

## OIG'S FY 2015 TOP MANAGEMENT AND PERFORMANCE CHALLENGES FACING THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Management Challenge 1: 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 expenditures and beneficiaries served continue to grow. As of September 2015, 29 states and the District of Columbia are expanding Medicaid eligibility to include a larger group of qualifying adults pursuant to the Patient Protection and Affordable Care Act (*Affordable Care Act*) and Medicaid waivers. Further, states that have not expanded eligibility have also seen increases in Medicaid enrollment. Taking into account the obstacles associated with expanding eligibility, along with long-standing program integrity issues, Medicaid continues to be a top management challenge for the Department of Health and Human Services (Department or HHS).

**Expansion of Medicaid Eligibility.** As of August 2015, the Centers for Medicare & Medicaid Services (CMS) reported that enrollment in Medicaid and the Children's Health Insurance Program (CHIP) had increased by 13.6 million people since *Affordable Care Act*-expanded eligibility criteria went into effect in October 2013. To ensure effective management of the expanding program, updating eligibility systems to ensure appropriate eligibility determinations and applicable Federal Medical Assistance Percentage (FMAP) is imperative. A main source of Medicaid's 6.7 percent improper payment rate (as reported in fiscal year (FY) 2014) is attributed to payments made on behalf of ineligible individuals. (For more information on improper payments, see [Management Challenge 4](#).) For example, eligibility errors occur when beneficiaries lose eligibility status because they are no longer residents of the state and/or failed to report a change in circumstances but remain enrolled in a state's Medicaid program. The Public Assistance Reporting Information System (PARIS) Medicaid Interstate Match program was designed to reduce these errors by identifying beneficiaries who are enrolled in multiple state Medicaid programs, but state participation in the match is limited and its effectiveness in reducing improper payments is inconsistent.

**Improving Oversight of Medicaid Managed Care.** As of 2011, approximately 75 percent of Medicaid beneficiaries nationwide are enrolled in managed care. To be effective, oversight must include robust program integrity measures, have and use accurate and timely data, and ensure that beneficiaries have sufficient access to services. In a December 2011 report, the Office of Inspector General (OIG) found that the predominant program integrity concerns of both states and plans are provider fraud – billing for services that were not provided, were medically unnecessary, or upcoded – and beneficiary fraud – including prescription drug abuse. Fraud or abuse by managed care plans themselves, such as manipulating bids to increase reimbursement, also pose program integrity challenges. States are required to collect and submit encounter data that document the managed care services that beneficiaries receive, but some states do not submit any data and others do not submit all of the required data elements. As a result, CMS does not have the data necessary to identify and address possible fraud, waste, and abuse. Further, OIG has identified issues that may impede beneficiaries'

access to care, including limited appointment availability and varying state standards for access (e.g., states range from requiring one primary care provider for every 100 to 2,500 enrollees.).

**Improving the Effectiveness of Medicaid Data and Systems.** A functional, national Medicaid database is essential to effective oversight. However, national Medicaid data are not complete, accurate, or timely, and additional data are needed to enhance national program integrity activities. CMS still faces challenges in its attempts to improve the availability and quality of Medicaid data. Limited implementation by states has hindered CMS's Transformed Medicaid Statistical Information System (T-MSIS) initiative, which is CMS's key effort to modernize and enhance the usefulness of state Medicaid data. Other CMS attempts to improve data sharing between states have not been fully successful. For example, CMS established a data-sharing system to implement the *Affordable Care Act* requirement that providers terminated for cause (i.e., for reasons of fraud, integrity, or quality) in one state Medicaid program, CHIP, or that have had their Medicare billing privileges revoked are terminated by all other state Medicaid programs. However, data within that system was often incomplete and did not provide useful information to states in order to carry out the *Affordable Care Act* requirement for terminating providers. OIG work found 12 percent of providers terminated for cause in one state Medicaid program in 2011 were still participating in other states' Medicaid programs as of January 2014. (For more information on data systems and information, see [Management Challenge 3](#).)

**State Policies That Inflate Federal Costs.** Long-standing concerns exist about states' Medicaid policies that result in the federal government paying a greater share of Medicaid costs than the FMAP percentages dictate. Misalignment of costs and payments at certain state-operated facilities can inflate federal costs. For example, New York Medicaid payments to state-run developmental centers were inflated by more than \$1 billion in 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. Additionally, the lack of transparency related to state waiver programs present challenges to ensure that payments are consistent with efficiency, economy, and quality of care, and do not improperly inflate federal costs. The Government Accountability Office (GAO) has found that CMS's approval process for section 1115 waivers may increase federal costs, in part, because it is not clear how CMS determines whether a waiver is budget neutral.<sup>1</sup>

**Ensuring Quality Care for Medicaid Beneficiaries.** OIG work has demonstrated that children enrolled in Medicaid do not receive all required preventive screenings and has identified quality-of-care concerns regarding children's treatment with antipsychotic drugs. Some of the quality-of-care concerns included poor monitoring of the children's treatment with drugs, children being prescribed the wrong treatment, and children taking too many drugs. Furthermore, OIG has identified significant and persistent vulnerabilities related to Medicaid personal care services, which often includes ineffective program safeguards intended to ensure medical necessity, patient safety, and quality. (For more information on ensuring quality in nursing home, hospice, and home-and community-based care, [see Management Challenge 6](#)).

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<sup>1</sup> GAO, [Medicaid Demonstrations: More Transparency and Accountability for Approved Spending are Needed](#), June 24, 2015 (<http://www.gao.gov/products/GAO-15-715T>)

## Progress in Addressing the Challenge

CMS is working to promote Medicaid expansion program integrity by providing technical assistance to the states, developing new procedures on eligibility determination and payment accuracy, and training state staff on reporting and accounting for expenditures of newly eligible individuals. For FYs 2014-2017, CMS required each state to implement an annual 50-State Medicaid and CHIP Eligibility Review Pilot program strategy.

If implemented, CMS's June 2015 Notice of Proposed Rulemaking (NPRM), which revises its Medicaid managed care regulations, may address several identified issues, including requirements for providers participating in Medicaid managed care to enroll in Medicaid, new standards for beneficiary access, more timely, complete and accurate submission of managed care encounter data to states, and increased safeguards against fraud, waste, and abuse. CMS also reports that it has updated its guidance on program integrity in Medicaid managed care.

CMS reports that it continues to improve its data and technology capabilities. In May 2015, CMS implemented T-MSIS with the first state. CMS reports that states are fully engaged in the transition from the Medicaid Statistical Information System (MSIS) to T-MSIS, which includes a CMS-led process to test implementation to address data gaps and other issues. However, CMS has not indicated when all states will be submitting T-MSIS data. CMS has also issued a NPRM to permit partial disallowance or deferral of Medicaid Management Information System (MMIS) expenditures if a state fails to produce all federally required program management data and information, including T-MSIS.

In response to the *Affordable Care Act* requirement regarding provider terminations, CMS reported that it implemented a new Medicaid provider termination notification system (TIBCO) in 2014. Under this new system, CMS reports that it is verifying state-submitted provider termination data before the data is made available to other states through TIBCO.

CMS is continuing to work with states to curb policies that inflate federal costs. CMS has approved a State Plan Amendment and entered into a \$1.9 billion settlement with New York for the state to repay amounts associated with inflated costs for state-run developmental centers and other related costs. Finally, CMS issued a letter to state health officials on the treatment of health care-related taxes and their effect on federal matching funding.

In response to OIG's work, CMS reported that it plans to work with states to monitor the use of antipsychotic drugs, implement additional quality measures related to treatment of children with antipsychotic drugs, and encourage states to request their managed care programs to address quality-of-care concerns by conducting periodic reviews of medical records of children treated with antipsychotic drugs. CMS also reported that it has disseminated two strategy guides on required preventive screenings to states and providers, began developing a quality measure specific to vision screenings, held listening sessions with states, and provided training related to federal Early and Periodic Screening, Diagnosis, and Treatment (EPSDT). CMS reported that it performed state-specific program integrity reviews, one of which focused on curbing fraud and abuse in personal care services.

## What Needs To Be Done

CMS should continue to develop robust oversight for the Medicaid expansion. CMS must be vigilant in addressing program integrity risks associated with Medicaid 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. OIG is conducting work regarding CMS's and states' progress in implementing T-MSIS.

CMS should continue to improve the data available for states to terminate providers terminated from another state Medicaid agency, CHIP, or Medicare by implementing a mandatory state reporting requirement of all for cause provider terminations. Required reporting is a crucial part of creating a comprehensive data source and effective oversight.

CMS should strengthen its oversight of state Medicaid waivers, including monitoring the costs of such waivers, and ensure that any oversight actions taken are publicly reported.

CMS should continue to promote awareness of safe treatment and best practices for treating children with antipsychotic drugs and consider ways that states could implement periodic reviews of medical records of children who receive antipsychotic drugs. CMS should also continue its efforts to improve delivery of preventive screenings for children, particularly on required reporting of vision and hearing screenings.

## Key OIG Resources

- OIG Testimony, [Examining the Federal Government's Failure to Curb Wasteful State Medicaid Financing Schemes](http://oversight.house.gov/wp-content/uploads/2014/07/Hagg-HHS-OIG-Final.pdf), July 2014 (<http://oversight.house.gov/wp-content/uploads/2014/07/Hagg-HHS-OIG-Final.pdf>)
- OIG Report, [CMS's Process for Sharing Information About Terminated Providers Needs Improvement](http://oig.hhs.gov/oei/reports/oei-06-12-00031.pdf), March 2014 (<http://oig.hhs.gov/oei/reports/oei-06-12-00031.pdf>)
- OIG Reports on Medicaid data and systems, [OEI-09-11-00780](http://oig.hhs.gov/oei/reports/oei-09-11-00780.pdf) (<http://oig.hhs.gov/oei/reports/oei-09-11-00780.pdf>), [OEI-05-12-00610](http://oig.hhs.gov/oei/reports/oei-05-12-00610.pdf) (<http://oig.hhs.gov/oei/reports/oei-05-12-00610.pdf>)
- OIG Reports on Medicaid managed care, [OEI-01-09-00550](http://oig.hhs.gov/oei/reports/oei-01-09-00550.pdf) (<http://oig.hhs.gov/oei/reports/oei-01-09-00550.pdf>), [OEI-02-11-00320](http://oig.hhs.gov/oei/reports/oei-02-11-00320.pdf) (<http://oig.hhs.gov/oei/reports/oei-02-11-00320.pdf>)
- OIG Reports on Medicaid quality of care, [OEI-05-13-00690](http://oig.hhs.gov/oei/reports/oei-05-13-00690.pdf) (<http://oig.hhs.gov/oei/reports/oei-05-13-00690.pdf>), [OEI-07-12-00320](http://oig.hhs.gov/oei/reports/oei-07-12-00320.pdf) (<http://oig.hhs.gov/oei/reports/oei-07-12-00320.pdf>)

## Management Challenge 2: Fighting Fraud, Waste, and Abuse 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 on unnecessary services, excessive administrative costs, fraud, and other problems.<sup>2</sup> Waste in health care programs is a multidimensional problem. HHS faces challenges—and opportunities—in each of the key areas of focus addressed below.

**Reducing Improper Payments.** CMS reported an improper payment rate of 12.7 percent for Medicare fee for service (Parts A and B), corresponding to an estimated \$45.8 billion in improper payments in FY 2014. 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. (For more information on improper payment rate measurement and reporting, see [Management Challenge 4.](#))

Challenges affect every stage of the payment process, from making the initial payment accurately (including implementing appropriate payment edits) to recovering overpayments. High Medicare improper payment rates exist for various services, including home health, skilled nursing, and evaluation and management services. Audits of hospitals have uncovered and sought to remedy improper billing and payments for myriad issues, such as incorrect billing for transfers to post-acute care and inaccurate patient diagnosis codes. Furthermore, accurate billing by hospitals for short inpatient stays versus outpatient observation stays has been an area of considerable challenge and concern. CMS relies on contractors for most of these crucial functions; however, OIG has identified deficiencies in contractor performance and in CMS's oversight of these contractors. Medicare's recent transition to a new system of diagnosis codes, the ICD-10, may bring implementation challenges and potential increases in improper billing as providers and suppliers transition to the new codes. In the lead-up to implementation of ICD-10, CMS has issued [guidance](#) providing temporary flexibility in the claims auditing and quality reporting process in response to requests from the provider community. (<https://www.cms.gov/Medicare/Coding/ICD10/Downloads/ICD-10-guidance.pdf>)

The Department is facing significant challenges in adjudicating provider appeals of Medicare overpayments – which primarily include Parts A and B claims – including a substantial backlog of appeals at the administrative law judge (ALJ) level (third level of appeals, administered by the Office of Medicare Hearings and Appeals); inconsistent decisions among the ALJs and between the ALJs and Qualified Independent Contractors (second level of appeals, administered by CMS); and insufficient CMS participation in the appellate process.

**Preventing and Deterring 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. They include services provided by durable medical equipment (DME) suppliers, home health and hospice agencies, community mental health centers, clinical laboratories, ambulance transportation suppliers, outpatient therapy providers, and chiropractors. CMS's contractors play a key role in fighting Medicare fraud. However, CMS is not realizing the full potential of contractors to proactively identify fraud and address other program integrity concerns.

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<sup>2</sup> Institute of Medicine, [Best Care at Lower Cost: The Path to Continuously Learning Health Care in America](#), September 6, 2012. The Institute of Medicine report includes fraud and abuse as components of waste. (<http://iom.nationalacademies.org/Reports/2012/Best-Care-at-Lower-Cost-The-Path-to-Continuously-Learning-Health-Care-in-America.aspx>)

**Fostering Economical Payment Policies.** As a result of certain payment policies, 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). For low-risk patients who do not need hospital-level care at an outpatient hospital department, Medicare could save billions of dollars by paying for those services at ASC rates. In another example, Medicare could reduce expenditures by millions of dollars per year if infusion drugs administered in conjunction with DME were paid on the basis of average sales prices, as is the case with most other drugs covered by Medicare Part B.

Certain payment policies that create incentives for providers to bill for more expensive care instead of the appropriate levels of care result in billions of dollars in wasteful spending and compromised care for beneficiaries. For example, Medicare's payment policy for skilled nursing facility (SNF) beneficiaries who also need therapy give providers incentive to bill for higher levels of therapy than necessary.

### Progress in Addressing the Challenge

Overall, the Department has taken steps, including implementing many of OIG's recommendations, to combat Medicare waste, including fraud, resulting in cost savings, improved program operations, and enhanced protections for beneficiaries. 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 \$7.70 for every \$1 invested. In FY 2014, OIG audits and investigations resulted in expected recoveries of \$4.9 billion in improperly spent federal health care dollars. In addition, OIG reported estimated savings of more than \$15 billion from legislative, regulatory, and administrative actions supported by OIG recommendations.

CMS has moved to improve the integrity and accuracy of billing for numerous types of services. For example, CMS implemented 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. CMS modified this requirement, effective January 1, 2015, and is continuing to work to improve this requirement's low rates of compliance. Additionally, CMS started a demonstration project that requires prior authorization for scooters and power wheelchairs in seven states with high incidences of fraud and improper payments, and in FY 2015 expanded this demonstration project to include an additional 12 states. CMS continues to work to address hospital billing for short inpatient stays and outpatient observation stays, which significantly affects Medicare spending, beneficiary cost-sharing, and hospital revenue.

CMS reports that it is working to identify potential alternatives to the existing methodology used to pay for therapy services under the SNF Prospective Payment System (PPS). CMS initiated the SNF PPS Payment Model Research project and reports that it is working to identify potential alternative SNF payment models for further analysis.

In connection with the International Classification of Diseases, 10th Revision (ICD-10), CMS reports that it has established an ICD-10 Coordination Center for monitoring the implementation of ICD-10, identifying and triaging issues for resolution, and responding to inquiries. It also has named an ICD-10 ombudsman to help receive and deal with provider issues.

OIG noted reductions in Medicare billing and payments for certain services and geographic areas known for fraud risks. For example, following 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 also instituted temporary moratoria on the enrollment of new home health agencies and ambulance transportation suppliers in select cities and known fraud hot spots. Additionally, CMS continues to develop its Fraud Prevention System (FPS), which had a \$133 million in adjusted actual and projected savings in its third implementation year, and represented a positive return on investment of \$2.84 for every \$1 spent that was [certified by OIG](http://oig.hhs.gov/oas/reports/region1/11400503.pdf). (<http://oig.hhs.gov/oas/reports/region1/11400503.pdf>)

CMS reported improvements in 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 reports that it has taken steps toward this goal.

### What Needs To Be Done

Despite progress in key areas, more needs to be done to protect Medicare from waste, including fraud. CMS needs to better ensure that Medicare payments are accurate and appropriate. 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 appeals efficiently, effectively, and fairly. OIG has recommended numerous actions to advance these outcomes.

### Key OIG Resources

- OIG Testimony, [Fraud in Medicare](http://oig.hhs.gov/testimony/docs/2015/cantrell-032415.pdf), March 2015 (<http://oig.hhs.gov/testimony/docs/2015/cantrell-032415.pdf>)
- OIG Testimony, [Medicare Program Integrity: Screening Out Errors, Fraud, and Abuse](http://oig.hhs.gov/testimony/docs/2014/cantrell_testimony_06252014.pdf), June 2014 ([http://oig.hhs.gov/testimony/docs/2014/cantrell\\_testimony\\_06252014.pdf](http://oig.hhs.gov/testimony/docs/2014/cantrell_testimony_06252014.pdf))
- OIG Testimony, [Medicare Mismanagement: Oversight of the Federal Government Efforts to Recapture Misspent Funds](http://oig.hhs.gov/testimony/docs/2014/Ritchie_testimony_05202014.pdf), May 2014 ([http://oig.hhs.gov/testimony/docs/2014/Ritchie\\_testimony\\_05202014.pdf](http://oig.hhs.gov/testimony/docs/2014/Ritchie_testimony_05202014.pdf))
- [OIG Compendium of Unimplemented Recommendations](http://oig.hhs.gov/testimony/docs/2014/Ritchie_testimony_05202014.pdf), March 2015 ([http://oig.hhs.gov/testimony/docs/2014/Ritchie\\_testimony\\_05202014.pdf](http://oig.hhs.gov/testimony/docs/2014/Ritchie_testimony_05202014.pdf))
- OIG Report, [The Medicare Payment System for Skilled Nursing Facilities Needs To Be Reevaluated](http://www.oig.hhs.gov/oei/reports/oei-02-13-00610.pdf), September 2015 (<http://www.oig.hhs.gov/oei/reports/oei-02-13-00610.pdf>)

## Management Challenge 3: The Meaningful and Secure Exchange and Use of Electronic Information and Health Information Technology

### Why This Is a Challenge

In support of its mission and operations, the Department maintains and uses expanding amounts of sensitive information. Complete, accurate, and timely data can help ensure efficient operations of the

Department and its programs, as well as support proactive program oversight. Similarly, 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. However, the Department faces a number of significant challenges in this information-rich environment.

***Ensuring Privacy and Security of Information.*** Safeguarding privacy and ensuring data security are, and should remain, top priorities for the Department. The Department must ensure that the data it creates and maintains are protected. Equally important is the need to ensure appropriate protection of health information when considering and implementing policies related to the adoption of health IT, and the exchange, storage, and use of electronic health information. The frequency of notable data breaches has increased significantly, and data breaches can have serious consequences for the health care industry, the Department, and those the Department serves. Those consequences can include identity theft, which, in the health care context, can negatively affect the care that patients receive and lead to wasteful, including fraudulent, spending of public funds. Frequently identified weaknesses include inadequacies in access controls, patch management, encryption of data, and Web site security vulnerabilities at the Department, health care providers, and other entities that do business with the Department. Such weaknesses could result in unauthorized access to sensitive information.

***Improving Information Flow.*** To make use of the benefits of the growing amounts of data in the health care context,<sup>3</sup> data must be available, subject to appropriate privacy and security safeguards, where and when needed. However, enabling and encouraging the flow of information remains a challenge for the Department. Several factors may impede the flow of information. These include technical barriers (e.g., lack of interoperability), the complex nature of federal and state privacy and security laws, financial considerations (e.g., the cost of health IT acquisition), and behavioral issues—such as information blocking<sup>4</sup> and consumer confidence—that relate to a willingness to share information.

Improving the appropriate flow of health information is critical to the success of many delivery reform and other initiatives, including the [President's Precision Medicine Initiative](https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative) (<https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative>) Without appropriate information sharing, those who participate in the initiatives may face challenges in coordinating care and meeting performance and other goals. Impediments to information sharing can also present patient safety concerns. For example, a patient could be subjected to additional invasive testing that could have been avoided had information about prior results held by a different provider been shared. (For more information on health delivery reforms, see [Management Challenge 8](#).)

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<sup>3</sup> Sources of relevant health care data are ever increasing, particularly as the Internet of Things continues to expand. For more information about the Internet of Things, particularly related privacy and security issues, see FTC's Staff Report, *Internet of Things: Privacy and Security in a Connected World*, January 2015. (<https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-staff-report-november-2013-workshop-entitled-internet-things-privacy/150127iotrpt.pdf>) See also, Federal Bureau of Investigation Public Services Announcement, *Internet of Things Poses Opportunities for Cyber Crime*, September 10, 2015. (<http://www.ic3.gov/media/2015/150910.aspx>)

<sup>4</sup> For more information on the topic of information blocking, see ONC's Report to Congress, *Report on Health Information Blocking*, April 2015 ([https://www.healthit.gov/sites/default/files/reports/info\\_blocking\\_040915.pdf](https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf))

The flow of information is also important between the Department and others, including providers. For example, 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 certain initiatives also receive Departmental data for their use in improving the care they furnish. Additionally, the Department increasingly uses and shares data as part of its program operations and program integrity efforts. It is critical that, as the flow of information improves, the information is complete, accurate, timely, and appropriately protected.

***Ensuring a Return on Health IT Investments.*** The Department has made significant investments in health IT. However, the Department faces challenges in ensuring that the goals associated with investing in the widespread adoption and use of EHRs and other health IT are fulfilled. In addition to the challenge of improving the flow of information, challenges to ensuring a return on the Department's investments in health IT include preventing inappropriate payments to participants who do not meet program requirements; ensuring that the beneficial characteristics of EHRs, including efficiency and ease of storage and access, are not used as tools for fraud; and ensuring that patient safety benefits are realized. When addressing these challenges, the Department must ensure coordination among internal agencies, as well as other federal partners, with overlapping responsibility for various aspects of health IT to avoid potential gaps in policy and oversight that could undermine the promise of the investments.

### **Progress in Addressing the Challenge**

The Department has made progress with respect to privacy and security of its systems and information. Like others in the federal government, the Department has participated in the U.S. Chief Information Officer's [30-day Cybersecurity Sprint](#), which aims to "further improve federal cybersecurity and protect systems against . . . evolving threats."

([https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/fact\\_sheets/enhancing-strengthening-federal-government-cybersecurity.pdf](https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/fact_sheets/enhancing-strengthening-federal-government-cybersecurity.pdf))

The Department has made great strides in developing a nationwide health IT infrastructure that supports the appropriate flow of information. As of September 2015, more than 548,000 eligible professionals, eligible hospitals, and critical access hospitals (CAH), are actively registered in the EHR incentive programs.<sup>5</sup> Additionally, the Office of the National Coordinator (ONC) recently issued \$38 million in grants to encourage better information exchange for care coordination and population health.

Further, the Department's participation in the Healthcare Fraud Prevention Partnership (HFPP) has improved the flow of information to address program integrity issues. The HFPP, a public-private partnership, brings interested parties—including private insurers, law enforcement agencies, and others—together to share and use data and analytic tools to proactively address health care fraud.

The Department has continued to oversee the EHR incentive programs and has made a concerted effort to advance the national conversation about important health IT issues to ensure that the potential benefits of health IT investments are realized. Last year, ONC issued a document entitled "[Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure](#)" (<http://healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf>) (10-Year Vision

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<sup>5</sup> CMS, "[State Breakdown of Registration by Medicaid and Medicare Providers through September 30, 2015](#)," September 2015.

Paper), which describes plans 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. More recently, ONC issued a document entitled “[Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0](https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf),” (<https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>) which supports the vision laid out in the 10-Year Vision Paper. ONC has also issued an [information-blocking report to Congress](https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf), ([https://www.healthit.gov/sites/default/files/reports/info\\_blocking\\_040915.pdf](https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf)) a [Health IT Safety Center Roadmap](http://www.healthitsafety.org/uploads/4/3/6/4/43647387/roadmap.pdf), (<http://www.healthitsafety.org/uploads/4/3/6/4/43647387/roadmap.pdf>) and an [updated Federal Health IT Strategic Plan for 2015–2020](http://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf). ([http://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal\\_0.pdf](http://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf))

### What Needs To Be Done

Threats to information privacy and security are evolving, and the Department must remain vigilant. While the Department has made progress with respect to protecting its own information, as highlighted in OIG work and a [recent Congressional Report](#), more remains to be done. The Department also must use available policy levers to address health IT privacy and security issues, such as through the EHR incentive programs. OIG work will continue to focus on HHS systems’ privacy and security to support the Department’s efforts to mitigate the risk of unauthorized access to its sensitive information. OIG work will also focus on privacy and security issues in the regulated community and on the related agencies to address concerns about similar risks for health information. Future work may consider privacy and security issues that arise from the continuing expansion of the Internet of Things, such as connected medical devices. (A link to the Congressional Report: <http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Analysis/20150806HHSinformationsecurityreport.pdf>)

To fully realize the value of health IT investments—which included, as of September 2015, over \$31 billion through the EHR incentive programs—and achieve the goal of a learning health system identified in the 10-Year Vision Paper, the Department must do more to improve the flow of information, subject to appropriate privacy and security safeguards.

Finally, given the magnitude of the investment in EHRs and other health IT programs, it will become increasingly important to measure the extent to which EHRs and health IT have achieved the Department's goals, which include improved health care and lower costs. As the Department progresses through the development and implementation of meaningful use stages and looks to implement the meaningful use portion of the Merit-based Incentive Payment System created in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), it should continue to consider feedback from stakeholders to ensure that adopted policies advance the Nation toward the Department's stated goals, while appropriately reflecting the changing health IT landscape and balancing privacy and security considerations. Additional guidance and technical assistance should be issued to address adoption, meaningful use, 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. Ongoing OIG work is examining the accuracy of Medicare and Medicaid EHR incentive payments for meaningful use. Future work may examine health IT interoperability across providers

(including those participating in accountable care organizations), 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, [A-06-13-00047](http://oig.hhs.gov/oas/reports/region6/61300047.pdf) (<http://oig.hhs.gov/oas/reports/region6/61300047.pdf>); [OEI-09-11-00380](http://oig.hhs.gov/oei/reports/oei-09-11-00380.pdf); (<http://oig.hhs.gov/oei/reports/oei-09-11-00380.pdf>) [A-06-12-00041](http://oig.hhs.gov/oas/reports/region6/61200041.pdf) (<http://oig.hhs.gov/oas/reports/region6/61200041.pdf>); [OEI-05-11-00250](http://oig.hhs.gov/oei/reports/oei-05-11-00250.pdf) (<http://oig.hhs.gov/oei/reports/oei-05-11-00250.pdf>); [OEI-05-11-00080](http://oig.hhs.gov/oei/reports/oei-05-11-00080.pdf) (<http://oig.hhs.gov/oei/reports/oei-05-11-00080.pdf>)
- OIG Reports on EHR program integrity, [OEI-01-11-00570](http://oig.hhs.gov/oei/reports/oei-01-11-00570.pdf) (<http://oig.hhs.gov/oei/reports/oei-01-11-00570.pdf>), [OEI-01-11-00571](http://oig.hhs.gov/oei/reports/oei-01-11-00571.pdf) (<http://oig.hhs.gov/oei/reports/oei-01-11-00571.pdf>)
- OIG Report, CMS Response to Breaches and Medical Identity Theft, October 2012 (<http://oig.hhs.gov/oei/reports/oei-02-10-00040.pdf>)
- OIG Summary Report, Information Technology Infrastructure and Operations Office Had Inadequate Information Security Controls, April 2015 (<http://oig.hhs.gov/oas/reports/region1/181430420.pdf>)
- OIG Reports on hospital IT security, including HIPAA Security Rule Oversight, [June 2011](http://www.oig.hhs.gov/newsroom/news-releases/2011/security.asp) (<http://www.oig.hhs.gov/newsroom/news-releases/2011/security.asp>), [OEI-09-10-00510](http://www.oig.hhs.gov/oei/reports/oei-09-10-00510.pdf) (<http://www.oig.hhs.gov/oei/reports/oei-09-10-00510.pdf>), and [OEI-09-10-00511](http://www.oig.hhs.gov/oei/reports/oei-09-10-00511.pdf) (<http://www.oig.hhs.gov/oei/reports/oei-09-10-00511.pdf>)

## Management Challenge 4: Administration of Grants, Contracts, and Financial and Administrative Management Systems

### Why This Is a Challenge

HHS is the largest grant-making organization and third-largest contracting agency in the federal government, with \$402 billion and \$21 billion awarded, respectively, in FY 2014. The *Affordable Care Act* provided additional grant and contract funding, adding to the Department's management and oversight responsibilities. Responsible stewardship of these program dollars is vital, and operating a financial management and administrative infrastructure that employs appropriate safeguards to minimize risk and protect resources remains a challenge for the Department.

**Grants and Contracts Management.** Across the Department, vulnerabilities have been identified in HHS grants, demonstrating the need for purposeful and consistent federal oversight. Awarding agencies lack a systematic method of and timing for sharing grantee risk information; sharing occurs infrequently; and oversight of grantee progress during the life of the grant needs improvement. Many grantees lack the robust financial management systems required to provide effective accountability for federal funds. For example, a community health center receiving *Affordable Care Act* grant assistance was not providing the services as described in its grant application and was unable to accurately account for how HHS funds were spent. Recent OIG investigations of HHS grantees reveal similar vulnerabilities in grants management. For example, in June 2014, four former officials of the Blackfeet Tribe's Po'ka Project, a multimillion-dollar HHS-funded effort to address the needs of troubled youth on the reservation, were convicted of fraud, embezzlement, and conspiracy and sentenced in federal court.

Previously identified weaknesses in the oversight of grantees, including late or absent financial reports and insufficient documentation on salaries and indirect costs, present challenges to the Department's implementation of the Office of Management and Budget's (OMB) Uniform Guidance.<sup>6</sup> Another challenge is implementation of the DATA Act that establishes governmentwide financial data standards related to expenditures of federal grants, contracts, and loans.

HHS is the second-largest payer under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, awarding \$680.7 million and \$96.6 million, respectively, in such grants and contracts in FY 2014. Three significant issues exist with the programs: awardees who appeared not to meet eligibility requirements, inconsistent collection of information needed to evaluate commercialization success, and failures to check consistently for duplicative funding within the Department and across other agencies.

Given the high dollar amount and complexity of contracts, weaknesses in Department monitoring of the corrective actions taken, processes, oversight, and management is a concern. Oversight vulnerabilities have been identified through a range of issues across Departmental programs. For example, OIG has raised concerns about acquisition planning and procurement, contract monitoring, and payments to contractors related to the federal health insurance marketplaces operated by CMS. OIG has also identified weaknesses in CMS's oversight and performance measurement for its benefit integrity contractors. (For more information on specific contract management concerns, see [Management Challenges 2](#) and [7](#).)

**Financial Statement Audits.** An audit of the Department's grant and contract systems, which are responsible for processing, awarding, and monitoring grants and contracts, uncovered multiple deficiencies in effective system controls. Deficiencies were related to segregation of duties, configuration management, and access to financial systems. The deficiencies represent a material weakness in internal controls – affecting the Department's ability to accurately manage financial information.

The financial statement audit also revealed challenges the Department continues to face in addressing violations of certain provisions of the Anti-Deficiency Act (ADA). These ADA violations highlight weaknesses in an agency's control over budgetary resources. Prior OIG audits of the National Institutes of Health (NIH) revealed ADA violations. The Department followed up with GAO regarding the violations. OIG will be doing a status report to assess and summarize the remedial actions taken by the Department to address the ADA violations.

**Improper Payments.** Improper payments cost federal programs billions of dollars annually. In FY 2014, the Department reported improper payments totaling almost \$78.4 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. In OIG's most recent audit of the Department's IPIA reporting, we found that the Department did not meet all IPIA requirements, including reporting an improper payment rate for the Temporary Assistance for Needy Families (TANF) program and performing a risk assessment of payments to employees and charge

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<sup>6</sup> Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (commonly referred to as the Uniform Guidance).

card payments. HHS asserts that it does not have the statutory authority to collect from states the data that is necessary for the calculation of a TANF improper payment rate.

### **Progress in Addressing the Challenge**

The Department has worked to strengthen its grants and contracts program integrity efforts. New grant regulations were published at 45 CFR Part 75, implementing OMB's Uniform Guidance requirements. Pursuant to those rules, the Assistant Secretary for Financial Resources (ASFR) is implementing a single audit resolution tracking system -- scheduled for completion by September 30, 2017. These rules also create a 270-day requirement to ensure all grant close out activities are complete. The Department is also serving as the governmentwide lead to identify the standardized data needed to meet the DATA Act requirements and has developed a Departmental implementation strategy to ensure adoption of approved data standards into business policies, processes, and systems.

The Department proposed an update to the HHS Acquisition Regulation (HHSAR) in March 2015 to supplement the Federal Acquisition Regulation. The HHSAR provides additional policy and procedural guidance to foster financial integrity and accountability across the acquisition lifecycle from the concept of need through contract close out. Additionally, HHS issued the Acquisition Strategy Directives in March 2015 and Acquisition Plan Directives in April 2015 which articulated the value and importance of HHS program offices adopting and implementing the acquisition lifecycle framework as a means to ensure business process/practices and mission/program needs drive requirements, and ensure the most appropriate vehicle is utilized to deliver critical results.

With respect to ADA 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. Further, the Department released a major update to its internal grants policies, featuring enhanced guidance on grants closeout, suspension and debarment, grants systems, and grants payments.

The Department has made efforts to assess grant program performance and improve grant and contract oversight. For example, the Substance Abuse and Mental Health Services Administration (SAMHSA) has improved outcome measurements for its largest program, the Substance Abuse Prevention and Treatment Block Grant. The Indian Health Service (IHS) and OIG partnered to provide training on using single audit reports to improve oversight of tribal health care funds. Furthermore, the Department and OIG sponsored training for grants and contracts officers on identifying and reporting potential fraud, waste, and abuse across all programs, including the SBIR/STTR programs, and OIG has encouraged contractors to self-report contract fraud and overpayments.

The Department has increased its use of suspension and debarment authorities, resulting in an increase from 8 debarments and 8 suspensions in FY 2013 to 32 debarments and 7 suspensions in FY 2014 -- preventing offenders from receiving federal funding.

The Department has taken corrective actions to resolve the IT-related deficiencies reported in the Agency Financial Report. The impact of this effort will be assessed during the FY 2015 audit of these systems.

With respect to IPPIA, the Department has stated in its comments on our IPPIA-compliance audit report pertaining to the Department's FY 2013 AFR that it would submit a legislative proposal to Congress that

would allow for a TANF error rate measurement. The Department, however, did not do so. Instead, the Department has reported that it submitted legislative proposals to Congress to improve TANF's program integrity. Specifically, the Department noted that ACF's FYs 2015 and 2016 Budget requests for TANF included \$10 million for program improvement initiatives, including technical assistance on strengthening state program integrity efforts. The requests also proposed to prohibit the use of non-governmental third-party expenditures in meeting state maintenance-of-effort (MOE) requirements, and limiting the expenditure of TANF and MOE funds to benefits and services to needy families. The Department asserts that both of these proposed legislative changes would strengthen state accountability to the purposes of the TANF statute. CMS reports that it has prioritized closing out contracts. Since February 1, 2014, CMS closed 2,077 contracts with an obligated value of \$1.3 billion and de-obligated \$29.95 million. In October 2014, CMS implemented a goal of closing out approximately 20 percent—or 2,250—overdue contracts per year.

### **What Needs To Be Done**

The Department needs to take more aggressive action to identify poorly performing grantees and those at risk of misspending federal dollars and either provide increased technical assistance and monitoring or prevent them from continuing to receive grant funds. Sustained focus is needed to monitor and address vulnerabilities, and the Department must continue diligent efforts to ensure that recipients use funds according to the award terms and consistent with the law. The Department has improved its contractor performance evaluation monitoring but is still underperforming compared to other government agencies.

The Operating Divisions (OPDIV) need to increase their monitoring efforts, including implementing program integrity initiatives, such as evaluating and mitigating risks, identifying and addressing cross-cutting issues; resolving grantee audit findings; and sharing best practices across the Department. In accordance with the new Uniform Guidance, the Department must implement processes to ensure that grantees have appropriate internal controls, including improved use of single audit reports throughout the grant cycle to ensure proper stewardship of funds. The Department will need to develop tracking and monitoring mechanisms for audit findings and the audit resolution process to effectively carry out this responsibility. The Department must also prepare for implementation of DATA Act requirements.

The Department needs to develop an improper-payment estimate for TANF and submit a legislative proposal to Congress to require state participation in such a measurement. In addition, the Department needs to meet improper-payment reduction targets, and reduce improper payments to less than 10 percent for all programs. The Department needs to conduct thorough root cause analyses of significant improper payments and develop robust corrective action plans that target identified causes. The Department also needs to conduct a risk assessment of payments made to employees and charge cards. The Department should resolve all financial control weaknesses identified by OIG, GAO, and other internal and external auditors.

The Department and OIG should continue to provide training on identifying and pursuing misconduct in grants and contracts. Grant and contract officers should more actively coordinate with and refer potential fraud to OIG for investigation. The Department also needs to continue to refine its suspension and debarment procedures by streamlining the referral and decision process, to continue providing

training and decrease the processing time of referrals. Moreover, the Department needs to implement a program to actively pursue fraud under the Program Fraud Civil Remedies Act (PFCRA).

### Key OIG Resources

- 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 2014](http://oig.hhs.gov/oas/reports/region1/171552000.pdf), May 2015 (<http://oig.hhs.gov/oas/reports/region1/171552000.pdf>)
- OIG Reports on grant oversight, [OEI-04-12-00160](http://oig.hhs.gov/oei/reports/oei-04-12-00160.pdf) (<http://oig.hhs.gov/oei/reports/oei-04-12-00160.pdf>), [OEI-04-11-00530](http://oig.hhs.gov/oei/reports/oei-04-11-00530.pdf) (<http://oig.hhs.gov/oei/reports/oei-04-11-00530.pdf>), [OEI-07-12-00110](http://oig.hhs.gov/oei/reports/oei-07-12-00110.pdf) (<http://oig.hhs.gov/oei/reports/oei-07-12-00110.pdf>), [OEI-07-11-00190](http://oig.hhs.gov/oei/reports/oei-07-11-00190.pdf) (<http://oig.hhs.gov/oei/reports/oei-07-11-00190.pdf>), [A-03-14-03304](http://oig.hhs.gov/oas/reports/region3/31403304.pdf) (<http://oig.hhs.gov/oas/reports/region3/31403304.pdf>)

## Management Challenge 5: Ensuring Appropriate Use of Prescription Drugs

### Why This Is a Challenge

CMS provides prescription drug coverage for 41 million Medicare Part D (Part D) and 71 million Medicaid beneficiaries. Part D is the fastest growing component of the Medicare program. Since its inception in 2006, spending for Part D has more than doubled to \$121 billion in 2014. Medicaid expenditures for prescription drugs are also increasing, influenced by Medicaid expansion and rising specialty drug costs. In 2014, Medicaid expenditures exceeded \$44 billion and Medicaid beneficiaries in states that expanded the program filled 25 percent more prescriptions, compared with a 3 percent increase in non-expansion states.<sup>7</sup> The Department's oversight of its prescription drug programs faces numerous challenges affecting beneficiary and community safety and the integrity of the benefit itself.

**Oversight.** Ensuring the integrity of programs as expansive as Part D and Medicaid requires coordinated, constant, and proactive efforts. In Part D, CMS contracts with plan sponsors, which are responsible for paying claims, monitoring billing patterns, and establishing compliance plans. CMS also contracts with the Medicare Drug Integrity Contractor (MEDIC) to detect and prevent fraud, waste, and abuse in Part D. CMS oversees the plan sponsors and the MEDIC, defines their requirements for carrying out program integrity functions, and monitors their performance. Weaknesses continue to exist in the use of data to identify vulnerabilities as well as in the oversight by each of the three key players. For example, CMS does not require plan sponsors to report information on fraud and most have chosen not to voluntarily report. (For more information on Medicaid's oversight challenges, see [Management Challenge 1](#).)

**Drug Abuse and Diversion.** The abuse and diversion of prescription drugs is an ongoing problem. As of May 2015, OIG has 540 pending complaints and cases involving Medicare and Medicaid prescription drug fraud, a 134 percent increase in the last 5 years. Pharmaceutical manufacturers and pharmacies accounted for more than 60 percent of Medicaid Fraud Control Units' cases that resulted in civil

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<sup>7</sup>IMS Institute for Healthcare Informatics, [Medicine Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014](http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=3f140a4331e8c410VgnVCM1000000e2e2ca2RCRD), April 2015. (<http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=3f140a4331e8c410VgnVCM1000000e2e2ca2RCRD>)

settlements and judgments in 2014. The Centers for Disease Control and Prevention (CDC) characterizes prescription drug abuse as an epidemic, reaching virtually all demographics and geographic locations. Drug diversion is the transfer of legitimate prescription drugs for unlawful purposes. The diversion of controlled substances is of particular concern because of its severe health risk and potential for abuse. In 2012, over 700,000 inpatient hospital stays were related to the overuse of opioids.

The diversion of noncontrolled substances is also a concern because these drugs are becoming more common in schemes that defraud Medicare and Medicaid. Schemes include billing for drugs that are not dispensed, combining prescribed drugs with opioids to create an enhanced euphoria, and illegal dispensing of expired or adulterated drugs. These schemes increasingly involve criminal networks ranging from informally connected street traffickers to complex criminal enterprises comprised of health care professionals, pharmacies, marketing companies, and even program beneficiaries. Criminal networks and others target brand-name, high-cost medications, including respiratory, HIV, and anti-psychotic medications.

***Questionable and Inappropriate Utilization.*** The responsibility of overseeing prescription drugs also involves ensuring that safe and high-quality care is provided to seniors and children. Serious concerns surrounding the overprescribing of drugs exist. For example, Medicare spending for commonly abused opioids has grown faster than spending for all Part D drugs. Additionally, quality-of-care concerns were identified with the prescription drug treatment of children enrolled in Medicaid who have mental health conditions. (For more information on ensuring Medicaid quality of care, see [Management Challenge 1.](#))

Several operating divisions within the Department are responsible for programs related to the safety and efficacy of drugs, drug abuse prevention and treatment, and the safety and quality of health care – including care involving drugs, biologics, and other therapies. Effectively coordinating all Department efforts and prioritizing initiatives are key to combating this complex epidemic. (For more information on challenges for the Food and Drug Administration (FDA) and Medicaid, see [Management Challenges 10](#) and [1.](#))

### **Progress in Addressing the Challenge**

CMS has taken steps to improve data coordination among the key players tasked with safeguarding Part D. Specifically, CMS has begun sharing plan sponsors' voluntarily reported fraud data with the MEDIC and has increased data sharing between plans. CMS is working to enroll over 400,000 prescribers of Part D drugs, addressing an OIG recommendation that CMS require Part D sponsors to verify prescribers' authority. These prescribers will be subject to risk-based screening requirements, and plan sponsors will be better able to deny Part D claims for drugs ordered by ineligible prescribers.

CMS is also taking steps to prevent pharmacy billing fraud and overutilization of prescription drugs. CMS regularly monitors pharmacy billing patterns and collaborates with Part D sponsors to perform audits or take other appropriate actions on high-risk pharmacies. CMS works with plan sponsors to prevent overutilization of certain prescribed medications and share information about beneficiaries that may over use prescription drugs. In April 2015, CMS launched a Web-based tool to allow CMS, law enforcement, and plan sponsors to share information and coordinate actions against high-risk pharmacies.

The Department has taken actions to restrict the manufacture, possession, or use of potentially dangerous controlled substances. The Food and Drug Administration (FDA) is working to reduce the abuse of opioids by encouraging formulations that make it more difficult to tamper with these products. Additionally, through coordination with the Drug Enforcement Administration (DEA), access to opioids is now better controlled because hydrocodone-combination products have been moved from Schedule III to the more restrictive Schedule II. Many state Medicaid programs have reported savings linked to implementing lock-in programs, which involves restricting certain beneficiaries to a limited number of pharmacies or prescribers. Additional benefits to lock-in programs include more appropriate beneficiary drug utilization and prevention of drug abuse and diversion. Additionally, CDC is developing guidelines to help primary care physicians improve the way they prescribe opioids to treat chronic pain, and CMS has established a new Medicaid initiative to undertake improvements in the delivery of care to beneficiaries with substance use disorder.

### What Needs To Be Done

Despite progress in key areas, further actions are needed to achieve effective oversight. CMS needs to do more to monitor plan sponsors' fraud detection and compliance programs. For example, CMS should require plan sponsors to report the number of instances of probable fraud, waste, and abuse that they identify, and the actions they took to address them. Collecting and sharing this data would increase each players' ability to identify and address program vulnerabilities. Additionally, CMS should improve existing safeguards to prevent improper payments in Part D and its ability to recoup those payments when identified. When the MEDIC identifies inappropriate payments there are no established procedures to recommend recoupment other than referrals to law enforcement. While CMS does require plan sponsors to return overpayments that they self-identify, CMS has no mechanism to recover inappropriate payments identified by the MEDIC during its investigations.

The Department should continue to prioritize and coordinate efforts to reduce opioid misuse and abuse. For example, CMS and plan sponsors should monitor beneficiary use of a wider range of drugs susceptible to abuse than they do now. Also, more needs to be done to effectively deal with beneficiaries who may be abusing the program or inflicting harm on themselves by overusing drugs. This could be addressed by implementing a Medicare lock-in policy, which would require a legislative change to CMS's authority.

### Key OIG Resources

- OIG Portfolio, [Ensuring the Integrity of Medicare Part D](http://oig.hhs.gov/oei/reports/oei-03-15-00180.pdf), June 2015 (<http://oig.hhs.gov/oei/reports/oei-03-15-00180.pdf>)
- OIG Report, [Second-Generation Antipsychotic Drug Use Among Medicaid-Enrolled Children: Quality-of-Care Concerns](http://oig.hhs.gov/oei/reports/oei-07-12-00320.pdf), March 2015 (<http://oig.hhs.gov/oei/reports/oei-07-12-00320.pdf>)
- OIG Report, [Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D](http://oig.hhs.gov/oei/reports/oei-02-15-00190.pdf), June 2015 (<http://oig.hhs.gov/oei/reports/oei-02-15-00190.pdf>)
- OIG Report, [Medicaid Fraud Control Units Fiscal Year 2014 Annual Report](http://oig.hhs.gov/oei/reports/oei-06-15-00010.pdf), April 2015 (<http://oig.hhs.gov/oei/reports/oei-06-15-00010.pdf>)

## Management Challenge 6: Ensuring Quality in Nursing Home, Hospice, and Home- and Community-Based Care

### Why This Is a Challenge

As Americans continue to live longer and with more chronic medical conditions, the Department must ensure that beneficiaries receive high-quality nursing home, hospice, and home- and community-based services (HCBS), including personal care services (PCS). Nursing home and HCBS programs provide ongoing assistance with daily living, as well as care for those who need temporary help recuperating from hospital stays or other acute care. Hospice care provides comfort for terminally ill beneficiaries and supports family and other caregivers.

**Nursing Home and Hospice Care.** Problems with nursing home and hospice care continue to be identified. Concerns raised include the frequency and severity of preventable adverse events because of substandard nursing home care, limited compliance with federal regulations for reporting abuse and neglect, lack of monitoring of nursing homes' resident hospitalization rates, failure to correct deficiencies identified during the survey process, and employment of caregivers who do not meet relevant licensure requirements. Additional concerns regarding hospice care include inadequate oversight of certification surveys and hospice-worker licensure requirements and fraudulent hospice enrollments undertaken without beneficiary consent.

**Home- and Community-Based Services.** HCBS programs serve several targeted populations, including people with mental illness, or physical, cognitive, or developmental disabilities. HCBS programs help beneficiaries avoid costly and disruptive facility-based care. These programs help promote beneficiary choice and preferences, but persistent payment, compliance, and quality vulnerabilities continue. Medicaid is the primary payer for PCS, a critical component of HCBS. Without effective PCS, the HCBS goals of keeping beneficiaries out of institutions cannot be achieved. Of significant note are vulnerabilities specific to PCS, such as delivery in private settings in which care may be harder to observe and oversee.

### Progress in Addressing the Challenge

The Department continues efforts to improve the quality of nursing home, hospice, and HCBS programs, including PCS. CMS developed the CMS Adverse Drug Event Trigger Tool for use by nursing homes and state surveyors to improve medication safety and reduce medication-related adverse events. In July 2015, the Department published a proposed rule on Reform of Requirements for Long-Term Care Facilities. Along with other quality improvement initiatives, the proposed rule would implement section 6102 of the *Affordable Care Act*, which requires each nursing facility to have an operational compliance and ethics program that effectively promotes quality of care.

CMS made the following improvements to the *Five Star Quality Rating System* posted on the *Nursing Home Compare* Web site to improve beneficiaries' and consumers' ability to determine meaningful differences between nursing homes, incentivize increased quality, and ensure the accuracy of the information posted: added two Quality Measures (QM) for antipsychotic medication use; raised the threshold for nursing homes to achieve a high rating on all measures in the QM dimension of the Five Star System; and expanded focused surveys nationwide to assess coding practices and its relationship to resident care in nursing homes to improve the accuracy of the QMs.

In August 2015, CMS finalized a rule for the PPS and Consolidated Billing for SNFs for FY 2016. This rule implemented section 6106 of the *Affordable Care Act*, which allows for greater oversight and increased accuracy for reporting of nursing home staffing on the *Nursing Home Compare* website and in the *Five Star Quality Rating System*. Also, this rule specified a SNF all-cause all-condition hospital readmission measure and adopts that measure for a new SNF Value-Based Purchasing (VBP) Program. Additionally, the rule will implement a new quality reporting program (QRP) for SNFs that authorizes CMS to reduce payments to nursing homes that do not report certain resident assessment items and establishes the plan to standardize certain elements of assessment tools and quality measures across post-acute care settings.

In July 2015, CMS published a proposed rule to improve the quality of nursing home care that updates Medicare requirements for long-term-care facilities. This proposed rule also would implement provisions of the *Affordable Care Act*, including requirements for facilities to implement a Quality Assurance and Performance Improvement (QAPI) program that would ensure that facilities continuously identify and correct quality deficiencies and promote and sustain performance improvement. Additional provisions would implement requirements for a Compliance and Ethics program, requirements for dementia and abuse prevention training, and requirements for reporting suspected crimes.

The Department continues efforts to improve access to hospice care. Traditionally, to qualify for hospice services, Medicare required beneficiaries to forego curative services. CMS, through the Medicare Care Choices model, is now testing allowing beneficiaries to receive hospice care to manage discomfort and receive end-of-life counseling while still allowing Medicare payment for treatments aimed at curing the underlying terminal illness. CMS has also taken steps to encourage patients and their physicians to discuss end-of-life issues to improve patients' quality of life and increase the likelihood that the end-of-life care the patients ultimately receive conforms to their informed wishes. As access improves, the Department must continue efforts to ensure that the quality of hospice care delivered to beneficiaries who select hospice meets quality standards.

Federal agencies, including OIG, DOJ, and CMS, continue to pursue enforcement actions against nursing homes, hospices, and HCBS providers, including PCS providers that render substandard care. In the past year, OIG launched an initiative to combat hospice fraud in regions identified as areas of particular concern. In the summer of 2015, OIG completed a national health care fraud takedown that included arrests of several Medicaid providers accused of committing HCBS fraud. 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 accused of abuse or neglect. State Medicaid Fraud Control Units (MFCU) devote substantial resources to the investigation and prosecution of abuse and neglect.

In addition to the Department's efforts to improve quality of care, OIG invests substantial efforts in helping providers 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 900 facilities) under corporate integrity agreements that include quality-monitoring provisions designed to ensure that beneficiaries receive the care they deserve.

Ensuring high-quality home- and community-based services and enabling beneficiaries to avoid institutionalization, relies heavily on appropriate personal care services. CMS is in the second year of a

four-year cycle of grants to nine qualified states to test quality measurement tools and demonstrate the use of electronic tools in Medicaid community-based long-term services and supports. These tools are designed to establish standardized interoperable data sets for HCBS plans and assessment items, measure the experience of care for beneficiaries and test the use of personal health records. An experience-of-care tool has been designed, tested and is in the final stages of certification. The Department entered into a contract last year with the National Quality Forum and began work on the development of a national quality measure set for home- and community-based services. Domains of measures have been made and an environmental scan started to identify key measures as well as gaps in measures for domains that might not have been developed to date.

### What Needs To Be Done

The Department should continue to prioritize quality of care in nursing homes and hospices as well as the care rendered as HCBS, with particular focus on PCS. The Department should 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. In addition, the Department should improve internal controls and offer better guidance and training for surveyors to ensure that nursing homes with recorded quality and safety issues correct their deficiencies. CMS should improve coordination with state agencies to ensure that care providers meet relevant licensure requirements. The Department should seek to link payments for services to meeting quality-of-care requirements and work with OIG to hold accountable the providers that have rendered substandard care, thereby preventing additional harm to vulnerable beneficiaries.

Lastly, the Department should ensure the integrity of Medicaid-funded PCS by establishing minimum federal qualification standards for providers based on needs of the individual being served; improving CMS's and states' ability to monitor billing and care quality; and issuing operational guidance for claims documentation, beneficiary assessments, person-centered plans of care, and supervision of personal care attendants when hired by an agency. For self-directed programs in which a beneficiary directs his/her own PCS, CMS and the states should improve oversight of controls to ensure individual health and welfare and financial integrity. 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, [Personal Care Services: Trends, Vulnerabilities and Recommendations for Improvement – A Portfolio](http://oig.hhs.gov/reports-and-publications/portfolio/portfolio-12-12-01.pdf), November 2012 (<http://oig.hhs.gov/reports-and-publications/portfolio/portfolio-12-12-01.pdf>)
- OIG Report, [The Medicare Payment System for Skilled Nursing Facilities Needs to Be Reevaluated](http://oig.hhs.gov/reports-and-publications/report/region2/21101024.pdf), September 2015
- OIG Reports on hospice quality of care, [OEI-02-14-00070](http://oig.hhs.gov/oei/reports/oei-02-14-00070.pdf) (<http://oig.hhs.gov/oei/reports/oei-02-14-00070.pdf>), [A-02-11-01024](http://oig.hhs.gov/oas/reports/region2/21101024.pdf) (<http://oig.hhs.gov/oas/reports/region2/21101024.pdf>)
- OIG Reports on home health quality of care, [OEI-01-12-00390](http://oig.hhs.gov/oei/reports/oei-01-12-00390.pdf) (<http://oig.hhs.gov/oei/reports/oei-01-12-00390.pdf>), [OEI-07-14-00130](http://oig.hhs.gov/oei/reports/oei-07-14-00130.pdf) (<http://oig.hhs.gov/oei/reports/oei-07-14-00130.pdf>)
- OIG Reports on nursing home quality of care, [OEI-07-13-00010](http://oig.hhs.gov/oei/reports/oei-07-13-00010.pdf) (<http://oig.hhs.gov/oei/reports/oei-07-13-00010.pdf>), [OEI-02-13-00611](http://oig.hhs.gov/oei/reports/oei-02-13-00611.pdf) (<http://oig.hhs.gov/oei/reports/oei-02-13-00611.pdf>), [A-09-13-](http://oig.hhs.gov/reports-and-publications/report/region2/21101024.pdf)

02039 (<http://oig.hhs.gov/oas/reports/region9/91302039.pdf>), OEI-06-11-00370 (<http://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf>)

## Management Challenge 7: Implementing, Operating, and Overseeing the Health Insurance Marketplaces

### Why This Is a Challenge

The health insurance marketplaces (marketplaces), also known as health insurance exchanges, are critical components of the health care reforms enacted through the *Affordable Care Act*. Implementation, operation, and oversight of the marketplaces were among the most significant challenges for the Department in FYs 2014 and 2015 and will continue to present a top management and performance challenge in FY 2016.

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 the Internal Revenue Service (IRS) is particularly important for sound administration of the premium tax credit program. In addition, CMS needs to ensure that state marketplaces comply with federal requirements and provide accurate, timely data used for federal payments. Further, CMS must take appropriate steps to promote compliance by Qualified Health Plans (QHP) with federal requirements, including network adequacy and nondiscrimination requirements. Key focus areas for the federal and state marketplaces include:

**Payments.** Ensuring sound expenditure of taxpayer funds for insurance affordability and other marketplace purposes poses a substantial management challenge, especially given the continued use of interim solutions and manual systems. For example, CMS's internal controls did not effectively ensure the accuracy of nearly \$2.8 billion in advance premium tax credits and cost-sharing reductions. CMS must improve its financial systems to ensure accurate and timely initial payments and reconciliations of these payments. CMS must also prioritize effective management of the risk corridor, reinsurance, and risk adjustment programs. CMS must validate information received from issuers to ensure that it is timely, complete, and accurate for payment purposes. In addition, CMS must ensure the correct use of federal establishment grant funds by state marketplaces. (For general information about challenges associated with grants management and contract administration, see [Management Challenge 4](#).)

**Eligibility.** Accurate eligibility determinations are critical. During the first open enrollment period, not all internal controls at certain marketplaces were effective in ensuring that individuals were properly determined eligible for QHPs, advance premium tax credits, and cost-sharing reductions. CMS reported a large number of unresolved inconsistencies in which applicants' self-reported data did not match other data sources. Effective internal controls and timely and accurate resolution of inconsistencies are critical to ensure that eligible consumers receive appropriate benefits and that ineligible individuals are not enrolled.

**Management and Administration.** Management and administration of the marketplaces requires, among other things, clear leadership, disciplined operations, and effective strategies and communication. OIG has raised concerns with, among other issues, CMS's acquisition planning and

procurement, contract monitoring, and administration of payments for marketplace contracts. The Department also must ensure, to the greatest extent possible, that the government obtains specified products and services from its contractors on time and within budget.

**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. 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 and the Multidimensional Insurance Data Analytics System (MIDAS), a data warehouse and repository. (For more information on privacy and security, see [Management challenge 3.](#))

### Progress in Addressing the Challenge

The Department has reported improvement in the operations of the federal marketplace. Following the initial launch of Healthcare.gov, CMS implemented several core management principles that enabled the organization to recover the Web site and improve agency management and culture. In addition, CMS has reported progress in marketplace operations, including publishing additional guidance regarding the use of federal establishment grant funds, implementing parallel processing and multiple levels of review of financial assistance payments information, working to develop a strategic and unified view of marketplace procurement and costs, and developing of a strategy to improve marketplace program integrity. CMS has 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, particularly the eligibility, administrative, and financial management functions. CMS must ensure that all pathways for enrollment operate with integrity and that consumers' personal information is secure. Vigilant monitoring and testing and rapid mitigation of identified vulnerabilities are essential. Attention must be paid to sound operation of financial assistance and the risk corridor, reinsurance, and risk-adjustment programs. CMS must ensure that consumers and issuers receive accurate marketplace information, including information relevant for tax purposes, such as Form 1095A tax forms. Furthermore, marketplaces must continue to protect personally identifiable information and strengthen security controls.

CMS must continue to work with its state partners to improve state marketplace operations and to ensure compliance with federal requirements for marketplaces and QHPs. CMS must monitor for and address fraud, waste, and abuse risks in marketplace programs. CMS must respond quickly and effectively to fraud that is detected, working with partners at the federal and state level to hold those involved accountable.

### Key OIG Resources

OIG has a broad portfolio of reviews examining various aspects of marketplace operations. For a complete list of these OIG reports, as well as OIG's Health Reform Oversight Plan, please see the [Affordable Care Act Reviews](#) section on the OIG Web site. (<http://oig.hhs.gov/reports-and-publications/aca/>)

## Management Challenge 8: Reforming Delivery and Payment in Health Care Programs

### Why This Is a Challenge

As recently as 2011, almost none of the \$558 billion spent on traditional Medicare was paid through alternative payment models (APM). Instead, CMS paid the majority of claims through the fee-for-service (FFS) system. The incentives created by the fee-for-service (FFS) system—which pays for health care on the basis of the volume of items or services furnished—have been linked to wasteful spending in health care, including unnecessary utilization and fragmented, poor quality care.

In January 2015, Secretary Burwell announced goals to foster better care, smarter spending, and healthier people and propel a transition to new models in Medicare. The ambitious goals are twofold. First, HHS aspires to tie 30 percent of traditional Medicare payments to APMs by the end of 2016, including bundled payment arrangements, and 50 percent of payments by the end of 2018. Second, HHS set a broader goal of tying 85 percent of traditional Medicare payments to quality or value — including not only APMs but also quality-based adjustments to fee-for-service payments—by 2016 and 90 percent by 2018. HHS is working with state Medicaid programs and private payers, including Medicare Advantage plans and others, to make comparable reforms for their providers and beneficiaries.

Reforms under *Affordable Care Act*, MACRA, and other statutes are embedding multiple new payment and delivery models into Medicare, requiring concurrent, sustained, and multifaceted efforts at planning and implementation. New models touch on virtually every aspect of the Medicare program – including, for example, hospital, physician, home health, dialysis, and post-acute care payment – and experiment with a variety of payment structures, including shared savings, episode-based payments, population-based payments, and capitation. In addition, CMS must implement a new market-driven payment system for laboratory services beginning in 2017.

CMS must establish policy, infrastructure, data systems, and oversight mechanisms to successfully implement these substantial changes. The Center for Medicare and Medicaid Innovation (CMMI) has a 10-year budget of \$10 billion dollars; the Department must ensure that Medicare realizes a return on the government’s substantial investment in designing, testing, and implementing new models. Perhaps equally challenging is ensuring that models are viable in light of providers’ substantial investments in infrastructure and care redesign.

Payment and delivery reforms are not exclusive to fee-for-service Medicare. The Department is promoting new models for Medicare Advantage (Part C). Medicare Advantage is a growing program with potential for increased efficiency and quality through better coordinated care, aligned incentives, and performance measurement. OIG work has identified challenges in the Medicare Advantage program with respect to use of data, payment accuracy, and program integrity, including addressing vulnerabilities at both the plan and provider levels. Ensuring a sound Medicare Advantage program is essential to enabling this program to meet its intended cost and quality goals. (For more information on improving the effectiveness of Medicaid managed care, please see [Management Challenge 1.](#))

## Progress in Addressing the Challenge

The Department reports that an estimated 20 percent of Medicare fee-for-service payments had shifted to APMs by the end of 2014. On its Web site, CMS is compiling a steady stream of early results from and evaluations of new programs and models. Recently, for example, [CMS reported](#) that Medicare accountable care organization (ACO) programs generated total program savings of more than \$411 million for Medicare in 2014 and that ACOs qualified for shared savings payments of more than \$422 million. CMS further reported that nine of 17 participants in the Independence at Home (medical home) Demonstration met the requirements for practice incentive payments in the model's first performance year. (Link to CMS report: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-08-25.html>)

CMS reported in its second biannual report to Congress that it had undertaken 22 models, including accountable care and bundled payment models, with more in development. CMS is also testing initiatives to speed adoption of best practices, accelerate development and testing of new models, and reform Medicaid and CHIP. These include large collaborations with private stakeholders, including the Million Hearts Program to advance heart health and the Partnership for Patients to improve hospital safety. The Department initiated the Health Care Payment Learning and Action Network to collaborate on aligning reforms across health care sectors.

Through its Medicaid Innovation Accelerator Program, CMS is providing technical support to state Medicaid agencies pursuing delivery system reform related to reducing substance use disorders; improving care for Medicaid beneficiaries with complex care needs and high costs; promoting community integration for beneficiaries using long-term services and supports; and physical and mental health integration.

CMS continues to issue a range of guidance to participants in new models and has begun the regulatory process for the new physician and laboratory payment systems. Additionally, CMS has taken steps to include in new models program integrity safeguards, including transparency of data and monitoring for indicators of abuse or gaming.

## What Needs to Be Done

Much must be accomplished to meet the statutory and Department's reform goals and the promise of better quality of care at lower costs. CMS must manage a broad portfolio of complex models and reforms. CMS must continue to develop clear guidance for providers on program requirements; administer (or contract for) financial, beneficiary alignment, and other systems necessary for effective operations; and test, evaluate, and verify model progress and outcomes. The Department should carefully monitor for successes and benefits that can be scaled and replicated, as well as for potential problems—including inefficiencies and misaligned incentives. Further, CMS must clearly define actionable and meaningful quality measures and ensure that they, in fact, measure what CMS intends them to measure to achieve desired quality goals.

New models rely significantly on data, EHRs, and technology. CMS must ensure that data collected and provided for new payment models is timely, accurate, complete, and secure. Data from providers and others must be integrated and shared across models, as appropriate. (For more information on the challenges associated with electronic information and health IT, see [Management Challenge 3](#).) To the

extent that cost and quality performance are measured on the basis of Parts A and B claims data, CMS must ensure the soundness and reliability of such data. (For more information on fraud and abuse in Medicare Parts A and B, see [Management Challenge 2](#)).

CMS must monitor for program integrity risks in new models, incorporate safeguards tailored to specific risks in particular models, and assess the effectiveness of the safeguards it employs. Detected program integrity problems should be remediated promptly and safeguards strengthened to prevent program and patient abuse or gaming. Sharp attention to program integrity is especially important for models that introduce new payment incentives, which might lead to new fraud schemes, or for which waivers of payment or fraud and abuse laws may have been issued under sections 1899(f) or 1115A of the Social Security Act. As a critical element of program integrity, CMS must maintain accurate historical and real-time information identifying providers and beneficiaries in new models.

Finally, CMS must strengthen Medicare Advantage to ensure that benefits are provided only to eligible beneficiaries, that data from providers and the plans are available for fraud detection and prevention, and that plans have programs to address fraud and abuse. Ensuring the accuracy of risk-adjustment data used to establish payment rates is also critical to protect against gaming or abuse. CMS must also improve its use of data to review Medicare Advantage organizations' performance.

### Key OIG Resources

- OIG Resources, [Accountable Care Organization Resource Page](#) (<http://oig.hhs.gov/compliance/accountable-care-organizations/index.asp>)
- OIG Report, [Medicare Improperly Paid Medicare Advantage Organizations Millions of Dollars for Unlawfully Present Beneficiaries for 2010 Through 2012](#), April 2014 (<http://oig.hhs.gov/oas/reports/region7/71301125.pdf>)
- OIG Report, [Medicare Advantage Organizations' Identification of Potential Fraud and Abuse](#), February 2012 (<http://oig.hhs.gov/oei/reports/oei-03-10-00310.pdf>)
- OIG Report, [CMS Regularly Reviews Part C Reporting Requirements Data, but Its Followup and Use of the Data are Limited](#), March 2014 (<http://oig.hhs.gov/oei/reports/oei-03-11-00720.pdf>)

## Management Challenge 9: Effectively Operating Public Health and Human Services Programs

### Why This Is a Challenge

The Department funds and operates public health and human services programs to promote health and economic and social well-being. These include programs to prevent, track, and treat acute and chronic diseases; respond to natural and man-made disasters; protect against hazardous biological agents; and protect, care for, and educate children. Many of these programs serve vulnerable populations. Effective management is essential to ensure that the programs achieve their goals and best serve the programs' intended beneficiaries.

**Public Health Preparedness and Emergency Response.** Effective protection against public health threats requires a well-coordinated public health infrastructure that can rapidly respond to emergencies at home and internationally. The Department must ensure that health care facilities and personnel are

prepared and trained to address emerging infectious diseases and that the proper protocols are in place to foster response coordination with domestic and international partners. Experiences responding to natural disasters, such as Superstorm Sandy, illustrated the important service of first responders and other health care professionals, but also identified gaps in natural disaster emergency planning and execution. Shortcomings related to federal, state, and community organization collaboration; response team communication; shelter operations; and health care coverage were identified. Furthermore, the Department must ensure that select agents (e.g., anthrax, smallpox) remain safe and secure. CDC is tasked with overseeing the handling of select agents in private and government facilities. However, security vulnerabilities identified at many Department research facilities attest to the continuing problems with how these agents are inventoried and handled.

***Access to and Quality of Services.*** The Department must ensure that intended beneficiaries of public health and human services have access to services and that these services meet quality standards. Access to quality services has proven especially challenging in IHS, where one hospital recently lost its Medicare provider enrollment after being found to pose immediate jeopardy to patients. Illustrating the challenges of adequately serving another vulnerable population, nearly a third of children in foster care who were enrolled in Medicaid did not receive at least one required health screening, and the Administration for Children and Families (ACF) did not ensure that these children received the required screenings according to state schedules.

***Protecting Vulnerable Populations.*** The health and safety of children served by ACF's Child Care and Development Fund (CCDF) program – serving approximately 1.6 million children – continues to be an unaddressed vulnerability for the Department. Vulnerabilities in states' standards for and monitoring of childcare providers jeopardize safety. A total of 454 violations of state licensing requirements were identified, including noncompliance with requirements related to physical conditions, inspection procedures, registration, criminal records or protective service checks, and child abuse and neglect registry checks. In addition, states' onsite monitoring of providers was infrequent, and states did not have enough inspectors to meet the national standard. In 2014, there was an unprecedented, and unpredicted, increase of unaccompanied children arriving in the United States, which required ACF's Office of Refugee Resettlement, in coordination with interagency partners, to implement emergency response measures to quickly expand capacity and provide shelter for a significant number of children. (For general information about challenges associated with grants management and contract administration, see [Management Challenge 4](#).)

### **Progress in Addressing the Challenge**

The Department is undertaking several initiatives to strengthen federal, state, and community disaster response. The Assistant Secretary for Preparedness and Response (ASPR) launched the Technical Resources Assistance Center and Information Exchange, an emergency preparedness information gateway designed to ensure that all stakeholders have access to information and resources to improve preparedness, response, recovery, and mitigation efforts. With respect to deficiencies in responding to homebound individuals dependent on electrically powered medical equipment, ASPR released the emPOWER map as a tool to help communities plan for the disaster needs of these individuals. CMS is also developing more comprehensive emergency preparedness requirements. In December 2014, CMS published a proposed rule establishing emergency preparedness requirements for Medicare- and Medicaid-participating providers.

The Consolidated and Further Continuing Appropriations Act, 2015, provided \$2.7 billion in emergency funding to HHS for Ebola preparedness and response activities. Of this, \$1.77 billion was allocated to CDC to prevent, prepare for, and respond to Ebola domestically and internationally. Through its Hospital Preparedness Program cooperative agreements, ASPR has designated nine health departments and associated partner hospitals to become special regional treatment centers for patients with Ebola or other severe, highly infectious diseases. Through the newly announced National Ebola Training and Education Center, CDC and ASPR will support health care provider and facility training and management of Ebola and other emerging infectious diseases.<sup>8</sup>

The Department has made progress in improving physical security and employee training related to safe and secure storage and handling of select agents. CDC has revised its Vaccines for Children (VFC) Operations Guide, published a *Storage and Handling Toolkit*, and provided additional grantee and provider training to improve vaccine storage and handling practices. CDC also now requires grantees to perform unannounced visits to providers' offices, which was the technique that the OIG used to initially identify VFC program storage and handling vulnerabilities.

The Child Care and Development Block Grant Act of 2014 (P.L. No. 113-186) reauthorized the CCDF program and improved childcare health, safety, and quality requirements. The law requires states to perform an initial onsite monitoring visit and at least one annual unannounced onsite visit of licensed providers that have received CCDF subsidies, as well as annual inspections for license-exempt CCDF providers. The law also requires childcare providers to submit background checks at least once every 5 years for each childcare staff.

Since the sharp increase of unaccompanied children referred to HHS in the Spring/Summer of 2014, ACF has continued to support and participate in the DHS-led Unified Coordination Group, which monitors all aspects of unaccompanied children arrivals, including HHS and Department of Homeland Security (DHS) programs, along with the collaboration of other federal partners such as the Department of State and the Department of Defense. ACF has also awarded new contracts to support the operations of temporary surge shelters, should they need to be deployed in the future.

### What Needs To Be Done

The Department should continue to promote federal, state, and community collaboration during major disasters. 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. Additionally, improvements in the adoption and interoperability of health IT can facilitate medical care for displaced patients by ensuring continuity of access to health records. (For more information on the secure exchange of health information, see [Management Challenge 3](#).)

The Department should move swiftly toward finalizing emergency preparedness regulations. In conjunction with these regulations, detailed and clear guidance should be developed for surveyors assessing compliance with federal regulations. In addition, clear guidance should be developed for the transport of Medicaid patients across state lines. The Department must ensure the sufficiency and

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<sup>8</sup> Lead Inspector General Quarterly Progress Report on US Government Activities, [International Ebola Response and Preparedness](https://oig.usaid.gov/content/lead-inspector-general-quarterly-progress-report-us-government-activities-international-eb-0), June 30, 2015 (<https://oig.usaid.gov/content/lead-inspector-general-quarterly-progress-report-us-government-activities-international-eb-0>)

training of medical staff for disasters and severe infectious diseases to prepare them to maintain patient care during periods of poor conditions.

The Department will need to continue efforts to improve its inventory control policies and procedures for select agents to resolve vulnerabilities.

ACF should expand the scope of its Child and Family Services Reviews to determine whether children in foster care receive required screenings according to the timeframes specified in states' plans. Furthermore, ACF should work with states to identify the barriers that prevent children in foster care from receiving required screenings and identify, disseminate, and implement strategies for overcoming those barriers. ACF must continue to effectively implement the Child Care and Development Block Grant Act of 2014 to strengthen the Department's oversight of the health and safety of children. OIG continues to recommend that the Department continue coordination with partner agencies, such as the Department of Homeland Security, to improve its ability to adequately care for unaccompanied children.

### Key OIG Resources

- OIG Reports on emergency preparedness and response, [OEI-06-13-00260](http://oig.hhs.gov/oei/reports/oei-06-13-00260.pdf) (<http://oig.hhs.gov/oei/reports/oei-06-13-00260.pdf>), [OEI-04-13-00350](http://oig.hhs.gov/oei/reports/oei-04-13-00350.pdf) (<http://oig.hhs.gov/oei/reports/oei-04-13-00350.pdf>)
- OIG Report, [Division of Unaccompanied Children's Services: Efforts to Serve Children](http://oig.hhs.gov/oei/reports/oei-07-06-00290.pdf), March 2008 (<http://oig.hhs.gov/oei/reports/oei-07-06-00290.pdf>)
- OIG Testimony, [The Foundation for Success: Strengthening the Child Care and Development Block Grant Program](http://oig.hhs.gov/testimony/docs/2014/jarmon-testimony-0314.pdf), March 2014 (<http://oig.hhs.gov/testimony/docs/2014/jarmon-testimony-0314.pdf>)
- OIG Report, [Not All Children in Foster Care Who Were Enrolled in Medicaid Received Required Health Screenings](http://oig.hhs.gov/oei/reports/oei-07-13-00460.asp), March 2015 (<http://oig.hhs.gov/oei/reports/oei-07-13-00460.asp>)
- OIG Testimony, [Continuing Concerns with the Federal Select Agent Program: Department Of Defense Shipments of Live Anthrax](http://www.oig.hhs.gov/testimony/docs/2015/demske-0728.pdf), July 2015 (<http://www.oig.hhs.gov/testimony/docs/2015/demske-0728.pdf>)

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

### Why This Is a Challenge

The Department, through FDA, must ensure the safety, efficacy, and security of drugs, biologics, medical devices, dietary supplements, tobacco, feed, and much of our Nation's food supply. However, weaknesses exist. Areas of particularly high risk include drug compounding; the global supply chain; food safety; illegal marketing and promotion; and dietary supplements.

**Compounded Drugs.** Compounded drugs are produced outside of FDA's regulatory process designed to ensure the safety and efficacy of commercially manufactured drugs. The potential danger of compounded drugs drew national attention in 2012, when contaminated compounded sterile drug injections caused a fungal meningitis outbreak. The widespread use of compounded products in health care and FDA's limited ability to effectively oversee compounding entities, which number in the thousands and, generally, do not register with FDA, are causes for concern.

**Imported Food and Drugs.** Foreign sources account for about 40 percent of the drugs, 50 percent of the medical devices, 15 percent of the food, 85 percent of the seafood, and 50 percent of the fresh fruit used by Americans. The global nature and complexity of this supply chain complicates FDA's task of ensuring safety.

**Food Facilities.** Food-borne illnesses, such as those caused by salmonella, listeria and E. coli, pose a continuing public health threat. Despite legal requirements for food facilities to investigate and report adulteration and other serious food-safety concerns, food facilities' failures to comply impede the Department's ability to ensure the safety of the Nation's food supply.

**Off-label Promotion and Kickbacks.** 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, including unapproved uses, commonly called "off-label uses." However, manufacturers are prohibited from promoting products for off-label uses. Manufacturers are also prohibited from paying kickbacks to physicians or other health care providers to promote the use of their drug, biologic, or medical device. OIG continues to identify illegal off-label promotion and kickbacks that put patients at risk of receiving inappropriate or harmful care and lead to fraudulent claims for payment from federal health care programs. (For more information on drug diversion and utilization of prescription drugs, see [Management Challenge 5](#)).

**Dietary Supplements.** Dietary supplement manufacturers use structure/function claims to persuade consumers to purchase and use their products. Structure/function claims can describe the effect of a dietary supplement on the structure and function of human bodies but may not claim to prevent, treat, mitigate, cure, or diagnose a disease. Reliable evidence must substantiate these claims as truthful and not misleading, but manufacturers are not required to submit the substantiation to FDA prior to marketing their products, and FDA has only voluntary standards for submission. Those substantiation documents submitted often do not reflect reliable evidence.

### **Progress in Addressing the Challenge**

In 2013, the Drug Quality and Security Act (DQSA), amended the Federal Food, Drug, and Cosmetic Act to enhance FDA's authority to oversee compounding, including by providing a new pathway for compounders to register as "outsourcing facilities" to legally compound drugs. The Department continues to work to fully implement DQSA, and FDA has issued numerous policy and guidance documents and increased its inspection and enforcement efforts. FDA continues to inspect compounding facilities; oversee recalls of compounded drugs for contamination or lack of sterility assurance; and issue warning letters to compounders that violate the law.

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 illegally buying drugs from foreign sources. In addition, FDA has continued to work with OIG and other law enforcement partners to investigate and prosecute physicians and drug suppliers that import unapproved drugs, most notably misbranded, unapproved chemotherapy drugs. Physicians who bill Medicare or Medicaid for such unapproved drugs can be subject to criminal liability under the False Claims Act and excluded from participating in federal health care programs. FDA

continues to cooperate with international partners and has introduced improved border screening to enhance oversight of imported products.

FDA continues to implement its enhanced food-safety authorities statutorily granted in 2011 by the Food Safety Modernization Act (FSMA). In September 2015, FDA promulgated new food safety rules that will require U.S. manufacturers of both human and animal foods to make detailed plans to identify and prevent contamination risks in their production facilities. FDA's food scientists have helped improve genome sequencing technologies to better detect and prevent foodborne illnesses, and FDA continues to work on improving nutrition and calorie labeling to better inform consumers.

OIG and its law enforcement partners have pursued numerous enforcement actions against drug, biologic, and device manufacturers for illegally promoting their products in ways that could harm patients and waste federal health care program money.

FDA endeavors to continue to make progress in addressing OIG recommendations to improve oversight of dietary supplements. In response to an OIG recommendation, FDA stated that it would consider seeking enhanced authority to review substantiation for structure/function claims.

### What Needs To Be Done

The Department and FDA must continue issuing rules and guidance documents to fully implement FSMA, and DQSA, as well as the July 2012 Food and Drug Administration Safety and Innovation Act (FDASIA). FDA must continue to implement its new authorities to enhance oversight of drug compounders and better ensure the safety of compounded products, including by inspecting drug compounders and pursuing regulatory action when deficiencies are identified. OIG plans continued oversight of FDA's inspection of food facilities and monitoring of food recalls. OIG continues to recommend that FDA remedy identified weaknesses in its inspections and recall procedures and better ensure that states properly conduct contracted food facility inspections. The Department also must continue combating off-label promotion and illegal importation of unapproved drugs. OIG, in cooperation with DOJ and other law enforcement partners, will continue to employ investigative and enforcement authorities to protect federal health care programs and beneficiaries from these potentially dangerous products.

### Key OIG Resources

- OIG Report, [Penetration Test of the Food and Drug Administration's Computer Network](http://oig.hhs.gov/oas/reports/other/181330331.pdf), October 2014 (<http://oig.hhs.gov/oas/reports/other/181330331.pdf>)
- OIG Report, [High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them](http://oig.hhs.gov/oei/reports/oei-01-13-00150.pdf), April 2013 (<http://oig.hhs.gov/oei/reports/oei-01-13-00150.pdf>)
- OIG Report, [FDA Lacks Comprehensive Data To Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety](http://oig.hhs.gov/oei/reports/oei-04-11-00510.pdf), February 2013 (<http://oig.hhs.gov/oei/reports/oei-04-11-00510.pdf>)
- OIG Report, [Dietary Supplements: Structure/Function Claims Fail to Meet Federal Requirements](http://oig.hhs.gov/oei/reports/oei-01-11-00210.pdf), October 2012 (<http://oig.hhs.gov/oei/reports/oei-01-11-00210.pdf>)