FISCAL YEAR 2014 TOP MANAGEMENT AND PERFORMANCE CHALLENGES IDENTIFIED BY THE OFFICE OF INSPECTOR GENERAL

Management Challenge 1: Implementing, Operating, and Overseeing the Health Insurance Marketplaces

Why This Is a Challenge

The new Health Insurance Marketplaces, also known as Health Insurance Exchanges, (Marketplaces) are critical components of the health insurance market reforms enacted through the *Affordable Care Act*. In 2014, The Centers for Medicare & Medicaid Services (CMS) operated Marketplace functions on behalf of 36 states. Implementation, operation, and oversight of the Marketplaces were among the most significant challenges for the Department of Health and Human Services (Department or HHS) in fiscal year (FY) 2014 and will continue to present a top management and performance challenge in FY 2015, http://oig.hhs.gov/reports-and-publications/top-challenges/2013/.

In 2015, CMS and the Health Insurance Marketplaces face new and ongoing challenges including, for example, ensuring accurate eligibility determinations; processing enrollments, re-enrollments, and qualifying life change events; and communicating timely and accurate information to health insurance issuers (issuers) and consumers. Marketplaces must also facilitate Medicaid enrollment for those who qualify. In coordination with states, CMS will implement premium-stabilization programs. To carry out these complex Marketplace functions, the Department must ensure effective communication and coordination between and among all internal and external parties with Marketplace responsibilities, including within HHS and with contractors, issuers, and partners in state and federal government. Effective coordination with, and timely provision of accurate data to, the Internal Revenue Service (IRS) will be particularly important for sound administration of the premium tax credit program. In addition, CMS will need to be attentive to state Marketplace operations to ensure state compliance with requirements, including transmitting accurate and timely data used for federal payments. Key focus areas for the federal and state Marketplaces should include:

Payments. Ensuring sound expenditure of taxpayer funds for intended purposes poses a substantial management challenge, especially given the use of manual systems. The Department must implement financial management and payment systems that produce accurate and timely payments to issuers of advance payment of premium tax credits, cost-sharing reduction amounts, and premium-stabilization payments. In addition, CMS must validate information received from issuers to ensure that it is timely, complete, and accurate for payment purposes. Given the substantial federal funds involved, the Department should undertake a thorough risk assessment and, where appropriate, develop error rates to measure the integrity of program payments.

Eligibility. Ensuring accurate eligibility determinations is critical. Recent Office of Inspector General (OIG) work addressing eligibility verification systems during the first open enrollment period found that not all internal controls at reviewed Marketplaces were effective and that Marketplaces were unable to resolve most inconsistencies between applicants' self-reported information and data obtained by the Marketplaces from other sources. Moreover, for the second open enrollment period, Marketplaces must add functionality for processing re-enrollments. Effective internal controls and timely and accurate resolution of inconsistencies are, and will continue to be, critical to ensure that eligible consumers receive appropriate benefits and that ineligible individuals are not enrolled.

Management and Administration. Following the October 1, 2013, launch of the Marketplaces, the Department acknowledged the need for improved management and oversight, including clear leadership, disciplined operations, and better communication across the Department. Challenges include selecting capable contractors and providing appropriate oversight to ensure successful operation of the federal Marketplace, including both

public-facing and administrative systems. The Department must ensure, to the greatest extent possible, that the Government obtains specified products and services from its contractors on time and within budget. In addition, problematic operations at some state Marketplaces have prompted questions regarding the use of Federal establishment grant funds, and the Department must ensure that these grants have been properly managed. (For general information about challenges associated with grants management and contract administration, see Management Challenge 9.)

Security. Protecting and ensuring the confidentiality and integrity of consumers' sensitive personal information and Marketplace information systems is paramount. Effective operation of the Marketplaces requires rapid, accurate, and secure integration of data from numerous federal and state sources, issuers, and consumers. It also requires an established large-scale means of communication among many federal and state systems. The Department must vigilantly guard against intrusions and continuously assess and improve the security of Marketplace related systems, including, among others, the Data Services Hub. OIG work found that selected Marketplaces generally protected personally identifiable information, but could improve some information security controls. The Department also must ensure that non-automated systems used to process consumer enrollment information, such as the call center and paper application processes, incorporate effective security measures.

Progress in Addressing the Challenge

Since October 1, 2013, the Department has reported improvement in the operations of the federal Marketplace, as well as substantial enrollment figures. Key progress reported by CMS includes:

- changes to CMS's management of the federal Marketplace, including closer oversight by CMS leadership, designation of a systems integrator, use of cross-functional teams, and procurement of a new contractor for federal Marketplace construction and maintenance;
- establishment of (1) an interim process for resolving data inconsistencies pending automated functionality, (2) an interim process for paying issuers that are owed financial assistance payments pending automated functionality, and (3) functionality for reporting life change events;
- an improved application on a redesigned HealthCare.gov intended to streamline the eligibility process and improve the consumer experience;
- actions taken to address OIG recommendations to improve information technology (IT) security; and
- screening of call center representatives and focused training on protecting sensitive information.

CMS also reported regular communications with the IRS to validate payment information and the provision of technical and other support to the state Marketplaces.

What Needs To Be Done

The Department must continue to improve the federal Marketplace, including the public-facing consumer functions, as well as the back-end administrative and financial management functions. The Department must ensure that alternate pathways for enrollment operate with integrity and that consumers' personal information is secure. The Department must operate a well-run second open enrollment period for individuals and small businesses, employing lessons learned, taking all steps practicable to avoid problems that marred the first open enrollment period and rapidly and effectively addressing any problems that arise. Vigilant monitoring and testing and rapid mitigation of identified vulnerabilities are essential. In addition, attention must be paid to sound operation of financial assistance and premium-stabilization programs. The Department must ensure that consumers and issuers receive accurate Marketplace information, including information relevant for tax purposes, such as Form 1095A tax forms.

As with other new programs, the Department must continue to work with its partners to develop program integrity measures and processes. It must monitor for and address fraud, waste, and abuse risks to protect the federal investment in health care reform. If fraud schemes are identified, the Department must respond quickly and effectively, working jointly with partners at the federal and state level to ensure program integrity and hold those involved accountable. Further, the Department must continue to coordinate closely with states and others in federal government to monitor the operations and security of the Marketplaces and to implement Marketplace programs.

Key OIG Resources

- OIG Testimony, "Failure To Verify: Concerns Regarding PPACA's Eligibility System," July 2014, http://oig.hhs.gov/testimony/docs/2014/Daly_Greenleaf_testimony_07162014.pdf
- OIG Report, *Marketplaces Generally Protected Personally Identifiable Information but Could Improve Certain Information Security Controls*, September 2014, http://oig.hhs.gov/oas/reports/region1/181430011.asp
- OIG Report, *Not All Internal Controls Implemented by the Federal, California, and Connecticut Marketplaces Were Effective in Ensuring That Individuals Were Enrolled in Qualified Health Plans According to Federal Requirements*, June 2014, http://oig.hhs.gov/oas/reports/region9/91401000.asp
- OIG Report, *Marketplaces Faced Early Challenges Resolving Inconsistencies with Applicant Data*, June 2014, http://oig.hhs.gov/oei/reports/oei-01-14-00180.pdf
- OIG Report, *An Overview of 60 Contracts That Contributed to the Development and Operation of the Federal Marketplace*, August 2014, http://oig.hhs.gov/oei/reports/oei-03-14-00231.asp
- OIG 2015 Work Plan, http://oig.hhs.gov/reports-and-publications/archives/workplan/2015/FY15-Work-Plan.pdf

Management Challenge 2: Ensuring Appropriate Use of Prescription Drugs in Medicare and Medicaid

Why This Is a Challenge

CMS provides prescription drug coverage for 37.4 million Medicare beneficiaries through Part D and 59.4 million Medicaid beneficiaries. In 2012, combined Part D and Medicaid prescription drug expenditures totaled over $93 billion. Medicare Part D alone accounted for $66.9 billion of those expenditures. Maintaining the integrity of these two programs is critical to ensuring patient safety; safeguarding the quality of care; protecting the programs from fraud, waste, and abuse; and protecting taxpayer dollars.

OIG has extensively examined ongoing monitoring and oversight of the programs and the effectiveness of controls designed to ensure appropriate payment and patient safety. In both the Medicare Part D and Medicaid programs, OIG has uncovered improper and potentially harmful prescribing practices, pharmacies billing for drugs not dispensed, and diversion of prescription drugs.

Questionable Utilization and Billing Patterns. A 2014 OIG report examining questionable utilization patterns for HIV drugs by beneficiaries revealed claims on behalf of many beneficiaries with no indication of HIV in their Medicare histories, claims for excessive doses or supplies of HIV drugs, claims for HIV drugs from a high number of pharmacies or prescribers, or claims for contraindicated drugs. These patterns may indicate that beneficiaries are receiving inappropriate prescription drugs and selling them illegally, pharmacies are billing for drugs that beneficiaries never received, or that beneficiaries' Medicare identification numbers were stolen. Medicare paid $32 million for HIV drugs for beneficiaries with questionable utilization patterns in 2012.

Additional health care fraud schemes have involved providers submitting fraudulent claims to Medicare for deceased beneficiaries. A 2013 report revealed that, in 2011, Part D inappropriately paid more than $1 million for prescription drugs for 5,101 deceased beneficiaries, including some beneficiaries who had died in 2009.

Drug Diversion and Abuse of Controlled Substances. The diversion and abuse of prescription drugs is an ongoing problem. Drug diversion is the transfer of legitimate prescription drugs for unlawful purposes. Controlled substances, such as opiate pain relievers, are potentially so dangerous that they require restrictions on their manufacture, possession, or use. The Centers for Disease Control and Prevention (CDC) characterizes prescription drug abuse as an epidemic, reaching virtually all demographics and geographic locations. As abuses of these drugs have increased over the past five years, OIG has also increased its investigations of abuses in this area, many of which involve harm to individual beneficiaries. Diversion of these drugs may also result in profound public harm. In one noteworthy example, an OIG investigation found that a health care worker infected with Hepatitis C diverted a controlled prescription drug from a hospital for his own personal use. In an attempt to remain undetected, the worker inserted saline solution into the vials to replace the diverted drugs. Because the worker used his contaminated syringes to switch the fluids, several patients treated from these vials contracted the infectious disease.

Drug Diversion and Abuse of Non-Controlled Substances. A rapidly growing trend is the illegal billing and diversion of non-controlled medications (e.g., anti-psychotics), which presents a substantial financial vulnerability to federal health care programs. Many cases involve pharmacies billing federal programs for expensive brand-name medications that were never dispensed. Other common cases involve Medicare or Medicaid beneficiaries combining prescribed drugs with opioids to create an enhanced euphoria; such drugs are called "potentiators." Some HIV drugs are examples of non-controlled substances that can be used as potentiators.

Progress in Addressing the Challenge

CMS has taken steps to strengthen oversight of appropriate drug utilization in Medicare Part D. For example, CMS responded to an OIG recommendation that it strengthen the Medicare Drug Integrity Contractor's (MEDIC) monitoring of pharmacies and its ability to identify pharmacies with questionable billing patterns and develop pharmacy risk scores. In June 2013, CMS and the MEDIC developed pharmacy risk scores and released a list of "high risk" pharmacies to Part D plans. CMS instructed Part D plans to use the risk score information in conjunction with their own data analysis to combat fraud, waste, and abuse. CMS suggested that plans use the list of high risk pharmacies to target pharmacies for audits and further review.

Moreover, OIG recommended that CMS require Part D sponsors to verify that prescribers have the authority to prescribe drugs. Beginning June 1, 2015, physicians and eligible professionals must be enrolled in Medicare to prescribe Part D drugs. In addition, to identify the prescribing physician or eligible professional, CMS will require that a pharmacy claim for a Part D drug contain the National Provider Identifier. This will enable CMS, Part D plans, and the MEDIC to verify that prescribers have the authority to prescribe Part D drugs before the claims are paid.

What Needs To Be Done

In addition to taking the steps described above, CMS must increase Part D plan sponsors' abilities to limit questionable utilization of drugs, particularly drugs that are vulnerable to diversion and recreational abuse. For example, CMS should expand sponsors' drug utilization review programs and use of beneficiary-specific controls. CMS should also restrict certain beneficiaries with questionable utilization patterns to a limited number of pharmacies or prescribers.

Additionally, CMS should improve existing safeguards to prevent improper payments in Part D. CMS needs to ensure that the MEDIC routinely analyzes billing data to detect pharmacies and providers with questionable billing patterns, including billing for deceased beneficiaries.

Key OIG Resources

- OIG Report, *Part D Beneficiaries with Questionable Utilization Patterns for HIV Drugs*, August 2014, http://oig.hhs.gov/oei/reports/oei-02-11-00170.pdf
- OIG Testimony, "Medicare Program Integrity: Screening Out Errors, Fraud, and Abuse," June 2014, https://oig.hhs.gov/testimony/docs/2014/cantrell_testimony_06252014.pdf
- OIG Report, *Medicare Payments Made on Behalf of Deceased Beneficiaries*, October 2013, http://oig.hhs.gov/oei/reports/oei-04-12-00130.pdf

Management Challenge 3: Protecting an Expanding Medicaid Program From Fraud, Waste, and Abuse

Why This Is a Challenge

Protecting the integrity of Medicaid takes on heightened urgency as the program continues to grow in spending and in the number of people it serves. As of October 2014, 27 states and the District of Columbia (28 states) are expanding Medicaid coverage to include qualifying adults earning up to 133 percent of the federal poverty level, pursuant to *Affordable Care Act* and Medicaid waivers. Further, states that have not expanded eligibility have seen increases in Medicaid enrollment. In addition to facing the challenges in implementing expanded eligibility in the 28 states, Medicaid programs face long-standing program integrity challenges. These include improving the effectiveness of Medicaid data; preventing and addressing fraud, waste, and abuse, including avoiding or recovering Medicaid improper payments; ensuring access to care in Medicaid managed care programs; and curbing state Medicaid policies that inflate federal costs. (See Management Challenge 5 for more information on Medicaid issues related to nursing homes and benefits provided in home- and community-based settings.)

Expansion of Medicaid Eligibility. As of August 2014, CMS reported that enrollment in Medicaid and the Children's Health Insurance Program (CHIP) had increased by 8.7 million people since individuals became eligible to apply under the *Affordable Care Act's* expanded eligibility criteria in October 2013. For individuals in expansion states who are "newly eligible" under the *Affordable Care Act's* expanded income limits, the Federal Government will pay the full costs of medical assistance through 2016, after which the federal share gradually falls to 90 percent by 2020 and continues at 90 percent thereafter. For Medicaid beneficiaries who are not "newly eligible," the Federal Government will continue to share costs with states according to its standard Federal Medical Assistance Percentage (FMAP), which currently ranges by state from 50 to 74 percent. Updating eligibility systems and ensuring appropriate eligibility determinations and FMAP designations for each beneficiary present implementation challenges.

Improving the Effectiveness of Medicaid Data. As Medicaid expands, implementing a functional, national Medicaid database is essential to effective oversight of Medicaid payments and services. OIG continues to find that the existing national Medicaid data are not complete, accurate, or timely and that additional data are needed to conduct national Medicaid program integrity activities. CMS has attempted to improve the access and quality of Medicaid data, most recently through the Transformed Medicaid Statistical Information System (T-MSIS) initiative. OIG found that as of January 2013, CMS and 12 volunteer states had made some progress in implementing T-MSIS; however, early T-MSIS implementation outcomes raised questions about the completeness and accuracy of T-MSIS data upon national implementation.

Identifying and Recovering Improper Payments. In 2013, CMS reported that Medicaid's improper payment rate was 5.8 percent. The projected federal share of the $24.9 billion improper payments was $14.4 billion; almost 97

percent of these improper payments were overpayments. Payments made on behalf of individuals who should not have been enrolled in the program were the main source of error. CMS is developing a Unified Program Integrity Contractor model in which program integrity work at the federal level will be consolidated so that each contractor will conduct Medicare, Medicaid, and Medicare-Medicaid Data Match (Medi-Medi Program) work within designated geographic areas; CMS expects to implement this strategy starting in FY 2015. OIG has found that CMS's national Medicaid integrity programs—Medicaid Audit Program and Medi-Medi Program—have had limited success identifying Medicaid overpayments and potential fraud. (See Management Challenge 8 for more information on error rate measurement and reporting.)

Program Integrity and Beneficiary Access in Managed Care Programs. CMS reports that, as of 2011, almost three-quarters of all Medicaid beneficiaries were enrolled in some type of managed care system. The private plans and Medicaid share financial risk from fraud, waste, and abuse by health care providers or beneficiaries. Such fraud, waste, and abuse drives up costs for both the plans and Medicaid. Fraud or abuse by the managed care plan (e.g., manipulating its bids) can further increase Medicaid costs. In a 2011 report, OIG work revealed that the predominant concerns of both states and plans were provider fraud—billing for services that were not provided, were medically unnecessary, or were upcoded—and beneficiary fraud, including prescription drug abuse.

Ensuring that beneficiaries enrolled in managed care plans have sufficient access to providers and services is paramount. OIG has found that standards for access to care vary widely across states. For example, standards range from requiring 1 primary care provider for every 100 enrollees to 1 primary care provider for every 2,500 enrollees. States do not commonly use "direct tests," such as making calls to providers, to identify whether plans are meeting access-to-care-standards. Further, CMS provides limited oversight of state access standards.

State Policies That Inflate Federal Costs. OIG has raised long-standing concerns, as noted in our Compendium of Priority Recommendations, about states' Medicaid policies that result in the Federal Government's paying a greater share of Medicaid costs than the FMAP percentages would dictate. Medicaid permits states to provide enhanced payments that qualify for federal reimbursement to non-state-owned government providers, such as county or local publicly owned nursing facilities and hospitals. But some states have required such facilities to transfer the funds to the states to be put to other uses, leaving the facilities underfunded. Misalignment of costs and payments at certain state-operated facilities can also inflate federal costs; for example, in New York, Medicaid payments to state-run developmental centers exceeded actual costs by more than $1 billion during New York's State FY 2009. In another example, Pennsylvania used a state tax on Medicaid managed care plans to draw down almost $1 billion in federal funds over a three-year period.

Progress in Addressing the Challenge

CMS has reported that it is working to promote program integrity with respect to the Medicaid expansion by providing tools and technical assistance to the states, developing new procedures and practices for ensuring eligibility determination and payment accuracy, and training state staff on reporting and accounting for expenditures associated with newly eligible individuals.

CMS has taken action to improve its data and technology capabilities with respect to Medicaid program integrity. Beginning in July 2014, all states were expected to demonstrate operational readiness to submit T-MSIS files to CMS. As of October 2014, CMS stated that over 38 states are engaged in testing with CMS regarding the transfer of their T-MSIS files. CMS stated that it will continue to monitor, evaluate, and improve the quality and consistency of T-MSIS data submissions.

CMS has also reported actions to improve the Medicaid Audit Program and the Medi-Medi Program consistent with OIG recommendations, such as assigning more Medicaid audits through a collaborative process, which

showed greater success than the traditional process. In addition, CMS stated that it will continue working with states and third parties to address problems identified by states with identification and collection from liable third parties.

In a June 2014 status update to OIG, CMS indicated that it is working with states to protect against fraud, waste, and abuse in managed care. Specifically, CMS is working to update guidelines to states on program integrity in Medicaid managed care. In addition, CMS indicated that it will advise states to work with their managed care entities to identify and implement effective strategies for verifying billed services in managed care settings. CMS also agreed with OIG's recommendations to strengthen oversight of managed care access standards, and it described plans to provide guidance and technical assistance to states.

CMS is continuing to work with New York to revise its methodology for Medicaid payments to state-run developmental centers to better align them with costs. CMS has approved a State Plan Amendment, issued a disallowance letter to New York for $1.25 billion for 2010-2011, and plans to review two subsequent fiscal years. Finally, CMS has issued guidance on Medicaid upper payment limits and is requiring all states to demonstrate annually the upper payment liability to the Federal Government for services that are subject to these limits. In addition, CMS recently issued a State Health Officials letter on the treatment of health-care-related taxes and their effect on federal matching funding, following OIG's audit work in Pennsylvania.

What Needs To Be Done

CMS should continue its efforts to develop robust oversight for the Medicaid expansion. CMS must be vigilant in addressing program integrity risks associated with the expansion, including monitoring states' compliance with eligibility requirements and FMAP expenditures.

CMS should continue to work with states to ensure the submission of complete, accurate, and timely T-MSIS data. If states fail to submit timely T-MSIS data, CMS should use its statutory enforcement mechanisms or seek legislative authority to employ alternative tools to compel state participation.

CMS should continue to build on its progress addressing Medicaid Integrity Contractors (MIC) and Medi-Medi performance in identifying Medicaid overpayments. In particular, CMS should expand its use of collaborative audits to ensure that all states and the District of Columbia are actively engaged with the MICs in identifying and auditing providers.

Given that concerns about identifying fraud and abuse remained among states and plans, particularly with respect to provider and beneficiary fraud, CMS should update guidance to states to reflect these concerns. CMS should work with states to ensure that contracts with managed care organizations contain adequate provisions for the identification and referral of potential fraud cases. CMS should also implement its plans to work with states to ensure adequate access to care for Medicaid beneficiaries enrolled in managed care plans.

OIG has long recommended that Medicaid payments to public providers be based on the costs of providing services. In 2008, CMS issued a final rule that, among other things, would limit Medicaid payments to public providers to their costs of providing care, but the rule was ultimately vacated by Federal District Court.

Key OIG Resources

- OIG Report, *State Standards for Access to Care in Medicaid Managed Care*, September 2014, http://oig.hhs.gov/oei/reports/oei-02-11-00320.asp
- OIG *Compendium of Priority Recommendations*, March 2014, http://oig.hhs.gov/reports-and-publications/compendium/files/compendium2014.pdf

- OIG Testimony, "Examining the Federal Government's Failure to Curb Wasteful State Medicaid Financing Schemes," July 29, 2014, http://oversight.house.gov/wp-content/uploads/2014/07/Hagg-HHS-OIG-Final.pdf
- OIG Report, *Early Outcomes Show Limited Progress for the T-MSIS*, September 2013, https://oig.hhs.gov/oei/reports/oei-05-12-00610.asp
- OIG Testimony, "Saving Taxpayer Dollars by Curbing Waste and Fraud in Medicaid," June 14 2012, http://oig.hhs.gov/testimony/docs/2012/Maxwell_testimony_06142012.pdf
- OIG Testimony, "Examining the Administration's Failure to Prevent and End Medicaid Overpayments," September 20, 2012, https://oig.hhs.gov/testimony/docs/2012/Hagg_testimony_09202012.pdf
- OIG Report, *Medicaid Managed Care: Fraud and Abuse Concerns Remain Despite Safeguards*, December 2011, https://oig.hhs.gov/oei/reports/oei-01-09-00550.asp

Management Challenge 4: Fighting Waste and Fraud and Promoting Value in Medicare Parts A and B

Why This Is a Challenge

To secure the future of health care for Medicare beneficiaries, the Department must be vigilant in reducing wasteful spending and promoting better health outcomes at lower costs. The Institute of Medicine estimated that 30 percent of U.S. health spending (public and private) in 2009—roughly $750 billion—was wasted.[1]

Waste in health care programs is a multi-dimensional problem. Key areas of focus for reducing waste in Medicare Parts A and B include reducing improper payments, fighting fraud, fostering economical payment policies, and transitioning from volume to value in health care. HHS faces challenges—and opportunities—in each of these areas.

Reducing Improper Payments. CMS reported an error rate of 10.1 percent for Medicare fee for service (Parts A and B), corresponding to an estimated $36 billion in improper payments in FY 2013. This measure includes payments for unnecessary services, billing or coding errors, and payments for claims that did not meet documentation or other Medicare coverage requirements. Medicare's pending transition to a new system of diagnosis codes, the ICD-10, may bring implementation challenges or potential increases in improper billing as providers transition to the new codes. (See Management Challenge 8 for more information on error rate measurement and reporting.)

Challenges affect every stage of the payment process, from making the initial payment accurately to adjudicating overpayment recoveries. OIG has documented high Medicare improper payment rates for various services, including home health services and evaluation and management services. OIG audits of hospitals have uncovered and sought to remedy improper billing and payments for a myriad of issues, such as incorrect billing for transfers to post-acute care and inaccurate patient diagnosis codes. Accurate billing by hospitals for short inpatient stays versus outpatient observations has been an area of considerable challenge and concern for the Department, hospitals, and beneficiaries.

CMS relies on contractors for most of these crucial functions; however, OIG has identified deficiencies in contractor performance and in CMS's oversight of contractors that process Medicare claims and that audit and recover overpayments. Finally, the Department is facing significant challenges in adjudicating provider appeals of Medicare overpayment recoveries, including (1) a substantial backlog of appeals at the administrative law judge (ALJ) level (third level of appeals), (2) inconsistent determinations among the ALJs and between the ALJs and

[1] Institute of Medicine, "Best Care at Lower Cost: The Path to Continuously Learning Health Care in America," September 6, 2012.

Qualified Independent Contractors (second level of appeals), and (3) insufficient CMS participation in the appellate process.

Preventing and Responding to Fraud. Curbing fraud is vital to conserving scarce health care resources and protecting beneficiaries. Fraud schemes shift over time, but certain Medicare services have been consistent targets. For example, OIG investigations continue to uncover fraud schemes and questionable billing patterns by durable medical equipment (DME) suppliers, home health agencies, community mental health centers, clinical laboratories, ambulance transportation suppliers, and outpatient therapy providers. CMS's contractors play a key role in fighting Medicare fraud. However, CMS is not realizing the full potential of this oversight tool. For example, OIG found that CMS contractors' program integrity efforts were limited with respect to home health and community mental health services, even though these services are known as fraud risk areas.

Fostering Economical Payment Policies. As a result of certain payment policies that OIG has identified, Medicare pays significantly different amounts for the same services for similar patients in different settings. For example, Medicare pays significantly more for services performed in an outpatient hospital department than for the same services performed in an ambulatory surgical center (ASC). While not all patients can safely receive services in an ASC, for low-risk patients that do not need hospital-level care at an outpatient hospital department, Medicare could save billions of dollars by paying for their services at ASC rates. In another example, Medicare generally reduces payments to hospitals for patients with early discharges to post-acute care, such as care provided in a skilled nursing facility, to avoid overlapping payments for the hospital care and the post-acute care. However, Medicare does not reduce hospital payments if a patient's early discharge is to hospice care.

Transitioning From Volume- to Value-Based Payment. Experts generally agree that the incentives created by paying for health care on the basis of the volume of items or services furnished, as in Medicare's fee-for-service program, contribute to waste by encouraging unnecessary utilization and fragmented, poor quality care. HHS is transitioning to value-based payments in Medicare, which are intended to produce better quality of care at lower costs by rewarding high-quality care, penalizing low-quality care, or enhancing care coordination. Models involve, for example: accountable care organizations (ACOs), value-based payments for hospitals, penalties for hospital readmissions, pay-for-performance systems, shared savings programs, gainsharing, care coordination payments, and bundled payments.

Designing bundled payment methodologies that reimburse for items and services across separate provider settings will pose additional challenges. Many value-based payment mechanisms rely on complex data, electronic health information, and sophisticated quality and performance measures. To be effective, the data must be correct and timely, the metrics meaningful, and the information usable.

Progress in Addressing the Challenge

Overall, the Department has implemented many of OIG's recommendations for combating waste and fraud in Medicare, resulting in cost savings, improved program operations, and enhanced protections for beneficiaries. In FY 2013, OIG audits and investigations resulted in expected recoveries of $5.8 billion in stolen or misspent funds across Department programs. In addition, OIG reported estimated savings of more than $19 billion resulting from legislative and regulatory actions supported by OIG recommendations. The Health Care Fraud and Abuse Control Program (a joint program of the Department, CMS, OIG, and the Department of Justice (DOJ) to fight waste, fraud, and abuse in Medicare and Medicaid) returned more than $8 for every $1 invested. Medicare Fraud Strike Forces, led by OIG and DOJ, have demonstrated success in investigating and prosecuting fraud and shutting down criminal networks.

CMS has taken actions intended to improve the integrity and accuracy of billing for numerous types of services. For example, CMS implemented (1) a provision of the *Affordable Care Act* that practitioners who certify Medicare patients as eligible for home health services must document their face-to-face encounters with those patients and (2) a demonstration project that requires prior authorization for scooters and power wheelchairs in seven states with high incidences of fraud and improper payments for these items. CMS is working with home health service providers and practitioners to improve the low initial rates of compliance with this requirement. CMS continues to work to address hospital billing for short inpatient stays and outpatient observation stays, which has significant impacts on Medicare spending, beneficiary cost-sharing, and hospital revenue.

OIG has also noted reductions in Medicare billing and payments for certain services and geographic areas with known fraud risks. For example, following high-intensity law enforcement activities and administrative actions by CMS, billing and payments for home health services and community mental health services declined significantly in fraud hot spots. CMS has also instituted temporary moratoria on the enrollment of new home health agencies in the Miami, Chicago, Fort Lauderdale, Detroit, Dallas, and Houston areas and ambulance transportation suppliers in the Houston and Greater Philadelphia areas. Additionally, CMS continues to develop its Fraud Prevention System (FPS). OIG certified CMS's reported $54 million in actual savings and $210 million in unadjusted savings resulting from year 2 of the FPS, representing a positive return on investment of $1.34 for every $1.

CMS has reported improvements to its oversight and measurement of its contractors' performance and its follow-up on improper payment vulnerabilities that contractors identify. The Department also continues to focus on resolving the backlog of Medicare appeals by providers.

CMS has implemented and is administering ACO programs, value-based purchasing programs, the Bundled Payment for Care Improvement initiative, the Health Care Innovation Awards program, the State Innovation Model program, and others. In September 2014, CMS reported first performance year results for the Medicare Shared Savings Program (MSSP) showing that 53 MSSP ACOs earned shared savings payments of more than $300 million and held spending $652 million below their targets; in total, the Medicare Trust Fund will save approximately $345 million.

What Needs To Be Done

Despite progress in key areas, further actions are needed to protect Medicare from waste and fraud. CMS needs to better ensure that Medicare makes accurate and appropriate payments. When Medicare improper payments occur, CMS needs to identify and recover them in a timely manner. CMS must also implement safeguards, as needed, to prevent recurrence. CMS relies on contractors for most of these crucial functions; therefore, ensuring effective contractor performance is essential. Finally, the Medicare appeals system needs fundamental changes to resolve issues about improper payments efficiently, effectively, and fairly. OIG has recommended numerous actions to advance these outcomes.

With respect to promoting value in Medicare, the Department should continue to prioritize the effective transition to value-based payment mechanisms and the development and refinement of quality, outcomes, and performance metrics. Data systems supporting programs that link payment to quality and value must be scrutinized for timeliness, accuracy, and completeness. CMS should continue to strengthen its program integrity tools and apply them as needed to ensure integrity in new models. As demonstration programs continue to unfold, the Department should carefully monitor for successes and benefits that can be scaled and replicated, as well as for potential problems—including inefficiencies, misaligned incentives, or abuses. As with any innovation and experimentation, missteps may occur; it is critical that the Department take effective and appropriate actions to address such missteps and prevent their recurrence.

Key OIG Resources

- OIG Testimony, "Medicare Program Integrity: Screening Out Errors, Fraud, and Abuse," June 2014, https://oig.hhs.gov/testimony/docs/2014/cantrell_testimony_06252014.pdf
- OIG Testimony, "Medicare Mismanagement: Oversight of the Federal Government Efforts to Recapture Misspent Funds," May 2014, http://oig.hhs.gov/testimony/docs/2014/Ritchie_testimony_05202014.pdf
- OIG *Compendium of Priority Recommendations*, March 2014, http://oig.hhs.gov/reports-and-publications/compendium/files/compendium2014.pdf

Management Challenge 5: Ensuring Quality in Nursing Home, Hospice, and Home- and Community-Based Care

Why This Is a Challenge

As the median age of Americans continues to rise and as more Americans live with chronic medical conditions, the Department faces challenges in ensuring that beneficiaries who require nursing home, hospice, or home- and community-based services (HCBS) receive high quality care. It is critical that these services be available, allowing beneficiaries to receive the care they need in the setting that best serves their needs and preferences. High quality nursing home and HCBS programs are important for the continued well-being of people who need ongoing assistance with daily living, as well as those who need additional help recuperating from hospital stays or other acute care. Hospice care provides comfort for terminally ill beneficiaries by reducing pain and addressing physical and other needs. High quality nursing home, hospice, and HCBS personal care services can often prevent the need for disruptive and costly hospitalizations.

OIG continues to identify various problems with nursing home and hospice care. For example, in reports on nursing homes, OIG raised concerns about the frequency of preventable adverse events due to substandard care, the extent to which nursing homes comply with federal regulations for reporting abuse and neglect, and the lack of monitoring of nursing homes' resident hospitalization rates. With respect to hospice care, OIG has raised concerns about insufficient monitoring of hospice service use, as well as inadequate oversight of hospice certification surveys and hospice-worker licensure requirements.

It is critical to ensure effective oversight of HCBS programs and Medicaid-paid personal care services. HCBS programs are important, in part, because they allow beneficiaries whose needs and preferences are better served by remaining in their own homes or other community-based settings to avoid or delay institutionalization. These programs offer many advantages for promoting beneficiary choice and preferences, but OIG efforts have revealed persistent payment, compliance, and quality vulnerabilities.

Progress in Addressing the Challenge

The Department continues to take steps to improve the quality of nursing home, hospice, and HCBS programs. Through its Web site and in various outreach strategies, CMS is providing guidance to nursing homes on how to meet newly expanded quality assessment and performance improvement (QAPI) activities required under the *Affordable Care Act*. Adding to this effort is a recent proposed rule that outlines actions CMS intends to take to remove obsolete or unnecessary provisions affecting nursing homes' ability to carry out these and other requirements. CMS also published rules strengthening nursing home requirements in areas such as emergency preparedness, dementia care, and infection control.

The Department has also taken steps to improve the quality of services beneficiaries receive in hospice settings and from HCBS programs. To improve hospice care, CMS proposed rules that would update the hospice quality reporting program and reform hospice payment methodologies. For HCBS programs, CMS finalized rules covering

minimum quality expectations for providers, new administrative flexibilities for states running HCBS programs, requirements for person-centered planning in these services, and enforcement actions CMS can take against HCBS programs out of compliance with requirements. The Department also entered into a contract with the National Quality Forum to begin work on the development of a national quality measure set for HCBS.

OIG continues to pursue enforcement actions against nursing homes, hospices, and HCBS providers that render substandard care. CMS and OIG work closely with law enforcement partners at DOJ and through the federal Elder Justice Interagency Working Group to promote better care for older adults and to prosecute providers committing abuse or neglect. Additionally, state Medicaid Fraud Control Units (MFCUs), which receive oversight and funding from OIG, devote substantial resources to the investigation and prosecution of abuse and neglect in Medicaid-funded facilities, such as nursing homes and board-and-care homes.

The decision to force a nursing home to shut down or stop serving federal health care program beneficiaries is never taken lightly, as the experience of being transferred is traumatic to displaced beneficiaries, and locating nearby facilities to adequately serve them can be challenging. Therefore, OIG invests substantial efforts in helping facilities improve. OIG has developed an innovative quality-oriented corporate integrity agreement process to work with nursing home providers so they may better serve beneficiaries. OIG has placed nearly 40 nursing home companies (covering more than 750 facilities) under corporate integrity agreements that include quality-monitoring provisions designed to ensure that beneficiaries receive the care they deserve.

What Needs To Be Done

The Department should continue to prioritize quality of nursing home, hospice, and HCBS. OIG has offered recommendations to assist the Department in this mission. For example, OIG recommended that the Department monitor how often nursing home residents are hospitalized and develop resources that can be used to help nursing home staff reduce the incidence of adverse events in nursing homes. OIG has also recommended that the Department seek to link payments for services to meeting quality-of-care requirements and work with OIG to hold providers that have rendered substandard care accountable, thereby preventing additional harm to vulnerable beneficiaries. Further, the Department should promulgate the regulations mandated under section 6102 of the *Affordable Care Act* concerning compliance and ethics programs for nursing homes. Such regulations could assist nursing homes in preventing and detecting fraud, waste, and abuse and promoting quality of care.

Recently, Congress passed two laws that gave the Department new tools to improve the quality of care in nursing homes and other post-acute care providers. The *Protecting Access to Medicare Act of 2014* (PAMA) establishes a value-based payment program for nursing homes under which incentive payments will be made to high performing providers. The *Improving Medicare Post-Acute Care Transformation Act of 2014* (IMPACT) includes new reporting requirements for nursing homes and other post-acute care providers, including standardized admission and discharge patient assessments. IMPACT also includes requirements that hospice programs be surveyed at least once every 36 months and that oversight entities perform chart reviews, in some cases, of hospice episodes longer than 180 days. The Department should use these tools to improve the care people receive in these settings.

Lastly, the Department should ensure the integrity of Medicaid-funded personal care services by establishing minimum federal qualification standards for providers; improving CMS's and states' ability to monitor billing and care quality; and issuing operational guidance for claims documentation, beneficiary assessments, plans of care, and supervision of personal care attendants. The Department should also issue guidance to states regarding adequate prepayment controls and help states access data necessary to identify overpayments.

Key OIG Resources

- OIG Report, *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*, February 2014, http://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf
- OIG Portfolio, *Personal Care Services: Trends, Vulnerabilities, and Recommendations for Improvement*, November 2012, http://oig.hhs.gov/reports-and-publications/portfolio/portfolio-12-12-01.pdf

Management Challenge 6: The Meaningful and Secure Exchange and Use of Electronic Health Information

Why This Is a Challenge

The American health care system increasingly relies on health information technology (health IT) and the electronic exchange and use of health information. Health IT, including electronic health records (EHRs), offers opportunities for improved patient care, more efficient practice management, and improved overall public health. The *Health Information Technology for Economic and Clinical Health Act of 2009* (HITECH) provided for Medicare and Medicaid incentive payments to eligible professionals, eligible hospitals, and critical access hospitals (CAHs) for adopting, implementing, upgrading, or demonstrating meaningful use of EHRs and established a variety of grant programs to encourage widespread adoption of EHRs. HITECH also included requirements for public reporting of breaches of unsecured protected health information. Although participation in the Medicare and Medicaid EHR Incentive Programs is high and has led to widespread adoption among eligible providers, significant challenges exist with respect to overseeing the EHR Incentive Programs, achieving interoperability of EHRs, and keeping sensitive health information secure. Additionally, as the Department works to link payments with care quality, health outcomes, or performance as part of health care delivery system reforms, it will need to ensure that EHR and other health information data are accurate and reliable and are protected from misuse. (For more information on linking health care payments to value, see Management Challenge 4.)

Medicare and Medicaid EHR Incentive Programs. As of September 2014, the EHR Incentive Programs have paid out $25.4 billion in incentive payments. Although program interest has been high among those eligible, recent data suggest that not all those currently participating will continue in the programs. If the number of program participants were to decrease, fewer eligible professionals, eligible hospitals, and CAHs would progress to Stage 2 meaningful use, which includes a focus on health information exchange. For example, a recent Office of the National Coordinator for Health Information Technology (ONC) report, http://dashboard.healthit.gov/quickstats/pages/FIG-Medicare-Professionals-Stage-One-Meaningful-Use-Attestation-Cohort-2011.php, shows that a substantial number of the first cohort of participants may be dropping out of the Medicare EHR Incentive Program. Of those that received a payment in 2011, 16 percent did not return for 2012. Further, 19 percent of participants dropped out of the Medicare EHR Incentive Program in 2013.

Challenges in program oversight also leave the EHR Incentive Programs vulnerable to inappropriate payments to participants that do not meet program requirements. OIG work has demonstrated vulnerabilities in oversight controls for EHR incentive payments, as well as the accuracy of EHR incentive payment calculations. OIG also found that CMS and states did not implement strong prepayment controls and relied primarily on postpayment audits of high-risk participants to confirm that payments were appropriate. Additionally, OIG found that CMS and states lacked adequate data to verify participants' self-reported attestations about their eligibility and meaningful use of EHRs. ONC requires EHRs to generate audit reports for some, but not all, meaningful use measures; this requirement may create some oversight obstacles for CMS to verify payment during postpayment audits.

An OIG audit of Medicaid EHR incentive payment accuracy in Louisiana found that the state did not always pay Medicaid EHR incentive payments, in accordance with federal and state requirements. OIG found incorrect incentive payments including both overpayments and underpayments, totaling $4.4 million.

Interoperability. Those who adopt health IT must be able to use their systems to exchange and meaningfully use health information in order to achieve the broader policy objectives and cost savings to the health care system. Health information is still not commonly exchanged between groups of health care providers that use different EHR products. For example, most Health Resources and Services Administration (HRSA) health centers had the capability to capture data, but few were able to meet the Stage 1 meaningful use standard for sharing data. As of September 2014, only 93 hospitals and 2,282 doctors had successfully progressed to Stage 2 meaningful use, which includes functionalities related to exchanging data, including for transitions of care between inpatient, outpatient, and postacute care providers. This may mean that patients' electronic health information is not shared across organizational, vendor, and geographic boundaries. A June 2014 study, http://jamia.bmj.com/content/21/6/1060.full.pdf+html?sid=30b4ae26-1916-4b0d-ac5a-0afd31e2cc95, published in the Journal of the American Medical Informatics Association found that customized health history documents in certified EHRs lead to errors in transmissions between EHR systems, often necessitating manual data entry—a counterproductive outcome. Sharing of data may be impeded by several factors, including costs to establish the capability to share data, complex federal and state privacy and security rules, and system variation.

Further, many health care delivery system reform initiatives envision providers, suppliers, and others coming together in new or enhanced ways to better coordinate patient care and increase efficiency. These reform initiatives include the Medicare Shared Savings Program, the Pioneer ACO Model, and the Bundled Payments for Care Improvement initiative, among others. To improve care coordination and meet performance goals, many participants in these and other reform initiatives will share data across settings and use data received from outside their own systems. A lack of data exchange and incompatibility across systems presents challenges to achieving the benefits promised by EHRs and other health IT and could undermine the goals of some reform initiatives. Data created, maintained, or transmitted using EHRs or other health IT are used to ensure correct Medicare and Medicaid payments, including value-based payments. Participants in some of these payment initiatives also receive Departmental data for their use in improving the care they furnish. Those data similarly must be accessible and accurate.

Protecting Sensitive Information. Safeguarding privacy and data security is, and should remain, a top priority in health IT adoption and health data exchange, storage, and use efforts. Health care data breaches can have serious consequences, including medical identity theft, misdiagnoses, delays in treatment, and mistreatment of illness. Following HITECH's enhancements of breach notification requirements, HHS's database of major breach reports affecting 500 people or more has tracked nearly 950 incidents affecting the personal information of about 30.1 million people. OIG consistently finds gaps in adherence to security standards set by the *Health Insurance Portability and Accountability Act* and the National Institute of Standards and Technology. During our audits of hospitals and covered entities, we identified weaknesses that included inadequacies in access controls, patch management, encryption of data, and Web site security vulnerabilities. Such weaknesses could result in unauthorized access to sensitive health information.

Safeguarding EHRs From Fraud. Some of the beneficial characteristics of EHRs, including efficiency and ease of storage and access, may also make them tools for fraud. OIG work in examining fraud safeguards in EHRs found that protections designed to improve validity, accuracy, and integrity in EHRs were not being used to their full extent. Only about one-quarter of hospitals have policies regarding the use of copy-paste, a feature that could be used inappropriately to add documentation to a patient's record to support a fraudulent bill for services that were never provided. Deleting or disabling audit logs could make it harder to prevent and detect fraud. Furthermore, CMS and its program integrity contractors have done little to update their practices to address EHR vulnerabilities.

Progress in Addressing the Challenge

The Department has made great strides in developing a foundational health IT infrastructure by making inroads with EHR adoption, establishing privacy and security guidance and standards, and offering services to support health information exchanges (HIE) and interoperability. As of September 2014, 95 percent of eligible hospitals and CAHs and 92 percent of physicians and other eligible professionals have registered to participate in the EHR Incentive Programs, amounting to more than 500,000 eligible professionals, eligible hospitals, and CAHs.

With respect to oversight of the EHR Incentive Programs, CMS has audited Medicare providers who received EHR incentive payments to gauge the accuracy of, among other things, attestations that risk analyses designed to protect electronic health information were conducted. CMS also reports that it began conducting pre-payment audits in 2013. If the Department continues to takes steps to ensure that meaningful use requirements include necessary safeguards, these audits will be a helpful oversight and enforcement tool.

ONC has issued a document entitled "Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure" (10-Year Vision Paper), http://healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf, which describes future efforts to expand the sharing of information for health beyond EHRs and identifies privacy and security protections for health information as a building block for a nationwide interoperable health information infrastructure.

What Needs To Be Done

The 10-Year Vision Paper states that, "[b]y 2024, individuals, care providers, communities, and researchers should have an array of interoperable health IT products and services that allow the health care system to continuously learn and advance the goal of improved health care." The desired "learning health system" should, according to the 10-Year Vision Paper, also enable lower costs, improved population health, and other benefits. To fully realize the value of an over $24 billion investment, the Department must do more to ensure that systems are interoperable in order to realize these goals.

As the Department progresses through the development and implementation of meaningful use stages, it should continue to consider feedback from stakeholders to ensure that adopted policies advance the Nation towards the Department's stated goals, while appropriately reflecting the changing health IT landscape. Guidance and technical assistance should be issued to address adoption, meaningful use, and interoperability barriers and program integrity safeguards. It is also essential that privacy, security, and fraud prevention remain at the forefront of the Department's, ONC's, and CMS's health IT efforts.

Finally, given the magnitude of the investment in EHRs and other health IT programs, it will become increasingly important to demonstrate and measure the extent to which EHRs and health IT have actually achieved the Department's goals, which include improved health care and lower costs. Ongoing OIG work is examining the accuracy of Medicare and Medicaid EHR incentive payments for the first stage of meaningful use and attempting to determine whether Medicaid safeguards prevent improper payments. Future work may examine health IT interoperability across providers, across HHS, and between providers and patients, as well as examine outcomes from health IT investments.

Key OIG Resources

- OIG Reports on EHR Incentive Program Oversight, January 2014, http://oig.hhs.gov/oei/reports/oei-09-11-00380.pdf; August 2014, http://oig.hhs.gov/oas/reports/region6/61200041.pdf; November 2012, http://oig.hhs.gov/oei/reports/oei-05-11-00250.pdf; July 2011, http://oig.hhs.gov/oei/reports/oei-05-10-00080.pdf; December 2013, http://oig.hhs.gov/oei/reports/oei-01-11-00570.pdf

- OIG Report, *Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology*, December 2013, http://oig.hhs.gov/oei/reports/oei-01-11-00570.pdf
- OIG Report, *CMS and Its Contractors Have Adopted Few Program Integrity Practices To Address Vulnerabilities in EHRs*, January 2014, http://oig.hhs.gov/oei/reports/oei-01-11-00571.pdf
- OIG Report, *The Office of the National Coordinator for Health Information Technology's Oversight of the Testing and Certification of Electronic Health Records*, August 2014, http://oig.hhs.gov/oas/reports/region6/61100063.pdf

Management Challenge 7: Effectively Operating Public Health and Human Services Programs To Best Serve Program Beneficiaries

Why This Is a Challenge

The Department funds and operates public health and human services programs that promote health and economic and social well-being. These include, among others, programs to prevent, track, and treat acute and chronic diseases; respond to natural and man-made disasters; and protect, care for, and educate children. Many of these programs target vulnerable populations. Effective management of these programs is essential to ensure that they achieve their goals and best serve the programs' intended beneficiaries. Key challenges include (1) ensuring effective preparedness and response to current and future public health emergencies, (2) protecting the health and safety of America's vulnerable populations, and (3) ensuring access for intended beneficiaries and delivery of quality services such that beneficiaries' needs are met.

Public Health Preparedness and Emergency Response. Recent natural disasters, such as Hurricane Sandy, and disease outbreaks, such as the Ebola virus outbreak, highlight the importance of an agile public health infrastructure that can rapidly and capably respond to emergencies at home and abroad. The ability to effectively communicate and coordinate with federal, state, local, tribal, and private entities, as well as with international partners, is critical. OIG's recent review of hospitals' experiences during Hurricane Sandy revealed that the vast majority of hospitals in affected areas reported substantial challenges, including infrastructure breakdown and communication failures. The recurrence of similar problems as experienced during prior disasters highlights the need to apply knowledge gained from past experience to anticipate and prepare for new problems going forward.

The Department is also responsible for ensuring that select agents (e.g., anthrax and smallpox), which have the potential to pose a severe threat to human, animal, or plant health, are handled safely and stored securely. Earlier work by OIG identified security vulnerabilities at many Department research facilities, and recent testimony and news accounts attest to continuing problems with how these agents are inventoried and handled.

Access to and Quality of Services. To achieve program goals, the Department must ensure that qualified beneficiaries have access to high quality services. OIG work has uncovered situations in which beneficiaries could not access key services and situations in which beneficiaries received substandard services. For example, OIG found that many HRSA-funded health centers, which provide primary care for millions of patients, failed to fully adopt CDC-endorsed practices for routine HIV testing that are recommended to help combat spread of the virus. In another example, OIG found that vaccines intended for use in the Vaccines for Children (VFC) program had expired or had been improperly stored in ways that could compromise their safety or efficacy. Additional challenges arise in ensuring that children in foster care receive required health screenings.

Protecting Vulnerable Populations. OIG work has revealed potential threats to the health and safety of children served by the Child Care and Development Fund (CCDF) program of the Administration for Children and Families. CCDF provides financial assistance for child care, each month serving approximately 1.45 million children from low

income families. OIG work identified vulnerabilities in states' standards for and monitoring of child care providers and suggested efforts the Department should undertake to better serve this vulnerable population.

Since first assuming responsibility for unaccompanied children in 2003, the Office of Refugee Resettlement (ORR) has cared for more than 100,000 such children, through the end of FY 2013. This year, the number of unaccompanied children arriving in the United States without lawful immigration status has dramatically increased. In 2014, the Department estimates that the total number of such unaccompanied children will reach nearly 60,000, more than double the number from the prior year. ORR faces substantial demands in adequately caring for this influx of children in an environment of heightened public and media scrutiny.

Progress in Addressing the Challenge

The Department reports that it has made progress in improving physical security and employee training related to secure storage and safe handling of select agents; however issues related to inventory control in HHS laboratories remain.

CMS is developing more comprehensive emergency preparedness requirements for Medicare providers and suppliers. The Department is currently undertaking several initiatives, including a technical assistance center, to support collaboration among federal, state, and community entities in disaster response. Similarly, in response to OIG's recommendations, the Department has established new training materials for its grantees and providers to ensure that VFC vaccines are stored according to requirements.

What Needs To Be Done

The Department must effectively deploy its resources and expertise to combat communicable diseases, such as Ebola. The Department should continue to promote federal, state, tribal, and community collaboration in major disasters and public health exigencies. While it may not be possible to predict when and where disasters will strike, the Department should prepare for a range of potential emergency scenarios and be ready to rapidly and effectively respond. Similarly, the Department must plan for, and meaningfully assist health care providers in planning for, a range of public health emergencies. Additionally, improvements in adoption and interoperability of health IT can facilitate medical care for displaced patients or patients with communicable diseases by ensuring continuity of access to health records. (For additional discussion on issues related to the secure exchange of health care information, see Management Challenge 6.)

The Department should also fully implement OIG recommendations to ensure that HRSA-funded health centers follow CDC recommendations regarding routine HIV testing to prevent disease transmission. Improved program operation will better serve beneficiaries and help prevent future public health emergencies.

Given the recent unprecedented surge in unaccompanied children, the Department must be prepared to meet future demand for services for additional children. OIG continues to recommend that the Department establish a memorandum of understanding with the Department of Homeland Security to clearly delineate the roles and responsibilities of each Department and facilitate gathering and exchange of information regarding unaccompanied children.

The Department should also fully implement OIG recommendations regarding CCDF to ensure compliance with state requirements related to the health and safety of children, implementation of controls for determining eligibility for receiving assistance payments, and ensuring that states implement better controls for regulating and monitoring childcare providers. OIG has also recommended strengthened health and safety requirements and use of provider background checks to reduce health and safety risks to children served by the programs.

The Department will need to take swift action to significantly improve its inventory control policies and procedures for select agents in light of recent news reports identifying significant issues with inventory controls, which the Department has confirmed.

Key OIG Resources

- OIG Report, *Hospital Emergency Preparedness and Response During Superstorm Sandy*, November 2014, http://oig.hhs.gov/oei/reports/oei-06-13-00260.asp
- OIG Testimony, "The Foundation for Success: Strengthening the Child Care and Development Block Grant Program," March 25, 2014, http://oig.hhs.gov/testimony/docs/2014/jarmon-testimony-0314.pdf
- OIG Report, *HIV Testing in HRSA-Funded Health Center Sites*, November 2013, http://oig.hhs.gov/oei/reports/oei-06-10-00290.asp
- OIG Report, *Vaccines for Children: Vulnerabilities in Vaccine Management*, April 2012, http://oig.hhs.gov/oei/reports/oei-04-10-00430.asp
- OIG Report, *Division of Unaccompanied Children's Services: Efforts To Serve Children*, March 2008, http://oig.hhs.gov/oei/reports/oei-07-06-00290.pdf

Management Challenge 8: Ensuring Effective Financial and Administrative Management

Why This Is a Challenge

The Department manages health care insurance, public health, social services, and research programs designed to enhance the health, safety, and well-being of all Americans. Responsible stewardship of these programs is vital. Underpinning such stewardship should be a financial management and administrative infrastructure that employs appropriate internal controls to minimize risk to the programs and safeguard resources.

Financial statement audits. Financial statement audit results provide an important assessment of financial management challenges an agency faces. For FY 2013, independent auditor Ernst & Young identified a material weakness in the Department's financial management systems related to IT security and a significant deficiency in its financial reporting systems, analyses, and oversight. Specifically, Ernst & Young recommended that the Department bolster IT security in its financial management systems and take steps to improve internal control deficiencies that impact HHS's ability to report accurate financial information on a timely basis.

The financial statement audit also revealed challenges the Department continues to face in addressing violations of certain provisions of the *Anti-Deficiency Act*. These violations highlight weaknesses in an agency's control over budgetary resources. Prior OIG audits of National Institutes of Health contracts revealed instances of improper funding in 11 of 18 contracts reviewed. Follow-up work is underway to assess the effectiveness of the remedial actions outlined by the Department in its 2011 report of *Anti-Deficiency Act* violations.

Improper payments. Improper payments cost federal programs billions of dollars annually. For FY 2013, the Department reported improper payments totaling almost $50 billion in the Medicare program and $65 billion overall. Pursuant to the *Improper Payments Information Act of 2002* (IPIA), as amended, federal agencies are required to provide uniform, annual reporting on improper payments and their efforts to reduce them. Inspectors General are required to report annually to Congress and The President regarding agency compliance with IPIA. Although the Department met many requirements of the IPIA in FY 2013, it did not fully comply. The greatest challenges in this area are to report on all programs deemed susceptible to significant improper payments and minimize improper payments to acceptable levels. The Department has not published an improper payment estimate and other required information for the Temporary Assistance for Needy Families (TANF) program. For the Medicare fee-for-service program, the Department reported an improper payment rate that exceeded 10 percent of program outlays in FY 2013.

Administrative Oversight. Careful coordination of Departmental staff, contract staff, grantees, and other partners is essential to achieve mission objectives in accordance with federal, departmental, and agency requirements. Many grantees receive multiple awards from HHS. The discontinuation of the Department-wide Alert List in 2007 may pose challenges for awarding agencies to share concerns with one another regarding grantees' abilities to handle federal funds. Moreover, OIG found that only one of four agencies within HHS that awarded Small Business Innovation Research (SBIR) funds checked for duplicative funding within the Department, and none of the four completed a required check for duplicative awards across other federal agencies. OIG is currently evaluating the extent to which HHS programs maintain and share information about grantees vulnerable to fraud, waste, and abuse. (For more information on specific issues associated with grantee and contractor oversight and effectiveness, see Challenge 9.)

Progress in Addressing the Challenge

The Department has been taking steps to address outstanding financial management challenges. Most significantly, to help address a number of shortcomings, it has scheduled an upgrade of its accounting systems, which the Department expects to complete in 2016, to alleviate internal control deficiencies it has reported in the financial statement audits.

With respect to *Anti-Deficiency Act* violations related to systemic contract funding problems, the Department continues to provide its contracting workforce with an online reference tool for contract funding, formation, and appropriations law compliance. The Department conducts appropriations law compliance reviews of all contract actions exceeding certain thresholds, depending on the type of requirement reviewed and the awarding Operating Division (OpDiv) or Staff Division (StaffDiv). HHS has also revised its contract funding guidance to more accurately describe appropriations law and policy; these revisions incorporated best practices and lessons learned. Further, in its FY 2013 *Agency Financial Report*, the Department stated that it released a major update to its internal grants policies, featuring enhanced guidance on grants closeout, suspension and debarment, grants systems, and grants payments.

With regard to improper payments, the Head Start program had reported a consistently low improper payment rate which has been below the mandated threshold for reporting, and Office of Management and Budget (OMB) granted the Department relief from reporting annual error rate estimates in FY 2013. Further, between FY 2012 and FY 2013, the Department reduced the improper payment rate for Medicare Advantage from 11.4 percent to 9.5 percent, for Medicaid from 7.1 percent to 5.8 percent, for the Child Care and Development Fund from 9.4 percent to 5.9 percent, and for the Foster Care program from 6.2 percent to 5.3 percent.

HHS is drafting regulations to implement OMB's new Uniform Guidance: Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, commonly referred to as the Uniform Guidance. The Uniform Guidance consolidates eight federal regulations into a single guide to ease administrative burdens and strengthens oversight of federal awards to reduce the risk of fraud, waste, and abuse.

What Needs To Be Done

To ensure better financial management across all program areas, the Department should resolve weaknesses identified across all financial management systems currently in operation, as recommended by internal and external auditors. To bring the Department into full compliance with the IPIA, it should continue to reduce error rates in all programs via appropriate corrective action plans. However, full compliance would also require the Department to publish an improper payment estimate for the TANF program. To do this for TANF, the Department reports it needs legislative changes to require states to report information necessary to calculate and report improper payment estimates for TANF. The Department should actively seek such legislative changes. CMS should

work to improve its oversight of corrective action plans to ensure their relevance to contractors' error measurement.

Grant-making agencies, including HHS, are scheduled to implement OMB's new Uniform Guidance by the end of calendar year 2014. In accordance with the new guidance, the Department will need to implement robust new processes, including enhancements to processing the Single Audit reports. OIG will monitor the Department's implementation of these new processes and future reform efforts. OIG will also continue to examine existing administrative controls and grants management practices across the Department.

The Department should continue to leverage technology to further prevent improper payments and ensure responsible program stewardship. The Department should also continue to expand its education efforts for providers, grantees, staff, contractors, and other partners. Implementation of planned program integrity efforts, such as evaluating and mitigating risks, identifying and addressing cross-cutting issues, resolving reported grantee audit findings, and sharing best practices across HHS, will help the Department integrate program integrity into all aspects of its operations and culture and fortify the financial and administrative infrastructure.

Key OIG Resource

- OIG Report, *U.S. Department of Health and Human Services Met Many Requirements of the Improper Payments Information Act of 2002 but Did Not Fully Comply for Fiscal Year 2013*, April 2014, https://oig.hhs.gov/oas/reports/other/171452000.asp
- OIG Report, *Medicare Claims Administration Contractors' Error Rate Reduction Plans*, January 2014, http://oig.hhs.gov/oei/reports/oei-09-12-00090.asp

Management Challenge 9: Protecting HHS Grants and Contract Funds From Fraud, Waste, and Abuse

Why This Is a Challenge

HHS is the largest grant-making organization in the Federal Government; over 79,000 grants totaling $389 billion were awarded in FY 2014. That amount comprised $47 billion in discretionary awards and the remaining amount in formula/block grant and entitlement awards.

HHS is also the third largest contracting agency in the Federal Government. In FY 2013, HHS awarded over $20 billion in contracts across all program areas. The Government Accountability Office (GAO) and OIG both have identified weaknesses in HHS contracting processes and contract management throughout the Department. Oversight is a particular concern. An OIG audit of CDC contracts revealed poor execution of required contractor performance assessments by HHS. A recent GAO report, http://www.gao.gov/products/GAO-14-694, identified ineffective contract planning and management as one cause of the problematic rollout of HealthCare.gov. In addition, recent OIG work identified the large number of contractors responsible for aspects of the federal Marketplace and requiring appropriate oversight and management. Under the *Affordable Care Act*, contractors have a vital role in building, maintaining, and fixing the systems that underpin the federal Marketplace. HHS faces a challenge to ensure proper management and oversight of these and other contracts. (See Management Challenge 1 for more information on management and oversight of the Marketplaces.)

The size and scope of departmental awards make vigilant oversight by the Department crucial to the success of programs designed to improve the health and well-being of the public. Yet OIG has noted weaknesses in the oversight of grantees, as demonstrated by late or absent financial and related reports, insufficient documentation on progress toward meeting program goals, and failure to ensure that grantees obtain required annual financial audits.

A common problem uncovered by our reviews at the grantee level is that grantees have lacked robust financial management systems. Many grantees still do not account for specific costs on a grant-by-grant basis, making it difficult to reliably monitor and account for costs associated with specific grant awards. When combined with frequent findings of significant unallowable expenses, these conditions support the need for more purposeful and consistent oversight.

HHS is the second largest payer under the SBIR and Small Business Technology Transfer (STTR) programs. HHS awarded $13 million in SBIR contracts and $463,000 in STTR contracts in FY 2013. OIG has noted two significant issues with the programs: inconsistent collection of information needed to evaluate commercial success and failures to check for duplicative funding within the Department and across other agencies. (See Management Challenge 8 for more information on administrative oversight of HHS grants and contracts.)

Progress in Addressing the Challenge

HHS has strengthened its program integrity efforts by working with OpDivs and StaffDivs to implement a uniform risk management approach that encompasses developing strategies, plans, and metrics. The Department has established a Program Integrity Coordinating Council, which identifies common program challenges and explores solutions.

The Department has sponsored training for HHS grant and contracting officials to aid them in identifying potential fraud, waste, and abuse, including encouraging contractors to self-report contract fraud and overpayments. Training has also taken place on best practices for investigating fraud in HHS grants and contracts.

The Department has made progress in its Suspension and Debarment program by conducting training, finalizing the HHS Suspension and Debarment Guidance and accompanying Desk Reference, creating a Department-wide referral tracking system, and working with the Office of the General Counsel to streamline the referral review process. The total number of suspension and debarment referrals according to the Office of Recipient Integrity Coordination (ORIC) has increased from 22 in FY 2012 to 42 in FY 2013, and the total number of actions taken by the Suspension and Debarment Officer (SDO) has increased from 0 suspensions or debarments in FY 2012 to 8 debarments and 8 suspensions in FY 2013. The Department is on track to increase the number of suspensions and debarments in FY 2014.

What Needs To Be Done

Sustained focus by the Department is needed to address vulnerabilities in its grant programs and contract administration. For instance, although the Department designed internal controls with features specified by OMB Memorandum M-13-07, this effort must be followed by diligent monitoring to ensure that qualified individuals have access to grants and that recipients use the funds according to the award terms and in a manner consistent with the *Disaster Relief Appropriations Act of 2013*.

HHS could improve federal contracting by aligning more closely with the Office of Federal Procurement Policy (OFPP) strategy of improving contractor source selection decisions. A key part of OFPP's strategy is contractor performance monitoring. HHS has improved its rate of monitoring from 10 percent to 24 percent in the last two years. However, according to a recent GAO report, http://www.gao.gov/products/GAO-14-707, that rate is less than half the FY 2014 government-wide rate of 49 percent.

OpDivs must be vigilant in monitoring grant resources and take appropriate actions, including: implementing planned program integrity efforts, such as evaluating and mitigating risks and identifying and addressing cross-cutting issues; resolving grantee audit findings; and sharing best practices across the Department to better position HHS to integrate program integrity into all aspects of its operations and culture.

Training on identifying and pursuing misconduct in HHS grants and contracts should continue. HHS contract and grant officers should more actively coordinate with, and refer potential grant and contract fraud to, OIG for investigation. The Department needs to implement a program to actively pursue fraud under the *Program Fraud Civil Remedies Act* (PFCRA). The Department also needs to continue to refine its suspension and debarment procedures by further streamlining the referral and decision process, continuing to provide training and decreasing the processing time of referrals. Although HHS has begun to take suspension and debarment actions largely in response to conviction-based actions, OpDivs, StaffDivs, OIG, and the SDO need to make effective use of fact-based debarments and suspensions.

Key OIG Resources

- OIG Hurricane Sandy Grants and Contracts Training Videos, http://oig.hhs.gov/newsroom/podcasts/2014/sandy/
- OIG Report, *The Department of Health and Human Services Designed Its Internal Controls Over Hurricane Sandy Disaster Relief To Include Elements Specified by the Office of Management and Budget*, July 2014, http://oig.hhs.gov/oas/reports/region2/21302010.asp
- OIG Report, *Vulnerabilities in the HHS Small Business Innovation Research Program*, April 2014, http://oig.hhs.gov/oei/reports/oei-04-11-00530.asp

Management Challenge 10: Ensuring the Safety of Food, Drugs, and Medical Devices

Why This Is a Challenge

The Department, through the Food and Drug Administration (FDA), is responsible for protecting public health by ensuring the safety, efficacy, and security of drugs, medical devices, biologics, dietary supplements, tobacco, and much of our Nation's food supply. The Department must ensure that once a drug, biologic, or device has been approved for use, it conducts effective post-market monitoring. During a food emergency, the Department is responsible for finding the contamination source and overseeing the removal of these products from the market. However, OIG work has revealed weaknesses in FDA's ability to adequately oversee the safety of drugs, biologics, medical devices, and food. It has also revealed failures by industry participants to follow processes designed to ensure the safety and efficacy of food, drugs, biologics, and medical devices. These high risk areas include:

Drug Compounding. A fall 2012 nationwide fungal meningitis outbreak associated with contaminated compounded sterile drug injections raised major concerns about the quality of drugs supplied by compounders and FDA's ability to effectively oversee these entities. OIG reviewed hospitals' use of compounded drugs and found that in 2012, 92 percent of hospitals used compounded sterile preparations (CSPs). Additionally, we found that 56 percent of hospitals made changes or planned to make changes to CSP sourcing practices in response to the 2012 outbreak. After the meningitis outbreak, in November 2013, President Obama signed the *Drug Quality and Security Act* (DQSA), Public Law 113-54. Among other things, the DQSA added a new section to the *Federal Food, Drug, and Cosmetic Act*, section 503B, that provides a new pathway for entities called "outsourcing facilities" to legally compound human drugs. FDA also continues to identify serious deviations from acceptable practices for the production of compounded sterile drugs, as evidenced by the lists of inspectional observations issued to compounders at the conclusion of FDA inspections; the numerous recalls of compounded drugs because of contamination or lack of sterility assurance; and the warning letters issued to compounders addressing, in part, unsanitary conditions at their facilities. Implementation of the DQSA poses new challenges for the Department.

Imported Drugs. Medications imported from foreign or unlicensed suppliers may be unapproved by FDA and may be ineligible for reimbursement by Medicare, Medicaid, and other federal health care programs. Such drugs may also be counterfeit, contaminated, ineffective, and/or unsafe. FDA's Office of Criminal Investigations (OCI), OIG, and our law enforcement partners have investigated many instances in which physician practices, drug

distributors, and suppliers have imported such drugs. Among other consequences, importation of such drugs can lead to patient safety issues, the submission of improper claims to federal health care programs, and the circumvention of FDA drug approval and facility inspection processes.

Food Safety. Protecting the American public from food-borne illness, such as those caused by salmonella and E. coli, is an ongoing challenge. In the past, OIG has found that food facilities' failures to comply with FDA's requirements impede the Department's ability to ensure the safety of the Nation's food supply. Since September 2009, FDA has required food facilities to report to a new registry all instances when there is a reasonable probability that a food might cause serious adverse health consequences and to investigate the causes of any adulteration reported if the adulteration may have originated with the food facility. The *Food Safety Modernization Act* (FSMA), signed into law in January 2011, provides FDA important authorities to better protect the Nation's food supply. However, implementing these authorities could prove difficult given the broad preventive controls framework envisioned in FSAM, including establishing the new import oversight program and the training needed to ready both FDA and the states to conduct preventive control inspections.

Marketing Requirements. Manufacturers of drugs, biologics, and medical devices gain approval for sale of their products for specific uses once FDA determines that the products are safe and effective for those uses. Once approved for sale, qualified medical providers may prescribe them for any use on the basis of their medical judgment. However, manufacturers are prohibited from promoting products for uses for which FDA has not specifically approved them (known as off-label uses). OIG, in conjunction with its law enforcement partners, including FDA's OCI, has investigated many instances in which manufacturers illegally promoted products for off-label uses. Off-label promotion can undermine the system intended to ensure that drugs are safe and effective and can put patients at risk. Additionally, this illegal off-label promotion may lead to fraudulent claims for payment submitted to federal health care programs, including Medicare and Medicaid. (See Management Challenge 2 for more information on drug diversion and appropriate use of prescription drugs in Medicare and Medicaid.)

FDA faces ongoing concerns regarding dietary supplements and the structure/function claims made by manufacturers. Structure/function claims describe the role of a dietary supplement in the structure and function of human bodies, but the claims may not explicitly or implicitly claim to prevent, treat, mitigate, cure, or diagnose a disease. Manufacturers must have competent and reliable scientific evidence to show that dietary supplement claims are truthful and not misleading, but they do not have to submit the substantiation to FDA, and FDA has only voluntary standards for it. OIG found that substantiation documents for the supplements reviewed were inconsistent with FDA guidance on competent and reliable scientific evidence. OIG also found that FDA could not readily determine whether manufacturers had submitted the required notification for their claims. These results raise questions about the extent to which structure/function claims are truthful and not misleading.

Progress in Addressing the Challenge

To address risks associated with imported drugs, FDA has engaged in both outreach and enforcement actions. FDA has undertaken significant efforts to warn consumers, medical practitioners, and others about the risks associated with buying drugs from foreign sources. In addition, FDA has continued to work with OIG and other law enforcement partners to investigate and prosecute individuals and businesses (e.g., physicians and drug suppliers) that import unapproved drugs. In July 2013, three physicians previously associated with McLeod Cancer and Blood Center entered into civil settlement agreements and agreed to pay more than $4.25 million to resolve allegations that they purchased misbranded, unapproved chemotherapy drugs from foreign sources; used the drugs to treat their Medicare, Medicaid, and other patients; and billed federal health care programs for the drugs. Dr. William Kincaid, the managing partner, pled guilty to receiving misbranded drugs with intent to defraud and mislead. Dr.

Kincaid was sentenced to 2 years in prison and was excluded from participating in federal health care programs for 10 years.

With regard to drug compounding, FDA increased inspection and enforcement efforts, while developing the regulatory framework to implement the DQSA. In FY 2014, FDA conducted over 85 inspections of compounding pharmacies and outsourcing facilities and issued 29 warning letters. FDA's inspection and enforcement efforts are continuing. In addition, since the DQSA was enacted in November, 2013, FDA issued numerous policy documents to implement both section 503A (concerning pharmacy compounding) as well as the new section 503B (concerning outsourcing facilities) and continues to work on additional rules and guidance. FDA has made progress in addressing OIG recommendations. For example, as a result of OIG's identifying vulnerabilities in FDA's oversight of regulatory decisions, FDA implemented new operating procedures for resolving scientific disagreements. In response to OIG recommendations regarding oversight of dietary supplements, FDA stated that it is considering whether to seek explicit statutory authority to review substantiation for structure/function claims beyond its pre-existing authorities.

What Needs To Be Done

The Department and FDA will need to continue issuing rules and guidance documents to fully implement the various provisions in the July 2012 *Food and Drug Administration Safety and Innovation Act* (FDASIA) and in DQSA. FDA will need to continue to conduct inspections of compounding pharmacies and pursue regulatory action, as needed to protect public health, when deficiencies are identified. In addition, FDA will need to continue its efforts to fully implement FSMA to better protect the Nation's food supply. FSMA addresses many of OIG's recommendations; however, we continue to recommend that FDA remedy identified weaknesses in its inspections and recall procedures. FDA should also ensure that states properly conduct contracted food facility inspections. The Department also needs to continue its efforts to eliminate off-label promotion and reduce the importation of unapproved drugs from foreign sources to protect patients and HHS health care programs. Moreover, the Department and FDA will need to continue implementing the provisions under the 2009 *Family Smoking Prevention and Tobacco Control Act* to protect public health.

Key OIG Resources

- OIG Report, *High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them*, April 2013, https://oig.hhs.gov/oei/reports/oei-01-13-00150.asp
- OIG Report, *Dietary Supplements: Structure/Function Claims Fail To Meet Federal Requirements*, October 2012, http://oig.hhs.gov/oei/reports/oei-01-11-00210.asp
- OIG Report, *Vulnerabilities in FDA's Oversight of State Food Facility Inspections*, December 2011, http://oig.hhs.gov/oei/reports/oei-02-09-00430.asp
- DOJ press release, sentencing of William Kincaid, M.D., June 11, 2013, http://www.justice.gov/usao/tne/news/2013/June/061113%20Kincaid%20Sentencing%20Misbranded%20Drugs.html#top