incorporated (Synthes), and its subsidiary, Norian Corporation, pleaded guilty to conducting clinical trials of a medical device without FDA authorization. Both companies agreed to pay the maximum criminal monetary penalties. They had conducted unauthorized clinical trials of Synthes's medical devices in surgeries to treat vertebral compression fractures of the spine, despite an FDA-cleared label warning against this use for this device and in the face of serious medical concerns about the safety of the devices when used in the spine. In another case, Novartis Pharmaceutical Corporation agreed to pay $422.5 million and enter into a corporate integrity agreement with OIG to resolve civil liability resulting from Novartis' violations of the Anti-Kickback statute and criminal and civil liability resulting from Novartis' marketing and promotion practices for Trileptal, an epilepsy medication, for a variety of conditions that were not approved by FDA.

What Needs To Be Done

The Department needs to focus on reducing off-label promotion, which may put patients in harm's way and may increase fraudulent claims for payment by federal health care programs. OIG is increasingly using its administrative authorities to sanction individuals and entities that engage in fraud and abuse in the pharmaceutical and medical device industries.

Key OIG Reports

- FDA's Generic Drug Review Process. OEI-04-07-00280
- Adverse Event Reporting for Medical Devices. OEI-01-08-00110
- FDA's Oversight of Clinical Trials. OEI-01-06-00160

Why This Is a Challenge

Conflicts of interest in the health care system generally, and specifically in the Department, have been the subject of scrutiny by Congress, the medical community, and the media. With a heightened focus on transparency in the federal government and the need to use resources efficiently and appropriately, the Department must ensure that internal and external stakeholders (e.g., employees, grantees) are free of conflicts of interest or other ethics concerns. However, results of our work indicate that the Department can do more to ensure that ethics vulnerabilities are identified and addressed.

OIG work has found that the Department provides limited oversight of conflicts of interest of FDA clinical investigators, NIH grantees, and federal employees. For example, in a 2011 report, we found that 56 percent of the HHS employees' conflict-of-interest waivers reviewed were not documented as recommended in Governmentwide federal ethics regulations, guidance, and the Secretary's instructions. In another review, we found that only 70 of 156 responding NIH grantee institutions had written policies and procedures for addressing institutional conflicts of interest (these policies are not required by law). Increased reliance on contract personnel raises additional conflict concerns. For instance, we found inappropriate use of contractor personnel at CDC (i.e., contractors' supervising federal employees). To ensure public trust in Department programs and operations, the Department must be steadfast in its oversight and enforcement responsibilities regarding ethics matters.

Progress in Addressing the Challenge

CDC has taken significant steps to improve the process for granting waivers for identified conflicts of interest to Special Government Employees (SGE). CDC now ensures that SGEs' Confidential Financial Disclosure Reports are complete before certifying them. CDC also has a policy for tracking SGEs' compliance with ethics requirements, including recusal procedures for upcoming meetings in which an SGE might have a conflict.

FDA has also taken steps to address identified vulnerabilities related to its clinical investigators. FDA now requires companies applying to market drugs, devices, and biologics (sponsors) to submit a complete list of clinical investigators and either certify the absence of a financial conflict of interest or disclose the nature of the financial arrangement to FDA for each clinical investigator. Additionally, FDA updated the *Compliance Program Guidance Manual* chapter on clinical investigator inspections to help ensure that clinical investigators submit required financial information to sponsors.

Similarly, NIH has taken actions to address conflict-of-interest vulnerabilities identified among NIH grantees. For instance, NIH published a final rule on August 25, 2011, revising 1995 regulations covering financial conflicts of interest for investigators. It addresses a number of issues related to promoting objectivity in research and addresses our recommendation to require grantee institutions to provide details regarding the nature of financial conflicts of interest and the ways in which they are managed, reduced, or eliminated.

What Needs To Be Done

OIG has recommended that NIH develop regulations governing institutional conflicts of interest, but the final rule does not address our concerns regarding institutional conflicts. Instead, in the final rule, NIH States that "[w]e continue to believe that further careful consideration is necessary before PHS [Public Health Service] regulations could be formulated that would address the subject of institutional conflict of interest...." OIG continues to recommend that NIH issue regulations requiring institutions to have a written policy on institutional conflicts. This would provide consistency and clarity to institutions.

The Office of the General Counsel should provide guidance to OPDIVs and Staff Divisions and ensure that they document conflict-of-interest waivers in accordance with the Secretary's guidance. FDA and CDC should continue to build upon the actions they have undertaken to improve oversight of clinical investigators and SGEs.

Key OIG Resources

- Institutional Conflicts of Interest at NIH Grantees (OEI-03-09-00480)

- CDC's Ethics Program for Special Government Employees on Federal Advisory Committees (OEI-04-07-002600)
- The Food and Drug Administration's Oversight of Clinical Investigators' Financial Information, OEI-05-07-00730.