



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

TOP MANAGEMENT AND PERFORMANCE CHALLENGES FACING HHS

2017



Top Management and Performance Challenges Facing HHS: Introduction

The Office of Inspector General (OIG) has identified 10 top management and performance challenges facing the Department of Health and Human Services (HHS) as it strives to fulfill its mission “to enhance the health and well-being of Americans by providing effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.” These top challenges arise across HHS programs and cover critical HHS responsibilities that include delivering quality services and benefits, exercising sound fiscal management, safeguarding public health and safety, and enhancing cybersecurity. The Department should be mindful of these challenges and opportunities to address them as it undertakes its efforts to reimagine HHS as part of the Federal Government’s comprehensive plan to reform Government.

HHS is responsible for a \$1.1 trillion portfolio, and its programs impact the lives of virtually all Americans. In this context, management and performance challenges are plentiful and consequential. To identify the 10 top challenges, we synthesized our oversight, risk analysis, data analytics, and enforcement work. The section on each challenge includes a short list of key OIG reports and other products related to that challenge; additional OIG work can be found on our webpage at <https://oig.hhs.gov>.

Additionally, OIG maintains a list of recommendations it has made to address vulnerabilities detected in its audits and evaluations and tracks whether these recommendations have been implemented. From among these, OIG identifies the top unimplemented recommendations that, if implemented, are likely to garner significant savings and improvements in efficiency and effectiveness.¹

The top 10 challenges include four areas of priority for OIG:

- fighting opioid and prescription drug abuse,
- protecting the health and safety of children served by HHS programs,
- preventing improper payments and fraud in home-based services, and
- partnering with States to enhance Medicaid program integrity.

2017 Top Management and Performance Challenges

1. Ensuring Program Integrity in Medicare
2. Ensuring Program Integrity in Medicaid
3. Curbing the Opioid Epidemic
4. Improving Care for Vulnerable Populations
5. Ensuring Integrity in Managed Care and Other Programs Delivered Through Private Insurers
6. Improving Financial and Administrative Management and Reducing Improper Payments
7. Protecting the Integrity of Public Health and Human Services Grants
8. Ensuring the Safety of Food, Drugs, and Medical Devices
9. Ensuring Program Integrity and Quality in Programs Serving American Indian and Alaska Native Populations
10. Protecting HHS Data, Systems, and Beneficiaries from Cybersecurity Threats

¹ See OIG’s *Compendium of Unimplemented Recommendations*, May 2017. Available at <https://www.oig.hhs.gov/reports-and-publications/compendium/files/compendium2017.pdf>

Top Management Challenge #1: Ensuring Program Integrity in Medicare

Why This Is a Challenge

In fiscal year (FY) 2016, Medicare spent \$679 billion and provided health coverage to 56.8 million beneficiaries. Spending under Medicare is expected to increase significantly over time as a result of growth in the number of beneficiaries and increases in per capita health care costs. The 2017 Annual Report by Medicare's Board of Trustees estimates that the Trust Fund for Medicare Part A (hospital insurance) will be depleted by 2029. It also projects that spending for Medicare Part B (medical insurance) will grow by almost 7 percent over the next 5 years, outpacing the U.S. economy, which is projected to grow by 5 percent during that same time.

Key Components of the Challenge

- Reducing improper payments
- Combating fraud
- Fostering prudent payment policies
- Implementing health care reforms and the promise of health information technology (Health IT)

In addition to challenges inherent in managing a program of this size, scope, and impact, HHS faces the added challenges of navigating within a rapidly evolving health care landscape and implementing significant legislative changes to Medicare. The 21st Century Cures Act, which was signed into law in December 2016, and the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) incentivized changes to the ways health care is delivered and paid for and promoted the adoption and appropriate use of electronic health record (EHR) technology to share information across providers. More broadly, the Department is navigating the transformation from a volume-based health care system to a value-based, more accountable system.

To ensure that Medicare effectively serves beneficiaries well into the future, HHS must foster sound financial stewardship and program integrity. This includes protecting Medicare dollars from fraud, waste, and abuse; implementing prudent payment policies; and helping Medicare, providers, and beneficiaries achieve the goals of health care reforms and the promise of Health IT.

Key Components of the Challenge

Reducing Improper Payments. Reducing improper payments to providers is a critical element in protecting Medicare's financial integrity. In FY 2016, the Centers for Medicare & Medicaid Services (CMS) reported an improper payment rate of 11 percent, corresponding to \$41 billion, for Medicare Fee-for-Service, i.e., Medicare Parts A and B. *(For more information on measuring and reporting improper payment rates, see TMC #6.)* Some types of providers and suppliers pose heightened risk to the financial integrity of Medicare. For instance, OIG and CMS have identified high rates of improper payments for home health care, hospice care, and certain hospital services. Additionally, OIG estimated that Medicare improperly paid hundreds of millions of dollars for chiropractor services that did not meet Medicare requirements.

Identifying and recovering overpayments remains a critical tool for reducing improper payments. OIG has consistently found that Medicare contractors have difficulty identifying, collecting, and tracking overpayments. For example, OIG found that in 2014 Medicare Administrative Contractors collected only 20 percent of the overpayments that they sought to collect, based on referrals from benefit integrity contractors. Also, CMS is not using all tools available to recover misspent funds. For instance, Federal law requires Medicare durable medical equipment (DME) suppliers and home health agencies to obtain surety bonds. Federal law also authorizes HHS to require surety bonds for additional high-risk providers. However, CMS has implemented this requirement only for DME suppliers.

Combating Fraud. Stopping fraud in Medicare is vital to safeguarding health care resources and protecting beneficiaries. OIG has identified common fraud schemes, such as billing for unnecessary services or services not provided; billing for more expensive services than needed or provided; paying kickbacks to recruiters, providers, and patients; and medical identity theft. Program areas susceptible to widespread fraud include home health, hospice services, DME, ambulance transportation, and clinical laboratory testing.

OIG Focus Area: Reducing Improper Payments for Home Health Services

The Medicare home health benefit has long been recognized as vulnerable to fraud, waste, and abuse. Home health care represents a significant component of Medicare expenditures. In 2016, Medicare paid for more than 11,000 home health services, totaling approximately \$18.24 billion. In FY 2018, OIG will prioritize work that identifies ways the Department can reduce improper payments for home health by reducing Medicare spending in geographic “hot spots.”

To address fraud, CMS needs accurate information about the individuals and entities with which it does business, and it must take appropriate steps to avoid doing business with—and exposing beneficiaries to—untrustworthy actors or providers who are deemed ineligible to bill Medicare. For example, shortly after CMS implemented enhanced provider enrollment screening, OIG found weaknesses in Medicare contractors’ administration of this process that could leave Medicare vulnerable to enrolling unscrupulous providers.

Fostering Prudent Payment Policies. Medicare should act as a prudent payer on behalf of taxpayers and beneficiaries by instituting economical payment policies. However, in certain contexts, Medicare payment policies result in Medicare and beneficiaries paying more for care provided in certain settings than for the same care provided in other settings. For example, Medicare could potentially save \$4.1 billion over a 6-year period if swing-bed services at critical access hospitals were paid for at the same rates as at skilled nursing facilities (SNFs). Medicare also pays hospitals different amounts for the same care depending on whether the hospital admits beneficiaries as inpatients or treats them as outpatients. Beneficiaries’ coinsurance costs and eligibility for Medicare-covered SNF costs following discharge also vary depending on their status as hospital inpatients or outpatients, even if they receive the same care during their stay.

Further, some payment policies create financial incentives that may drive up Medicare costs without improving care for beneficiaries. For example, OIG found that Medicare payments to SNFs for therapy greatly exceeded SNFs’ costs for that therapy, creating incentives to bill for unnecessary therapy. Indeed, OIG’s work showed that SNFs have increasingly billed for the highest levels of therapy even

though the characteristics of their beneficiaries did not change. In another example, OIG found that Medicare payments for hospice care to beneficiaries in assisted living facilities have risen much more quickly than payments for hospice care in other settings and that hospices have financial incentives to target beneficiaries in assisted living facilities. In 2012, Medicare paid hospices about \$1,100 per week per beneficiary receiving care in assisted living facilities, yet hospices typically provided fewer than 5 hours of visits per week per beneficiary.

Implementing Health Care Reforms and the Promise of Health IT. Health care delivery has been evolving in recent years, driven most recently by major legislative changes such as those in the 21st Century Cures Act and MACRA. MACRA revamped Medicare’s physician reimbursement system by creating the Quality Payment Program (QPP) to replace the Sustainable Growth Rate formula and Physician Quality Reporting System for most Medicare physicians and other clinicians. The QPP introduces into physician reimbursement two mechanisms linked to quality and efficiency: (1) a Merit-Based Incentive Payment System (MIPS) and (2) advanced alternative payment models (Advanced APMs). Within this complex program, CMS must manage clinicians’ transition to MIPS and craft Advanced APMs. In so doing, CMS must be mindful of administrative burden and the specialized needs of many small and rural providers. Physicians must prepare for significant changes in reimbursement methodology, reporting, and—depending on circumstances—delivery of care and workflow.

CMS continues to manage a range of programs that address system reforms aimed at improving quality of care in Medicare and Medicaid and reduce costs. These programs include, for example, the Medicare Shared Savings Program (MSSP) and a variety of models tested under the authority of the CMS Innovation Center. Recent OIG work examining performance of the MSSP in its first 3 years concluded that accountable care organizations showed potential to improve quality and reduce costs, and that further study of successful strategies would be warranted to inform continued operation of the program. Managing a broad range of changes to Medicare poses management challenges for CMS. New payment structures, business arrangements among providers, and incentives all give rise to risk-management challenges. In pursuing innovative models to improve the health care system, CMS must take steps to prevent programs and policies from having unintended consequences, such as misaligned incentives or abusive practices.

Connecting those involved in health care, as well as in human services, is important in a value-driven health care system. Leveraging the benefits of Health IT to ensure the appropriate flow of complete, accurate, timely, and secure information and to improve patient care is also critical. HHS faces challenges in achieving a connected health system in which data flow freely, as appropriate. These challenges include ensuring that Health IT companies and providers do not inappropriately block the flow of information; preventing inappropriate payments to participants who do not meet program requirements; ensuring that EHRs are not used as tools for fraud; encouraging adoption and use of Health IT by those not eligible for existing incentive programs; ensuring that patient safety benefits are realized; and encouraging the use of exchanged data. To avoid potential gaps in policy and oversight that could undermine the promise of Health IT, HHS must ensure coordination among internal agencies and other Federal partners that have overlapping responsibility for various aspects of Health IT. *(For information on the cybersecurity challenges impacting Health IT, see TMC #10.)*

Progress in Addressing the Challenge

Reducing Improper Payments. CMS is taking action to reduce improper payments, including notifying providers and suppliers serving Medicare beneficiaries in Part A and Part B of their responsibility to report and return overpayments within 60 days of an overpayment being identified. To ensure that items and services are provided in compliance with Medicare requirements, CMS has implemented prior authorization demonstrations, models, and programs that cover power mobility devices; repetitive, scheduled nonemergent ambulance transports and nonemergent hyperbaric oxygen; and certain other DME, prosthetics, orthotics, and supplies. Additionally, CMS continues to make available and market educational products and messages about proper billing and documentation requirements to reduce improper payments.

Combating Fraud. OIG, HHS, and the U.S. Department of Justice have made substantial strides in fighting Medicare fraud. From 2014 to 2016, the joint Health Care Fraud and Abuse Control (HCFAC) program returned \$5 for every \$1 invested. In FY 2016, HCFAC-funded audits and investigations by OIG resulted in expected recoveries of \$2.5 billion. In July 2017, OIG, along with our State and Federal law enforcement partners, participated in the largest health care fraud takedown in history. More than 400 defendants in 41 Federal districts were charged with participating in fraud schemes involving about \$1.3 billion in false billings to Medicare and Medicaid. Effectively leveraging data is critical to successfully combating fraud. For example, HHS uses data to identify and prevent potential fraud via its Fraud Prevention System. OIG uses data analytics to target and support our audits and investigations and to evaluate the scope and patterns of suspected fraud across the Medicare program.

HHS has taken steps to enhance its use of program integrity tools. For example, CMS reports that it requires inspectors for national site-visit contractors to complete annual CMS-approved training and testing, terminating those inspectors who do not do so. CMS also reported that it is currently enhancing the training materials to provide specific guidance on determining whether facilities are operational. More broadly, CMS is in the process of unifying its program integrity oversight of Medicare Part A and Part B and Medicaid. The new Unified Program Integrity Contractors will oversee these programs in distinct jurisdictions across the country as the contracts continue to be awarded. Medicare billing and payments have decreased in certain services and geographic areas known for fraud risks. For example, following law enforcement activities and CMS administrative actions, billing and payments for community mental health services declined significantly from 2009 to 2016 in fraud “hot spots.” In addition, Medicare payments for home health services have decreased across the country by more than \$1 billion per year since CMS capped outlier payments in 2010. CMS reports that it has also continued to use its authority to suspend Medicare payments to providers during investigations based on a credible allegation of fraud or on the basis of reliable information that an overpayment exists, imposing 291 new payment suspensions during FY 2016.

Additionally, the Department has fostered relationships among Federal and State agencies as well as between government agencies and the private sector. These partnerships are valuable to the detection of fraud and to enforcement successes. For example, public- and private-sector partners in the Healthcare Fraud Prevention Partnership (the Partnership), facilitated by CMS, share data and information to detect and prevent fraud. The Partnership has completed several studies to address fraud, waste, and abuse—such as targeting false storefronts or phantom providers—that have yielded successful results for participating partners.

In addition, CMS is replacing the Social Security number on Medicare cards with a new, randomly assigned unique identifier to help prevent fraud, combat identity theft, and safeguard taxpayer dollars. CMS reports that it will begin mailing new cards to Medicare beneficiaries in April 2018 to meet the statutory deadline for replacing all existing Medicare cards by April 2019. CMS also recently started running fraud prevention advertisements that highlight the importance of safeguarding the Medicare card.

Fostering Prudent Payment Policies. HHS has been instituting changes to promote more prudent payment policies in some health care settings. For example, Medicare is required by law to stop paying certain new hospital-owned, off-campus, “provider-based” departments that charge higher hospital rates than freestanding facilities that perform the same services for less. CMS projects that this will save Medicare approximately \$50 million in 2017. CMS is also studying the extent to which Medicare payment rates for therapy at SNFs should be reduced by evaluating claims data and outlining potential new payment models for SNFs. CMS has solicited public comments on options to consider in their research on SNF payment rates for therapy.

The Medicare appeals process is experiencing a sustained increase in the number of appeals. For example, the number of requests for an Administrative Law Judge hearing or review increased 1,222 percent from FY 2009 through FY 2014. This increase has created a significant backlog of appeals at the third and fourth levels of appeal. The Benefits and Improvement and Protection Act of 2000 requires that Medicare appeals be adjudicated within 90 days of receipt. The average processing time for each Medicare appeal is now 1,082 days. As of June 30, 2017, HHS reported that OMHA has a backlog of approximately 580,000 Medicare appeals.

HHS has developed a three-pronged strategy to address the backlog:

- 1) Invest new resources at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog.
- 2) Take administrative actions to reduce the number of pending appeals and encourage resolution of cases earlier in the process.
- 3) Propose legislative reforms that provide additional funding and new authorities to address the appeals volume.

Implementing Health Care Reforms and the Promise of Health IT. Through the QPP, CMS continues to make steady progress in implementing substantial payment reforms. Since January 1, 2017, CMS reports that it has engaged more than 100 stakeholder organizations and over 47,000 people to raise awareness, solicit feedback, and help clinicians prepare for participation. CMS plans to maintain its focus on the clinicians’ perspective as it develops IT systems that support and streamline clinician participation, crafts flexible and transparent MIPS policies, and facilitates participation in Advanced APMs.

CMS is also developing additional Advanced APMs for the QPP, including recommendations received from the Physician-Focused Payment Model Technical Advisory Committee, which reviews and assesses stakeholder-submitted proposals for physician-focused payment models. Additionally, CMS has issued

a Request for Information from the public for the development and testing of new models through the Innovation Center, including those involving State programs and managed care.

HHS continues developing programs and policies that foster the development, adoption, and effective use of Health IT to support the appropriate flow of complete, accurate, timely, and secure information, including in connection with Medicare. HHS has sought to advance the national conversation about important Health IT issues to ensure that the potential benefits of Health IT investments are realized.² As of August 2017, more than 639,000 eligible professionals and hospitals—including critical access hospitals—were actively registered in the EHR incentive programs.³ HHS has also finalized a rule to implement the MACRA provisions that replaced the Medicare EHR Incentive Program for eligible professionals with a performance category within MIPS. Additionally, HHS has issued an array of tools to empower patients to access their electronic health information, with the goal of improving patient outcomes, health care delivery, and social services.⁴ HHS is also in the process of implementing various provisions of the 21st Century Cures Act that will facilitate the appropriate flow of complete, accurate, timely, and secure data.

What Needs To Be Done

Reducing Improper Payments. CMS should do more to reduce improper payments among the provider and supplier types and in the geographic locations that present a high risk to the financial integrity of Medicare. This includes focusing on provider types that OIG and CMS have found to have extremely high rates of improper payments, such as chiropractors and home health providers, as well as high-risk hospital services.

HHS should continue to address and resolve program integrity weaknesses that OIG has identified. For example, CMS should implement the requirement for home health agencies to obtain surety bonds to ensure that Medicare can recoup at least some of its overpayments and to potentially deter ill-intended providers. Additionally, CMS should prevent Medicare payments for services to incarcerated beneficiaries by developing and implementing a system that collects the information necessary to identify which beneficiaries are incarcerated.

Combating Fraud. Program integrity requires vigilance and sustained focus on preventing problems from occurring, quickly detecting problems that do occur, and swiftly addressing problems by holding

² Three years ago, the Office of the National Coordinator for Health Information Technology (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>). Known as the "10-Year Vision Paper," this document 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>), which supports the vision laid out in the 10-Year Vision Paper. ONC has also issued a report to Congress on "information blocking" (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>); and an updated Federal Health IT Strategic Plan for 2015–2020 (http://www.healthit.gov/sites/default/files/9-5-federalhealthitstratplanfinal_0.pdf).

³ CMS, "State Breakdown of Registration by Medicaid and Medicare Providers through August 31, 2017," October 2017.

⁴ The Office of Civil Rights (OCR) issued a factsheet (<http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>); OCR and ONC released educational videos (<https://www.healthit.gov/access>); and ONC issued a patient engagement playbook (<https://www.healthit.gov/playbook/pe/>).

any wrongdoers accountable and implementing appropriate risk-mitigation tools. Although progress has been made in some vital areas, more must be done to safeguard the Medicare program from fraud, waste, and abuse. CMS should fully employ available program integrity tools to prevent payment to fraudulent providers. For example, CMS must continue improving its oversight and the performance of contractors implementing Medicare provider enrollment safeguards. CMS should also make better use of the performance results within its Fraud Prevention System to refine and enhance its predictive analytic models.

Fostering Prudent Payment Policies. Certain reforms to the Medicare payment structures for hospitals, SNFs, and hospices may require legislative changes, and HHS should work with the Administration and Congress to consider policy options. However, CMS can take some actions within existing authorities to mitigate financial risks and quality-of-care risks under the current systems. For example, CMS should reform the payment policy for hospices to align payments to costs and address the financial incentives for hospices to target beneficiaries likely to have long stays. CMS should also adjust Medicare payments to SNFs to eliminate any increases in payments for therapy that is unrelated to beneficiary characteristics and use data analytics to target oversight to SNFs that may be inappropriately billing for therapy.

Health Care Reforms and the Promise of Health IT. To continue managing the transition to the QPP, CMS must address a variety of issues impacting a diverse set of stakeholders. Physician representatives have identified the following challenges: complex reporting and measurement; limited scope and availability of APMs; needs for provider education; daunting timelines; significant infrastructure investments needed to meet new business and reporting requirements; and administrative burden. CMS should allocate sufficient resources to ensure issuance of timely and clear program regulations and guidance that address physician representatives' concerns. In addition to supporting physician readiness, CMS must ensure that it has well-functioning, physician-oriented websites; fully operational back-end payment and data systems for the QPP; and robust program integrity systems to ensure the accuracy of submitted data. CMS also needs to develop quality measures as outlined in the Quality Measure Development Plan and monitor for any unintended impacts that the quality measures have on Medicare beneficiaries.

As CMS manages new Medicare models, it should continue to focus on program-integrity risks of those models and incorporate safeguards to reduce them. It should also assess the effectiveness of the safeguards it employs, promptly correcting identified issues. This is especially important for models that introduce new payment incentives, which might lead to new fraud schemes, and for models for which waivers of payment, coverage, or fraud and abuse laws may have been issued. CMS should also ensure that models achieve their intended outcomes with regard to quality of care and efficiency. Further, where applicable, CMS must clearly define actionable and meaningful quality measures, ensuring their reliability and accuracy.

New models and value-based designs rely significantly on data, EHRs, and technology. CMS must ensure that data collected and provided are complete, accurate, timely, and secure and that evolving technologies, such as telemedicine, achieve their intended results. HHS must address barriers to the appropriate flow of complete, accurate, timely, and secure data among providers, beneficiaries, and other stakeholders. To the extent that resources, cost, and quality performance are measured on the basis of Medicare Parts A and B claims data, CMS must ensure the soundness and reliability of such data.

CMS should adopt sound record-retention and documentation practices for all models while being mindful of minimizing the burdens placed on those implementing the practices.

Key OIG Resources

- OIG Testimony, “Medicare and Medicaid Program Integrity: Combating Improper Payments and Ineligible Providers,” May 2016.
(<https://oig.hhs.gov/testimony/docs/2016/maxwell-testimony05242016.pdf>)
- OIG Online Portfolio: Home Health, February 2016. (<https://oig.hhs.gov/reports-and-publications/portfolio/home-health/index.asp>)
- OIG Report, *The Medicare Payment System for Skilled Nursing Facilities Needs To Be Reevaluated*, September 2015. (<https://www.oig.hhs.gov/oei/reports/oei-02-13-00610.pdf>)
- OIG Report, *Medicare Could Have Saved Billions at Critical Access Hospitals If Swing-Bed Services Were Reimbursed Using the Skilled Nursing Facility Prospective Payment System Rates*, March 2015. (<https://oig.hhs.gov/oas/reports/region5/51200046.asp>)
- OIG Report, *Medicare Shared Savings Program Accountable Care Organizations Have Shown Potential for Reducing Spending and Improving Quality*, August 2017. (<https://oig.hhs.gov/oei/reports/oei-02-15-00450.asp>)
- OIG Report, *The Centers for Medicare & Medicaid Services Could Improve Performance Measures Associated With the Fraud Prevention System*, September 2017. (<https://oig.hhs.gov/oas/reports/region1/11500509RIB.pdf>)
- OIG Report, *Medicare Paid Hundreds of Millions in Electronic Health Record Incentive Payments That Did Not Comply With Federal Requirements*, June 2017. (<https://oig.hhs.gov/oas/reports/region5/51400047.pdf>)

Top Management Challenge #2: Ensuring Program Integrity in Medicaid

Why This Is a Challenge

With almost 69 million enrolled individuals, Medicaid serves more enrollees than any other Federal health care program and represents one-sixth of the national health care economy. Medicaid is jointly administered and funded by CMS at the Federal level and by States. CMS reported that combined Federal and State Medicaid expenditures were \$574 billion for FY 2016.

Effectively overseeing Medicaid continues to be a top management challenge for HHS. Challenges include longstanding program integrity vulnerabilities, including limitations in national Medicaid data that make it more difficult to detect and address improper payments and fraud. CMS needs to partner with and support States in efficiently and effectively delivering high-quality Medicaid benefits to those who are eligible and protecting the programs and enrollees from fraud, waste, and abuse. At the same time, CMS must also oversee States' adherence to Medicaid rules governing eligibility, payment, program integrity, and Federal–State cost-sharing. In addition, the vast majority of Medicaid beneficiaries are enrolled in privately run managed care plans. OIG has identified challenges to ensuring that these beneficiaries have access to high-quality care and that Medicaid funds are expended properly. (*For information on challenges specific to Medicaid managed care, see TMC #5.*)

Key Components of the Challenge

- Ensuring compliance with fiscal controls
- Leveraging fraud prevention tools
- Improving national Medicaid data to support program integrity

Key Components of the Challenge

Ensuring Compliance with Fiscal Controls. Reducing improper payments to providers is a critical element in protecting the financial integrity of the Medicaid program. In FY 2016, HHS reported an improper payment rate in the Medicaid program of 10.5 percent. (*For more information on HHS measurement and reporting of improper payments, see TMC #6.*) OIG audits have identified substantial improper payments to providers across a variety of Medicaid services, including school-based services, nonemergency medical transportation, targeted case management services, and personal care services (PCS). OIG has also uncovered improper payments made on behalf of individuals ineligible for Medicaid, deceased beneficiaries, and beneficiaries with multiple Medicaid identification numbers.

Drug manufacturers whose products are covered by Medicaid are required to report certain product and pricing information to CMS and pay rebates to States according to a statutorily defined formula. CMS and States share responsibility for ensuring that manufacturers pay all rebates to which the States and Federal Government are entitled. Ensuring that manufacturers report product and pricing information correctly is a challenge for HHS. Manufacturer misreporting can result in manufacturers' underpaying rebates, which inappropriately increases Federal and State Medicaid costs. For example, the drug manufacturer Mylan recently entered into a \$465 million settlement with the United States to resolve allegations that it misclassified a drug in a way that led to underpaying Medicaid rebates. Overseeing States' collection of manufacturer rebates is also a challenge for HHS. OIG has identified instances in which States have not billed for or collected Medicaid rebates for physician-administered drugs, forgoing money owed to those States and the Federal Government.

CMS also faces challenges in ensuring that States appropriately apply criteria for Medicaid eligibility and for waiver programs. This is crucial to ensuring that CMS pays States the correct Federal share of

Medicaid expenditures. For States that opted to expand Medicaid coverage, CMS faces the added challenge of ensuring that States do not incorrectly categorize enrollees as “newly eligible,” which would inappropriately shift costs from the State to the Federal Government. For example, OIG found that one State’s failure to verify Medicaid eligibility data resulted in \$105 million in Federal payments for potentially ineligible beneficiaries. OIG has also found that States have claimed unallowable and unsupported Federal Medicaid payments under waiver programs for home and community-based services (HCBS). While waiver programs can offer important flexibilities for States, CMS is challenged to oversee the financial integrity of these varied programs.

Further, the shared nature of Medicaid financing provides opportunities for States to shift costs to the Federal Government. OIG has identified a number of State policies that may distort the Federal share of Medicaid expenditures, causing the Federal Government to pay an increased amount of Medicaid expenditures. These include the improper use of provider taxes, intergovernmental transfers, supplemental payments, and inflated payment rates that may increase Federal funding that States receive. Such policies may distort the statutorily defined Federal share of Medicaid expenditures and undermine the Federal–State partnership.

Leveraging Fraud Prevention Tools. OIG has consistently found that there are opportunities to improve program integrity in Medicaid and better protect the program and its beneficiaries from fraud and harm by health care providers. The most effective way to prevent provider fraud is to keep bad actors from enrolling in the program. However, States are not screening high-risk providers with all of the tools at their disposal, including site visits and fingerprint-based criminal background checks. OIG has also raised concerns about the varying standards, and in some cases minimal vetting, for Medicaid PCS providers and providers in group homes that furnish care to the elderly and persons with disabilities. This leaves the Medicaid program vulnerable to financial fraud, and even more concerning, it leaves Medicaid beneficiaries vulnerable to abuse and neglect. *(For more information about quality of care and safety concerns for beneficiaries receiving personal care services, see TMC #4.)* Some States are not collecting and maintaining accurate ownership information about the Medicaid providers they are paying. Moreover, States do not currently have access to comprehensive data on providers that other States have terminated, leaving them vulnerable to enrolling unscrupulous providers already identified in another State.

Improving National Medicaid Data to Support Program Integrity. Data is an essential tool for detecting fraud, waste, and abuse; however, national Medicaid data have deficiencies that hinder timely and accurate fraud detection. One concern is that not all States are submitting data to the national Medicaid database known as the Transformed Medicaid Statistical Information System (T-MSIS). Despite an original deadline of July 2014, as of September 2017, CMS reported that 48 States have started submitting T-MSIS data, and 40 of these States have submitted all required data, including historical data. Getting all of the States to submit data to T-MSIS is not the only challenge. Concerns about the completeness and reliability of the data remain. Data must be complete and reliable to be of use to States, CMS, and other stakeholders in making comparisons across all States and identifying nationwide trends and vulnerabilities.

The lack of national Medicaid data hampers States, CMS, and other stakeholders’ ability to quickly detect potential fraud, waste, or quality concerns at the State, multi-State, and national levels. Unscrupulous providers may commit fraud or harm beneficiaries across multiple States. Fraud schemes

affecting multiple States are very difficult to detect without comprehensive national data. Localized schemes can also be harder to detect without national data. Utilization or spending patterns may not appear problematic until compared against another State's experience or national averages. Recognizing such schemes in one State can alert other States to indicators of fraudulent or abusive practices that may be occurring in their jurisdiction. This information can lead to referrals to State law enforcement agencies like the State Medicaid Fraud Control Units (MFCUs) or joint investigations across State lines.

Progress in Addressing the Challenge

Ensuring Compliance with Fiscal Controls. With regard to improper payments to Medicaid providers, CMS has engaged with State Medicaid agencies to develop corrective action plans that address State-specific reasons for improper payments as a part of CMS's Payment Error Rate Measurement program, which measures Medicaid improper payments. CMS has facilitated national best-practices calls to share ideas across States, provided State education through the Medicaid Integrity Institute, offered ongoing technical assistance, and provided additional guidance as needed to address the root causes of improper payments. CMS has indicated that it continues to provide guidance to States on their procedures for calculating and claiming costs under waiver programs for HCBS.

CMS has also taken actions to curtail inappropriate State financing mechanisms that inflate the Federal share of Medicaid costs. For example, CMS issued guidance to State Medicaid directors and State health officials to clarify the rules for health care provider taxes.

Leveraging Fraud Prevention Tools. CMS has issued guidance, known as the Medicaid Provider Enrollment Compendium, to assist States in strengthening their provider screening and enrollment processes. In particular, CMS's guidance allows States to rely on Medicare provider screening results for providers who participate in both Medicare and Medicaid. CMS also worked with the Federal Bureau of Investigation to issue guidance to help States implement fingerprint-based criminal background checks for high-risk providers. In addition, beginning in 2018 the 21st Century Cures Act will require States, upon terminating a provider from the Medicaid program, to submit certain data to CMS's database of terminated providers, which will improve the effectiveness of this database. In 2016, CMS published a Request for Information in seeking stakeholder input on policy options to address program integrity concerns in personal care and other home and community-based services. Overall, Medicaid fraud-enforcement efforts by OIG and the MFCUs, which OIG oversees, have continued to hold wrongdoers accountable, recover stolen taxpayer dollars, and send a strong message to deter would-be fraudsters. In FY 2016, MFCUs reported more than 1,500 convictions, nearly 1,000 civil settlements and judgments, and almost \$1.9 billion in criminal and civil recoveries.

OIG Focus Area: Partnering With MFCUs to Combat Medicaid Fraud

MFCUs are key partners in battling fraud, waste, and abuse in Medicaid. OIG administers grants to MFCUs, the State agencies authorized to fight waste, fraud, and abuse and to prevent patient neglect and exploitation. OIG also partners with MFCUs in joint investigations and provides them technical assistance. In FY 2018, OIG will continue to prioritize work that maximizes the effectiveness of MFCUs.

Improving National Medicaid Data to Support Program Integrity. CMS continues to work with all State Medicaid agencies to submit complete, accurate, and timely data to T-MSIS. According to CMS, as of September 2017, the number of States submitting any T-MSIS data had increased to 48, representing 94

percent of the total Medicaid population, and CMS indicated that it expects all States to submit T-MSIS data by the end of 2017. CMS also reported efforts underway to improve T-MSIS data quality, including working with States to improve the quality of their data submissions and convening a technical expert panel to make recommendations to improve T-MSIS data quality. In addition, CMS reported that it is working to develop “research-ready” T-MSIS analytic files to make the data more consumable by a wide array of users.

What Needs To Be Done

The Medicaid program can and should be designed to minimize fraud, waste, and abuse by following core program integrity principles. Better protection of Medicaid now and in the future requires continual vigilance to keep up with changes in the environment and constantly evolving fraud schemes.

Ensuring Compliance With Fiscal Controls. CMS should continue to engage with State Medicaid agencies to develop corrective action plans and provide specific guidance to States regarding services and benefits most vulnerable to improper payments. OIG is currently assessing CMS’s oversight of drug classifications and other aspects of the Medicaid drug rebate program and identifying opportunities for improvement as needed. CMS should work with States to ensure that they are applying Medicaid eligibility criteria correctly and should conduct sufficient oversight to prevent and detect any inappropriate assignment of enrollees to the higher Federal matching rate. In addition, CMS should closely review State Medicaid plans and plan amendments to identify any potentially inappropriate cost-shifting from States to the Federal Government.

Leveraging Fraud Prevention Tools. CMS should continue to work with States to leverage fraud-prevention tools. Providing guidance was an important step. CMS should also continue to work directly with those States that—despite the guidance—have not yet implemented tools like site visits or fingerprint-based criminal background checks for high-risk providers. In addition, CMS should develop a central repository or “one-stop shop” with provider information that all States and Medicare can use. This could reduce data-collection duplication and burdens on States and providers and improve the completeness and accuracy of the data available to all of these programs.

Improving National Medicaid Data to Support Program Integrity. CMS and the States need to make complete, reliable, and timely T-MSIS data a management priority. In doing so, CMS should establish and adhere to a deadline for when T-MSIS data will be available for program analysis and other management functions. CMS should monitor States’ progress toward complete, reliable, and timely data submissions and use its available enforcement authorities when appropriate.

Key OIG Resources

- OIG Testimony, “Combating Waste, Fraud, and Abuse in Medicaid’s Personal Care Services Program,” May 2017. (<https://oig.hhs.gov/testimony/docs/2017/grimm-testimony-05022017.pdf>)
- OIG Testimony, “Medicaid Oversight: Existing Problems and Ways to Strengthen the Program,” January 2017. (<https://oig.hhs.gov/testimony/docs/2017/maxwell-testimony01312017.pdf>)
- OIG Testimony, “Examining Medicaid and CHIP’s Federal Medical Assistance Percentage,” February 2016. (<https://oig.hhs.gov/testimony/docs/2016/hagg-fmap-hearing-02-05-2016.pdf>)
- OIG Report, *Providers Terminated from One State Medicaid Program Continued Participating in Other States*, August 2015. (<https://oig.hhs.gov/oei/reports/oei-06-12-00030.pdf>)

- OIG Report, *T-MSIS Data Not Yet Available for Overseeing Medicaid*, June 2017.
(<https://oig.hhs.gov/oei/reports/oei-05-15-00050.pdf>)

Top Management Challenge #3: Curbing the Opioid Epidemic

Why This Is a Challenge

Opioid abuse and related overdoses are a national epidemic. According to the Centers for Disease Control and Prevention (CDC), more than 33,000 people died in 2015 from overdoses involving opioids, both prescription and illicit, an increase from approximately 28,000 deaths in 2014.⁵ Yet despite the increase in the number of people suffering from opioid use disorder, only about one-fifth of individuals receive specialty treatment, and even fewer receive medication-assisted treatment (MAT).^{6, 7}

Across multiple operating divisions and programs, HHS has many opportunities to help curb this epidemic. Medicare provides prescription drug coverage for 41 million Part D beneficiaries and Medicaid for almost 69 million beneficiaries. The U.S. Food and Drug Administration (FDA) oversees the approval and safe use of prescription drugs. Agencies such as the National Institutes of Health (NIH), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Health Resources and Services Administration (HRSA), and the CDC award grants to support health care providers, researchers, and States in their efforts to combat the epidemic.

Key Components of the Challenge

- Addressing inappropriate prescribing of opioids
- Combating fraud and diversion of prescription opioids and potentiator drugs
- Addressing inadequate access to treatment
- Addressing misuse of grant funds
- Fighting fraud by treatment providers of opioid use disorder

Key Components of the Challenge

Addressing Inappropriate Prescribing of Opioids. OIG found that many patients in Medicare Part D received concerning amounts of opioids in 2016. Specifically, half a million Medicare Part D beneficiaries (without a cancer diagnosis and not in hospice care) received opioids with an average daily morphine equivalent dosing (MED) greater than 120 mg for at least 3 months, exceeding the 90-mg MED level that CDC recommends staying below. While many beneficiaries receive opioids to treat legitimate health needs, these numbers raise concern that a significant number of beneficiaries may be receiving levels of prescribed opioids that are medically unnecessary and unsafe. OIG has also found that FDA lacks comprehensive data to assess whether its Risk Evaluation and Mitigation Strategies (REMS), set up to improve drug safety, are indeed meeting their goal. FDA has asked drug companies to establish a number of such programs for various drugs, including opioids; however, REMS performance remains a concern.

⁵ Rose A. Rudd, Puja Seth, Felicita David, and Lawrence Scholl, *Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015*, *Morbidity and Mortality Weekly Report (MMWR)*, Centers for Disease Control and Prevention ePub, December 30, 2016. Available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>.

⁶ National Institutes of Health, “Substance Abuse and Mental Health Services Administration National Survey on Drug Use and Health 2016 Detailed Tables,” 2017. Available at <https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.htm>.

⁷ Anjalee Sharma, et al., “Update on Barriers to Pharmacotherapy for Opioid Use Disorders,” *Current Psychiatry Reports* 19(6): 35, 2017. Available at <https://link.springer.com/article/10.1007%2Fs11920-017-0783-9>.

Combating Fraud and Diversion of Prescription Opioids and Potentiator Drugs. Prescription opioids indicated to treat pain and those indicated to treat opioid use disorder (buprenorphine in particular) are at high risk of diversion. Also at risk for diversion are potentiator drugs, which exaggerate euphoria when combined with opioids and escalate the potential for opioid overdose. These nonopioid drugs can be prescription or over-the-counter medications and may be indicated to treat conditions very different from pain, such as HIV, psychiatric disorders, and even colds. OIG and State MFCUs have growing caseloads of Medicare and Medicaid drug-diversion investigations involving opioids and potentiator drugs.

Addressing Inadequate Access to Treatment. According to SAMHSA, 1.9 million people had disorders related to their nonmedical use of prescription pain relievers in 2015.⁸ Medicare and Medicaid beneficiaries make up a large proportion of those with opioid use disorders.⁹ With such high numbers of individuals in need, access to treatment of overdose and underlying opioid use disorders is a priority. Naloxone, an effective treatment for opioid overdoses, may not be readily available in an overdose emergency, and challenges exist in ensuring that people have access to quality treatment programs. In particular, an estimated 80 percent of people do not receive treatment for their underlying opioid use disorder.¹⁰

Addressing Misuse of Grant Funds. Through Federal grants, HHS commits substantial financial resources to combat the opioid epidemic. HHS awards grants for a range of efforts such as furthering pain management research; expanding access to opioid treatment programs; improving data access and quality to assist with prevention efforts; and providing education and training to health care practitioners. Ensuring that these funds are used for their intended purposes is paramount, and HHS faces challenges in protecting the integrity of grant programs. For instance, OIG has identified cases in which individuals falsified grant applications and used for personal gain grant funds that were intended to fight drug abuse.

Fighting Fraud by Treatment Providers of Opioid Use Disorder. Fraud committed by providers of treatment for opioid use disorder is a growing concern. Fraud schemes include the delivery of mental health services by unqualified providers and billing Medicare or Medicaid for medically unnecessary lab tests, such as urine drug screens recurring at a higher frequency than what is reasonable for that test. Such schemes may also involve billing for medically unnecessary drugs such as opioids or expensive specialty medications. Fraud in these settings can put beneficiaries at risk and diverts scarce funds needed to meet growing demand for legitimate treatment.

⁸ SAMHSA, *Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health*, 2015. Available at <https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf>.

⁹ According to CMS, more than 6 of every 1,000 Medicare beneficiaries and 8.7 of every 1,000 Medicaid beneficiaries have an opioid use disorder. See Centers for Medicare & Medicaid Services (CMS), *Opioid Misuse Strategy 2016*, January 5, 2017. Available at <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/Downloads/CMS-Opioid-Misuse-Strategy-2016.pdf>.

¹⁰ National Institutes of Health, National Institute on Drug Abuse, “[Drug Facts: Nationwide Trends](https://www.drugabuse.gov/publications/drugfacts/nationwide-trends),” June 2015. Available at <https://www.drugabuse.gov/publications/drugfacts/nationwide-trends>.

Progress in Addressing the Challenge

Effectively coordinating efforts across HHS programs and operating divisions and prioritizing initiatives are key to combating this complex public health emergency. To improve coordination and to focus efforts, the Department established the HHS Opioid Strategy, which aims to improve access to treatment and recovery services and support alternative improvements in pain management. Many operating divisions have also established their own strategic plans to help fight the opioid crisis.

Addressing Inappropriate Prescribing of Opioids. In recognition that prescribing practices can exacerbate the misuse and abuse of prescription opioids, CDC has issued *Guideline for Prescribing Opioids for Chronic Pain* to aid providers in treating chronic pain outside of active cancer treatment, palliative care, and end-of-life care. In turn, FDA has been expanding its efforts to ensure safe use of opioids through its REMS authorities and encouraging the efforts of pharmaceutical companies to develop formulations of opioids that are more resistant to abuse. *(For more information about FDA's roles in overseeing prescription drug safety, see TMC #8.)*

Combating Fraud and Diversion of Prescription Opioids and Potentiator Drugs. To identify and address suspected fraud, CMS conducts data analysis through its National Benefit Integrity Medicare Drug Integrity Contractor to identify outliers—including those related to opioid prescriptions—and to make referrals for investigation. For Medicaid, CMS compiles and publishes information that it collects from State Medicaid agencies and Medicaid MCOs about their drug utilization review program and processes, which could include employing Prescription Drug Monitoring Programs (PDMP) requirements and the use of “lock-in” programs, which restrict at-risk beneficiaries to particular pharmacies or prescribers. CMS officials reported developing a substance use disorder (SUD) tool for CMS's and State Medicaid agencies' use with T-MSIS data. This SUD tool will provide a standard method of assessing the care and treatment of Medicaid beneficiaries with SUD using a common data set. Through grants issued by CDC and SAMHSA, HHS has also been supporting States' development of PDMPs.

CMS also reported taking steps in the Part D program to address overutilization of potentiator drugs that are often abused in conjunction with opioids. These steps included encouraging Part D sponsors in its 2017 Call Letter to evaluate their claims data and use drug utilization management tools to help address the concurrent use of opioids and benzodiazepines. According to CMS, it started reporting concurrent opioid and benzodiazepine use to Part D sponsors in October 2016. CMS reported to OIG that it expects Part D sponsors to consider benzodiazepine use within their opioid overutilization review process and include this information in their discussions with prescribers.

Addressing Inadequate Access to Treatment. To improve access to the overdose treatment naloxone, FDA expedited approval of a nasal spray version of that drug. HHS has also been working to improve

OIG Focus Area: Protecting Beneficiaries From Opioid and Prescription Drug Abuse

OIG prioritizes program enforcement and oversight activities that protect beneficiaries from prescription drug abuse. Leveraging its enforcement authorities, OIG worked with other law enforcement partners to charge 120 defendants with opioid-related crimes during a national takedown in July 2017. So far this year, OIG has also issued exclusion notices to 295 providers for conduct related to opioid diversion and abuse. OIG's oversight work will continue to review issues related to opioids in HHS programs.

access to treatment for opioid use disorders. The Medication Assisted Treatment for Opioid Use Disorders final rule, published in July 2016, expands access to medication-assisted treatment services by allowing qualifying practitioners to request approval to treat up to 275 patients at a time with buprenorphine. HHS has also been implementing provisions of the Comprehensive Addiction and Recovery Act (CARA) of July 2016 that aim to increase access to addiction treatment services by expanding the buprenorphine-prescribing privileges of select providers, including nurse practitioners and physician assistants.

In addition, HHS has been supporting expansion of treatment options through a series of grant programs. Most of SAMHSA's \$500 million authorized under the 21st Century Cures Act for FY 2017 has been granted to support increased access to treatment. In addition, much of HRSA's \$94 million in grant funding for community health centers focused on treatment services—including medication-assisted treatment—for opioid use disorder.

Addressing Misuse of Grant Funds. Thus far, HHS efforts to address grant fraud have not been specific to opioids, but rather extend broadly to all types of grants. *(For more information on HHS efforts to prevent grant fraud, see TMC #7.)*

Fighting Fraud by Treatment Providers of Opioid Use Disorder. HHS published a final rule in September 2016 that outlined annual reporting requirements for providers with increased patient limits for medication-assisted treatment using buprenorphine, including reporting on diversion control plans. *(For more information about overall HHS efforts to prevent health care fraud in Medicare and Medicaid, see TMCs #1, #2, and #6.)*

What Needs To Be Done

In addition to deploying the grant funding for opioid use disorder treatment authorized under the 21st Century Cures Act, HHS should continue implementing new authorities under CARA that would help address the opioid epidemic. For example, CARA established new authority for Medicare Part D plan sponsors to develop lock-in programs, which help to protect beneficiaries from the harm of inappropriate utilization and protect the program from drug diversion. In addition, as discussed with OIG, CMS should continue to monitor available literature, clinical guidelines, information from other stakeholders, and internal data to proactively identify other opioid potentiators that may increase the risk of overdose when used together with opioids. Once identified, CMS should raise awareness on emerging trends and expand its policy and the Overutilization Monitoring System to include these drugs.

As access to treatment for opioid use disorders is expanded, HHS must also ensure that treatment programs and providers comply with program requirements. For example, in 2016 SAMHSA finalized regulations to increase access to providers of treatment for opioid use disorder. SAMHSA will need to oversee compliance with all these requirements. Likewise, SAMHSA will need to oversee the integrity and effectiveness of \$1 billion in funding for the State Targeted Response to the Opioid Crisis Grants.

In addition, HHS should improve access to data about drug utilization and prescribing patterns. CMS should strive toward the development of complete and reliable national Medicaid data to enhance fraud-fighting efforts through better detection of questionable billing of opioids and potentiator drugs. *(For more information on challenges for Medicaid, see TMC #2.)* FDA should continue to evaluate the effectiveness of its opioids REMS programs and adjust them accordingly. Relevant HHS agencies should

also continue supporting efforts to integrate PDMP data into the broader health care system, as these data enable providers to assess a patient's risk for abuse and misuse. In doing so, HHS will need to ensure appropriate safeguards to protect the privacy and security of these data. *(For more information on data security issues, see TMC #10.)*

In August 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis made a number of recommendations.¹¹ To the extent that these recommendations are followed, they may further expand HHS efforts to combat this crisis. OIG calls for HHS to include appropriate program integrity safeguards as it expands and implements new programs to attempt to curb the opioid epidemic.

Key OIG Resources

- OIG Data Brief, "Opioids in Medicare Part D: Concerns About Extreme Use and Questionable Prescribing," July 2017. (<https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf>)
- OIG Data Brief, "High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns," June 2016. (<https://oig.hhs.gov/oei/reports/oei-02-16-00290.pdf>)
- OIG Data Brief, "Questionable Billing and Geographic Hotspots Point to Potential Fraud and Abuse in Medicare Part D," June 2015. (<https://oig.hhs.gov/oei/reports/oei-02-15-00190.pdf>)
- OIG Report, *Early Outcomes Show Limited Progress for the Transformed Medicaid Statistical Information System*, September 2013. (<https://oig.hhs.gov/oei/reports/oei-05-12-00610.pdf>)
- OIG Fact Sheet, "2017 National Health Care Fraud Takedown," July 2017. (https://oig.hhs.gov/newsroom/media-materials/2017/2017HealthCareTakedown_FactSheet.pdf)
- OIG Report, *FDA Lacks Comprehensive Data To Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety*, February 2013. (<https://oig.hhs.gov/oei/reports/oei-04-11-00510.pdf>)

¹¹ Commission on Combating Drug Addiction and the Opioid Crisis, *Draft Interim Report*, July 31, 2017. Available at <https://www.whitehouse.gov/sites/whitehouse.gov/files/ondcp/commission-interim-report.pdf>.

Top Management Challenge #4: Improving Care for Vulnerable Populations

Why This Is a Challenge

HHS programs provide critical health and human services to many vulnerable populations, including individuals who receive nursing home care, group home care, hospice care, or home and community-based services (HCBS), as well as children from low-income families in foster care. HHS must ensure that these individuals have access to and receive high-quality services and are protected from abuse or neglect.

HHS faces challenges in serving these vulnerable populations. For example, many of these services are delivered through programs—such as Medicaid, the National Aging Network, and the Child Care and Development Fund—that are not operated directly by HHS. As such, HHS has less transparency into the programs and less direct influence.

(For more information about limitations in Medicaid data, see TMC #2.)

Furthermore, even where HHS has direct oversight levers, such as through the survey and certification process for nursing homes, OIG's work shows that the Department has not always taken action to ensure that deficiencies are corrected.

Key Components of the Challenge

- Addressing substandard nursing home care
- Reducing problems in hospice care
- Mitigating risks to individuals receiving home and community-based services
- Ensuring access to safe and appropriate services for children

Key Components of the Challenge

Addressing Substandard Nursing Home Care. Nursing facilities continue to experience problems ensuring quality of care and safety for people residing in them. OIG identified instances of substandard care causing preventable adverse events, finding that an estimated 22 percent of Medicare beneficiaries had experienced an adverse event during their nursing home stay. OIG has also raised concerns about the potentially inappropriate use of powerful antipsychotic drugs for nursing home residents. In addition, CMS has often failed to require nursing facilities to correct all deficiencies identified during the survey process, and OIG has identified nursing home staff who do not meet relevant licensure requirements.

Further, OIG continues to raise concerns about nursing home residents being at risk of abuse and neglect. In some instances, nursing home care is so substandard that providers may have liability under the False Claims Act. OIG recently alerted CMS to instances of nursing facilities' failures to identify and report abuse and neglect as required and deficiencies in procedures for enforcing these requirements. OIG alerted CMS about 134 Medicare beneficiaries treated in 2015 and 2016 for injuries that may have been caused by abuse or neglect while the beneficiary was receiving care in a nursing home.

Reducing Problems in Hospice Care. Hospice care provides comfort for terminally ill beneficiaries and supports family and other caregivers. OIG observed problems in hospice care including inadequate oversight of certification surveys and staff licensure requirements, care planning failures, inadequate medical and nursing care, and fraudulent enrollments undertaken without beneficiary consent and enrollment of beneficiaries who were not terminally ill. OIG found that some hospices billed Medicare for inappropriate general inpatient care (the second highest and most expensive level of hospice care), such as billing for care that was not provided and beneficiaries receiving care they did not need.

Furthermore, OIG found that some hospice care plans lacked required information, and our review identified numerous instances of quality-of-care problems in the hospice general inpatient care setting.

Mitigating Risks to Individuals Receiving HCBS. HCBS, including personal care services (PCS), respite care, home-delivered meals, and many other services help beneficiaries stay in their communities and avoid costly and sometimes nonpreferred institutional care. PCS, a critical component of HCBS, encompass all HCBS populations, including people with mental disorders and physical, cognitive, or developmental disabilities. Without effective PCS, the goal of integrating beneficiaries into their communities may be unattainable. These programs help promote beneficiary choice and preferences, but vulnerabilities persist in the areas of payment, compliance, and quality. OIG and MFCUs have uncovered numerous instances of PCS fraud and abuse or neglect causing serious harm to HCBS recipients. Some beneficiaries may be unable to report the abuse and neglect. In some cases, a beneficiary's guardian may collude with an unscrupulous PCS attendant. In one such case, the parents of a teenage boy with disabilities accepted kickbacks from a PCS attendant who for many years billed Medicaid for thrice-weekly home visits but did not provide the boy with desperately needed services. PCS claims often do not identify the dates of service or the PCS attendant who provided the service, which creates additional challenges for effective oversight and enforcement.

Many Medicaid beneficiaries with developmental disabilities and older adults use group-home settings to continue living in their communities. However, reports of abuse and even death in such settings raise significant concerns. OIG has found that State agency and group-home staff lack adequate training to correctly identify and report critical incidents and reasonable suspicions of abuse or neglect.

Ensuring Access to Safe and Appropriate Services for Children. In partnership with the States, HHS operates Medicaid and the Children's Health Insurance Program (CHIP) to provide medical care for nearly 36 million children, including children who are from financially needy families, reside in foster care, and have disabilities. The Child Care and Development Fund (CCDF) supports childcare for about 1.4 million children from low-income families while their guardians work or attend school. Ensuring that these beneficiaries enjoy access to safely delivered, high-quality services remains a longstanding challenge for HHS. OIG has identified vulnerabilities related to CCDF childcare providers who received neither a verified background check nor the necessary training.

Ensuring access to appropriate and high-quality care for children in foster care and those covered by Medicaid continues to be a challenge. OIG reviews revealed that many such children do not receive required medical or dental services. Further, OIG has raised quality-of-care concerns related to inappropriate prescribing of antipsychotic drugs for children in foster care and covered by Medicaid.

OIG Focus Area: Protecting the Health and Safety of Children in HHS Programs

Protecting the health and safety of children receiving childcare through HHS programs is a top priority for OIG. Ensuring that Federal funds for these programs serve their intended purposes and are not mismanaged or stolen is also crucial. Specifically, OIG is prioritizing work that identifies ways in which HHS can improve program integrity for the Child Care Development Fund. We will focus on internal controls; program effectiveness; and prevention of fraud, waste, and abuse in this grant program. This initiative will include monitoring States' implementation of criminal background checks for childcare providers at least every 5 years.

Additionally, OIG found that three out of four children covered by Medicaid did not receive all required dental services, with one in four children failing to see a dentist at all.

The Department also faces challenges caring for children who enter the United States unaccompanied by a parent or guardian. The Office of Refugee Resettlement, within the Administration for Children and Families (ACF), provides housing, medical care, and other services for unaccompanied alien children (UAC) and is responsible for placing many UAC with appropriate sponsors pending legal proceedings to resolve the UAC's immigration status.

Progress in Addressing the Challenge

HHS continues its efforts to improve the quality of nursing home, hospice, and HCBS programs, as well as services for especially vulnerable children.

Addressing Substandard Nursing Home Care. Through its Nursing Home Compare program and Five-Star Quality Rating System, HHS strives to provide residents and families accurate information about nursing home quality to enable informed care choices. Through the National Partnership to Improve Dementia Care in Nursing Homes and other initiatives, HHS continues efforts to reduce excessive use of antipsychotic drugs in nursing homes and has reported a 34 percent decrease in the use of these drugs among long-term nursing home residents since the program's inception. HHS reports progress developing the Skilled Nursing Facility Value-Based Purchasing Program, planned for launch in FY 2019, to better link payment to quality and achieve quality goals such as reducing preventable hospital admissions. HHS continues to work closely with law enforcement partners at the Department of Justice and through the Federal Elder Justice Interagency Working Group to promote better care for older adults and to prosecute providers that subject them to abuse or neglect.

When a False Claims Act settlement resolves allegations of poor, substandard, or worthless quality of care, OIG may impose obligations on the provider through a "quality of care" corporate integrity agreement (CIA), which requires providers to retain an independent monitor to perform clinical and quality reviews and assessments of the delivery of quality health care. OIG has entered into quality-of-care CIAs with more than 40 nursing home companies covering more than 1,000 facilities.

Reducing Problems in Hospice Care. HHS continues its efforts to help patients and families make informed hospice choices. In August 2017, it launched the Hospice Compare website to facilitate public access to hospice quality data. HHS also continues to undertake enforcement actions against hospice providers that fraudulently enroll Medicare beneficiaries.

Mitigating Risks to Patients Receiving HCBS. HHS continues to work with MFCUs and law enforcement partners to prevent, detect, and take enforcement action against fraudulent PCS providers. In July 2016, CMS issued guidance for PCS agencies and attendants on preventing improper payments. In August 2016, CMS issued an informational bulletin that discussed States' ability to implement basic training for home care workers in topics such as first aid and CPR certification. CMS also issued an informational bulletin summarizing program integrity vulnerabilities in Medicaid PCS and highlighting safeguards States can employ.

Ensuring Access to Safe and Appropriate Services for Children. In 2014, Congress reauthorized the Child Care and Development Block Grant (CCDBG) Act. The Act sets basic health and safety standards

for CCDF-funded childcare and requires that staff undergo criminal background checks. These staff background checks are required as of September 30, 2017, unless the Secretary of Health and Human Services grants the State an extension. ACF is working with States to overcome various implementation challenges and operationalize the background check processes for childcare providers.

CMS is also working with States to reduce inappropriate prescribing of antipsychotic drugs for children in foster care and those covered by Medicaid and to improve access to dental care for children in Medicaid. According to CMS, these efforts include providing technical assistance to support States in measuring, monitoring, and authorizing treatment of antipsychotic drug use in children. CMS is adding new measures related to antipsychotic drug use to the core set of children's health care quality measures for voluntary use by States. In addition, CMS reported that it engages with States that have lower reported rates of oral health services to collaborate with CMS, national oral health leaders, and other interested stakeholders through an effort called the Oral Health Initiative 2.0.

What Needs To Be Done

Addressing Substandard Nursing Home Care. OIG has recommended numerous strategies for HHS to strengthen its oversight of nursing homes and improve nursing home care. For example, HHS should monitor how often nursing home residents are hospitalized and develop additional resources to help providers avoid adverse events. In addition, HHS 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 and prevent their recurrence.

Federal law requires that crimes, like abuse or neglect, against residents in federally funded nursing homes be reported to law enforcement and the Department. HHS should take the following steps to ensure that such incidents are identified and reported: (1) implement procedures to use claims for emergency room treatment of nursing home patients to identify potential abuse or neglect or other serious events, and (2) appropriately delegate and operationalize the authority to impose civil monetary penalties or exclusion from participation in Federal health care programs against individuals or entities that fail to fulfill their reporting obligations.

Reducing Problems in Hospice Care. CMS should improve hospice oversight by (1) increasing physician involvement in decisions regarding general inpatient care, (2) establishing additional remedies for poor-performing hospices, (3) educating providers and beneficiaries about hospice enrollment requirements, and (4) developing and disseminating model text for hospice election statements. HHS should also continue developing policies that effectively link payment to quality. In addition, CMS should monitor hospice providers and claims and refer suspected fraud to OIG, as appropriate.

Mitigating Risks to Patients Receiving HCBS. Ensuring high-quality HCBS and enabling beneficiaries to avoid or delay institutionalization relies heavily on appropriate PCS. OIG has recommended that HHS should (1) establish minimum Federal qualifications and screening standards for PCS workers, (2) require States to enroll or register all PCS attendants and assign them unique numbers, and (3) require that PCS claims identify the dates of service and the PCS attendant who provided the service. In addition to PCS, States and HCBS providers, including those that deliver services in group homes, must better protect beneficiaries from abuse and neglect and establish better training and more effective policies and procedures to ensure critical incidents are reported to relevant authorities as required. Specifically, States need access to relevant Medicaid data for injuries that require emergency room visits or hospital

admissions in order to detect whether beneficiaries were involved with critical incidents and whether those incidents were reported and investigated within required timeframes. In addition, policies and procedures must be followed and results reported to State and Federal stakeholders to ensure accountability at the State and provider levels.

To assist States in developing and implementing better policies and procedures, OIG—in partnership with the Administration for Community Living and HHS Office for Civil Rights—is developing model practices for group homes. The model practices provide States with a roadmap for how to create a compliance oversight program that better protects the health and safety of individuals receiving HCBS in group homes. The model practices focus on four critical compliance areas: (1) incident management and investigation, (2) mortality review, (3) quality assurance, and (4) auditing.

Ensuring Access to Safe and Appropriate Services for Children. ACF must fully implement its new authorities to ensure safer CCDF-funded childcare. ACF must ensure that States have the required health and safety policies and procedures in place to better protect children receiving CCDF services. HHS should also work to better ensure children’s access to appropriate and high-quality Medicaid-covered medical and dental services. This includes ensuring the quality of the care provided to children receiving antipsychotic drugs.

Key OIG Resources

- OIG Report, *Early Alert: The Centers for Medicare and Medicaid Services Has Inadequate Procedures to Ensure that Incidents of Potential Abuse or Neglect at Skilled Nursing Facilities Are Identified and Reported in Accordance with Applicable Requirements*, August 2017. (<https://oig.hhs.gov/oas/reports/region1/11700504.pdf>)
- OIG Report, *Adverse Events in Skilled Nursing Facilities: National Incidence among Medicare Beneficiaries*, February 2014. (<http://oig.hhs.gov/oei/reports/oei-06-11-00370.asp>)
- OIG Report, *Maine Did Not Comply with Federal and State Requirements for Critical Incidents Involving Medicaid Beneficiaries with Developmental Disabilities*, August 2017. (<https://oig.hhs.gov/oas/reports/region1/11600001.pdf>)
- “Investigative Advisory on Medicaid Fraud and Patient Harm Involving Personal Care Services,” October 2016. (<https://oig.hhs.gov/reports-and-publications/portfolio/ia-mpcs2016.pdf>.)
- OIG Testimony, “Combating Waste, Fraud, and Abuse in Medicaid’s Personal Care Services Program,” May 2017. (<https://oig.hhs.gov/testimony/docs/2017/grimm-testimony-05022017.pdf>)
- OIG Report, *Some Florida Family Childcare Homes Did Not Always Comply With State Health and Safety Requirements*, March 2016. (<https://oig.hhs.gov/oas/reports/region4/41408034.pdf>)

Top Management Challenge #5: Ensuring Integrity in Managed Care and Other Programs Delivered Through Private Insurers

Why This Is a Challenge

Millions of enrollees in HHS programs receive health care coverage through private insurance companies and sponsors who contract with CMS or States to deliver benefits and services. In Medicare, approximately 18.6 million Medicare beneficiaries were enrolled in Medicare Advantage (MA) in 2016, more than a threefold increase since 2004, and 39 million beneficiaries received Part D (prescription drug) benefits through plans sponsored by private companies. The majority of Medicaid beneficiaries are enrolled in Medicaid MCOs. In addition, more than 10 million people received health insurance through private plans on health insurance marketplaces (marketplaces) in 2017.

HHS faces challenges in ensuring the integrity of these programs. Improper billing and fraud by health care providers is not limited to Medicare and Medicaid Fee-for-Service programs—MA organizations, Medicare Part D sponsors, and Medicaid MCOs also face these risks. An added challenge in combating health care fraud in these programs is the diffuse structure and responsibilities across HHS, private entities, and States. Further, HHS must oversee the MA organizations and Part D sponsors themselves to ensure that these entities are not inappropriately increasing the per capita payments they receive from Medicare and that they are providing beneficiaries with sufficient access to health care providers, services, and prescriptions as required. For Medicaid, HHS oversees the State's oversight of MCOs. Administering the marketplaces also requires extensive coordination among many Federal, State, and private entities.

Key Components of the Challenge

- Combating fraud, waste, and abuse by health care providers billing managed care plans
- Ensuring integrity and compliance by managed care and Part D sponsors
- Overseeing the health insurance marketplaces

Key Components of the Challenge

Combating Fraud, Waste, and Abuse by Health Care Providers Billing Managed Care Plans. Improper billing and fraud by health care providers is a concern. For example, CMS requires MA organizations and Part D sponsors to implement compliance plans that include measures to prevent, detect, and correct instances of fraud, waste, and abuse. However, these plans vary widely across sponsors, and so does detection of suspected fraud. For example, in 2012 several Part D sponsors reported no instances of potential fraud or abuse, while other sponsors reported identifying up to 13,000 instances of potential fraud. Furthermore, reporting this information to CMS is voluntary, and many sponsors choose not to report. Therefore, CMS lacks visibility into many MA organizations' and Part D sponsors' detection of suspected fraud and abuse incidents. In Medicaid managed care, program integrity responsibilities are even more dispersed, as they are shared among CMS, States, and MCOs, making effective oversight by HHS more complex and challenging.

Limitations in MA and Medicaid MCO encounter data (information about each service provided to beneficiaries) also hinder efficient and effective oversight to prevent fraud, waste, or abuse. OIG found that MA encounter data show promise for program oversight, but some improvements are needed. For example, CMS does not require MA organizations to include the identifiers of ordering or referring providers in their encounter data and requires identifiers for rendering providers only under certain circumstances. These provider identifiers are critical for using MA encounter data to identify patterns of

questionable billing and to pursue fraud investigations. OIG has also raised concerns about incomplete encounter data in Medicaid managed care. States have historically experienced difficulties collecting encounter data from MCOs. In 2011, OIG found that 19 of 38 States did not report some or all of their required MCO encounter data to CMS. *(For additional information on problems with national Medicaid data, see TMC #2.)*

Ensuring Integrity and Compliance by Managed Care and Part D Sponsors. HHS must be vigilant about risks posed to HHS funds and beneficiaries by the MA organizations, Part D sponsors, and Medicaid MCOs contracted to deliver health care services. These entities have incentives to maximize the capitated payments they receive from Medicare or Medicaid while minimizing their costs in providing health care services.¹² In 2016, CMS estimated a gross improper payment rate of \$16 billion to MA organizations, the majority of which was attributable to unsupported diagnoses. Medicare pays higher capitated payments on behalf of sicker beneficiaries than for healthier beneficiaries. In May 2017, the Department of Justice filed a complaint against the largest MA organization alleging that it obtained inflated Medicare payments based on untruthful and inaccurate information about the health status of beneficiaries. In May 2017, an MA organization agreed to pay \$32.5 million to resolve allegations related to inflated Medicare payments as well as allegations that the organization misrepresented the scope and content of its network of providers.

Ensuring that beneficiaries have sufficient access to health care providers through the provider networks of their respective MCOs is also a concern. In a study of Medicaid MCOs, OIG found that more than half of providers listed as participating in Medicaid MCOs were unable to offer appointments and more than a third were not at the location listed in the MCO's plan.

Likewise, protecting beneficiaries from inappropriate denials of services or prescriptions by private entities is also a challenge. Capitated payment models create incentives to keep health care costs low by providing fewer services or prescription drugs; in some cases, the services or drugs could be fewer than beneficiaries medically need. This presents risks to beneficiaries' health and misuses program dollars paid to those entities to provide needed health care. CMS audits have uncovered inappropriate denials of care or prescriptions by MA and Part D sponsors. These audits frequently cite entities for failing to explain to beneficiaries why they denied a request or how the beneficiary can appeal the denial.

Overseeing the Health Insurance Marketplaces. The marketplaces involve complex regulatory, operational, and technological challenges for HHS. Among these are effective communication and coordination between and among internal and external parties with marketplace responsibilities, including within HHS and with contractors, issuers, and partners in State and Federal Government. As the program and its operations evolve, new oversight challenges may arise.

Sound oversight of the marketplaces needs to include the following key program integrity areas:
(1) payments—ensuring that taxpayer funds are being expended correctly and for their intended

¹² For example, a Florida doctor was sentenced to 46 months in prison in 2016 for defrauding an MA organization by misdiagnosing patients to inflate payments. Combating fraud, waste, and abuse by providers in managed care differs from fee-for-service because CMS and managed care or Part D plan sponsors share responsibilities.

purposes; (2) enrollment—making certain that the right people are getting the right benefits; (3) management—ensuring that HHS administration of the program is efficient and effective; and (4) security—safeguarding consumers’ personal information. OIG’s work has identified management challenges and recommendations addressing these areas. These challenges include insufficient payment controls that could lead to wasteful spending; vulnerabilities in ensuring accurate eligibility determinations at the Federal and State-based marketplaces; and challenges for HHS management, including contract administration, contingency planning, and weaknesses in IT security controls.

Progress in Addressing Challenge

Combating Fraud, Waste, and Abuse by Health Care Providers Billing Managed Care Plans. CMS officials report that it is working to improve coordination, information sharing, and availability of reliable data to the Federal, State, and private entities with program integrity responsibilities. CMS has issued guidance on sharing information between CMS contractors and other program integrity stakeholders, such as State agencies, to more effectively coordinate efforts to identify and investigate fraud. CMS is also making progress in validating the completeness and accuracy of MA encounter data. Similarly, CMS continues to work with States to get complete, accurate, and timely Medicaid data. The agency issued a Medicaid managed care rule in 2016 giving States guidelines to work with MCOs on improving encounter data. CMS reports that it has also worked with States on T-MSIS to prioritize the need for complete and accurate encounter data. Further, the agency began requiring more consistent reporting of program integrity issues, such as recoupment of overpayments, from Medicaid MCOs. Finally, CMS issued requirements that MA providers enroll in Medicare through the same screening process as Medicare Fee-for-Service beginning January 1, 2019, which may help to prevent bad actors from entering the program.

Ensuring Integrity and Compliance by Managed Care and Part D Sponsors. CMS audits of MA organizations and Part D sponsors are an important program integrity tool. CMS has initiated dozens of audits to verify the accuracy of enrollee diagnoses (the basis for capitated payment increases or decreases) submitted by MA organizations. In addition, CMS conducts annual compliance audits of a subset of MA organizations and Part D sponsors, which include reviews of compliance program effectiveness and coverage determinations, appeals, and grievances.

CMS reports that it has made progress in reviewing Medicaid managed care rates to ensure that they are actuarially sound. These rates have been reviewed more closely since 2015, and CMS reports working with States to address issues identified in the course of these reviews.

CMS is also working to ensure that MA, Part D, and Medicaid beneficiaries have adequate access to health care providers through their plans. CMS requires State Medicaid agencies to develop and implement provisions that ensure beneficiaries have adequate access to Medicaid-covered services. State standards for provider networks are to be based on reasonable travel time and distance from enrollees’ homes and provider sites, and States must monitor enrollees’ access to care. CMS published a toolkit as a resource guide to assist State Medicaid staff with ensuring adequate provider networks and to highlight effective or promising practices to monitor beneficiaries’ access to providers through their managed care plans. CMS has also developed a tool to help assess network adequacy in MA plans and has proposed expanding its reviews of whether beneficiaries in MA plans have sufficient access to providers.

Overseeing the Health Insurance Marketplaces. CMS has made some progress in addressing the internal controls and management challenges that OIG has identified in the marketplaces. For example, CMS has implemented an automated financial management system for the Federal Marketplace. CMS has also improved its acquisition planning for Federal Marketplace contracts, and it has addressed some challenges in overseeing State-based marketplaces. This includes conducting annual open-enrollment readiness reviews of State-based marketplaces and creating a procedures manual for CMS employees to oversee and monitor the challenges specific to these marketplaces. CMS has developed an integrity program for the Federal Marketplace that addresses monitoring consumer complaints to identify potential fraud and abuse, conducting license verification on agents and brokers, and identifying areas of high risk that warrant further investigation and analysis.

What Needs To Be Done

Combating Fraud, Waste, and Abuse by Health Care Providers Billing Managed Care Plans. HHS should continue to partner with MA organizations, Part D sponsors, and State Medicaid agencies to ensure that payments for health care services are appropriate and to combat fraud by health care providers. This includes facilitating effective coordination and information sharing as well as maintaining accurate, complete, and timely national data to support effective oversight. For instance, CMS should require Part D sponsors and MA organizations to report on their identification of and response to potential fraud incidents. CMS should also require MA organizations to include identifiers for all ordering and referring providers and rendering providers in their encounter data to support fraud detection through data analytics.

Ensuring Integrity and Compliance by Managed Care and Part D Sponsors. CMS should continue to monitor MA organizations' and Part D sponsors' compliance with program requirements through audits and other oversight tools and take appropriate corrective and enforcement actions as needed. CMS should specifically focus on reducing and recouping overpayments resulting from MA organizations' misreporting of beneficiaries' diagnoses, which could save billions of dollars each year, and ensuring that MA plans and Part D plans are not inappropriately restricting beneficiary access to needed services, prescriptions, or providers.

Overseeing Health Insurance Marketplaces. CMS should continue to fix the internal controls and management deficiencies that OIG has identified, including working with States to address weaknesses in State marketplaces. In operating and overseeing the marketplaces, HHS should keep program integrity and sound management principles at the forefront.

Key OIG Resources

- OIG Report, *Access to Care: Provider Availability in Medicaid Managed Care*, December 2014. (<https://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf>)
- OIG Report, *Early Outcomes Show Limited Progress for the Transformed Medicaid Statistical Information System*, September 2013. (<https://oig.hhs.gov/oei/reports/oei-05-12-00610.pdf>)
- OIG Report, *MEDIC Benefit Integrity Activities in Medicare Parts C and D*, January 2013. (<https://oig.hhs.gov/oei/reports/oei-03-11-00310.pdf>)
- OIG Testimony, "Fraud, Waste, and Abuse Under the Affordable Care Act," January 2017. (<https://oig.hhs.gov/testimony/docs/2017/robinson-testimony01312017.pdf>)
- Inventory of OIG Reports on Health Insurance Marketplaces, 2013 to Present. (<https://www.oig.hhs.gov/reports-and-publications/aca/>)

Top Management Challenge #6: Improving Financial and Administrative Management and Reducing Improper Payments

Why This Is a Challenge

HHS is the largest civilian agency within the Federal Government. In FY 2016, HHS reported total budgetary resources of approximately \$1.1 trillion. Responsible stewardship of HHS programs is vital, and operating a financial management and administrative infrastructure that employs appropriate safeguards to minimize risk and provide oversight for the protection of resources remains a challenge for HHS. HHS must also ensure the completeness, accuracy, and timeliness of any financial and program information provided to other entities, both internal and external to the Federal Government.

Key Components of the Challenge

Addressing Weaknesses in Financial Management Systems. OIG continues to report a material weakness in HHS's financial management systems related to inadequate internal controls over segregation of duties in employees' job responsibilities, configuration management for approved changes to HHS financial systems, and access to HHS financial systems. OIG continues to report that HHS does not substantially comply with requirements for financial system management because of these issues. Under the Federal Financial Management Improvement Act of 1996, Federal agencies must establish and maintain financial management systems and OIGs must report on compliance by their respective agency. These systems are intended to help agencies ensure the effectiveness and efficiency of operations, reliability of financial reporting, and compliance with applicable laws and regulations.

Addressing Medicare Trust Fund Issues/Social Insurance. The Statement of Social Insurance (SOSI) presents the actuarial present value of (1) contributions and tax income (excluding interest income), (2) scheduled expenditures, and (3) the difference between the two for all current and future participants (open group) of the Medicare program for the projection period, which covers 75 years. The Statement of Changes in Social Insurance Amounts (SCSIA) reconciles the beginning and ending open group measures and presents the components of the changes for 2 years. These statements cover the Medicare Fee-for-Service, Medicare Advantage, and Medicare Prescription Drug Benefit programs, and the amounts they disclose are based on current law. The actuarial opinion expressed in the 2017 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds states:

Absent an unprecedented change in health care delivery systems and payment mechanisms, the prices paid by the Medicare fee-for-service program for most health services will fall increasingly short of the costs of providing those services. The Trustees assume that the various cost-reduction measures will occur as current law requires. To achieve this outcome, healthcare providers would have to realize productivity adjustments at a faster rate than experienced historically. As a result, the Medicare Board of Trustees have included in the Annual report to Congress an alternative scenario to illustrate, where possible, the potential understatement of Medicare costs and projection results. Since 2010, OIG has

Key Components of the Challenge

- Addressing weaknesses in financial management systems
- Addressing Medicare trust fund issues/social insurance
- Reducing improper payments
- Addressing concerns about contracts management
- Implementing the Digital Accountability and Transparency (DATA) Act

noted the inherent difficulties in projecting growth in health care costs over time and issued a disclaimer of opinion on the SOSI & SCSIA based on these uncertainties.

Reducing Improper Payments. Reducing improper payments is a critical element in protecting the financial integrity of HHS programs. Although not all improper payments constitute fraud, all improper payments pose a risk to the financial security of Federal programs. 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 the FY 2016 Agency Financial Report (AFR), HHS reported improper payments of nearly \$100 billion for seven of the eight programs designated high risk and susceptible to improper payments. Our audit of HHS's FY 2016 AFR, published in May 2017, found that HHS did not meet all IPIA requirements. Specifically, OIG found that HHS did not report an improper payment estimate for the Temporary Assistance for Needy Families (TANF) program, as HHS does not believe it has the statutory authority to collect from States the data necessary for calculating such a rate.

HHS has reported that the improper payment rate exceeded 10 percent for both Medicare Fee-for-Service and Medicaid. In addition, three other programs that the Office of Management and Budget (OMB) has deemed susceptible to risk of improper payments (Medicare Advantage, CHIP, and foster care programs) did not meet their FY 2016 target error rates. *(See TMC #1 for a discussion of reducing Medicare improper payments and TMC #2 for a discussion of reducing Medicaid improper payments.)*

Addressing Concerns About Contracts Management. HHS is one of the largest contracting agencies in the Federal Government. Given the high dollar amount and complexity of its contracts, it is paramount that HHS have strong monitoring and oversight. OIG has raised issues about acquisition planning and procurement, contract monitoring, and payments to contractors related to the Federal Marketplaces operated by CMS. OIG has also identified issues regarding contract closeouts. OIG found that CMS had not closed out contracts totaling \$25 billion as required by the Federal Acquisition Regulation (FAR). Because the closeout process is typically the final opportunity for improper payments to be detected and recovered, delays in the closeout process pose a substantial financial risk. Additionally, OIG has identified weaknesses in CMS's oversight and performance measurement for benefit integrity contractors.

Implementing the DATA Act. The DATA Act required OMB and the Department of the Treasury to establish Government-wide data standards for reporting financial and payment information by May 2015. Broadly, the DATA Act required that HHS begin using the Government-wide data standards to enter information into USASpending.gov by May 2017 in an effort to ultimately increase transparency and accountability. OIG's readiness review of HHS's implementation of the DATA Act as of June 30, 2016, found that although HHS made progress, it had not fully met the requirements of the four initial steps of Treasury's Agency 8-Step Plan. Specifically, we found that HHS did not complete detailed project plans or determine how it will certify that the data are accurate and complete. Given the difficulty of defining and developing common data elements across multiple reporting areas and the volume of diverse programs administered by HHS, OIG determined that HHS will face challenges implementing these uniform data standards and submitting information into USASpending.gov within the required timeframe.

Progress in Addressing the Challenge

Addressing Weaknesses in Financial Management Systems. HHS has taken corrective actions to resolve the IT-related deficiencies reported in the AFR. In FY 2016, senior leadership continued to take a role in monitoring activities across all HHS IT systems. OIG noted improvements in key financial systems as a result of investments in the underlying IT infrastructure, remediation of risk over key financial systems, and the strengthening of the HHS process to develop corrective action plans, which led to the remediation of a number of prior audit findings.

Addressing Medicare Trust Fund Issues/Social Insurance. In FY 2016, HHS continued to present an illustrative alternate scenario to the current legal projections for Medicare in the footnote disclosures of the AFR to illustrate the potential magnitude on Medicare outlays if certain components of current law are not sustainable. According to the Medicare Chief Actuary, the techniques and methodology used to evaluate the financial status of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund are based on sound principles of actuarial practice. With certain caveats, the principal assumptions used and the resulting actuarial estimates are individually and in the aggregate reasonable for the purpose of evaluating the financial status of the trust funds. At this time, OIG is not aware of any projects before the Federal Accounting Standards Advisory Board to revise existing guidance related to SOSI. OIG continues to expect to issue a disclaimer of opinion on the SOSI and SCSIA until the variances between income and expenditures between current law and the illustrative alternative scenario become much less significant.

Reducing Improper Payments. In its FY 2016 AFR, HHS reported a series of actions, including working with States to analyze Single Audit material noncompliance findings and performing a detailed risk assessment of the TANF program to assist States in reducing improper payments for TANF. HHS has also stated that it recognizes the need for continual and focused effort to prevent, detect, and reduce improper payments in HHS programs. For the Medicare Fee-for-Service program, CMS continued with existing efforts to analyze and address areas of highest risk. CMS built on the Healthcare Fraud Prevention Partnership, worked with its Medicare contractors to develop medical review strategies, leveraged multiple efforts to increase provider education, clarified existing policy, and analyzed the results of the Fraud Prevention System. For Medicaid, CMS worked with the States to develop State-specific corrective action plans. CMS also shared Medicare data to assist States with meeting Medicaid screening and enrollment requirements and provided ongoing guidance, education, and outreach. CMS also offered training, technical assistance, and additional support for the States' Medicaid program integrity.

Addressing Concerns About Contracts Management. In November 2015, HHS published a final rule that updated the HHS Acquisition Regulation (HHSAR) to supplement the FAR. 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 closeout. CMS has prioritized closing out contracts. In October 2014, CMS reported establishing a contract closeout goal of 2,250 contracts per year. Since 2013, CMS officials reported they closed out a total of 9,740 contracts, resulting in de-obligations of more than \$209 million that were returned to the Department of the Treasury. CMS continues to meet this goal and closed out 2,831 contracts in FY 2016 and 4,109 contracts in FY 2017.

Implementing the DATA Act. HHS believes that the actions it has taken enabled it to meet the May 2017 due date for implementing the Government-wide data standards and submitting data in

accordance with these standards into USASpending.gov. HHS established a DATA Act Project Management Office (PMO) within the Office of the Assistant Secretary for Financial Resources. The PMO included representatives from all of HHS's Operating Divisions. The PMO has also been appointed by OMB's Office of Federal Financial Management (OFFM) as the executing agent of the financial assistance portion of the pilot required by Section V of the DATA Act. OFFM maintains strategic oversight for the pilot, while HHS is tasked with providing tactical leadership and establishing a pilot program to inform Congress of recommendations on methods to standardize reporting elements across the Federal Government, eliminate unnecessary duplication in financial reporting, and reduce compliance costs for recipients of financial awards.

What Needs To Be Done

Addressing Weaknesses in Financial Management Systems. HHS should continue to address and resolve financial management system weaknesses identified by OIG, the Government Accountability Office, and other auditors contracted by OIG or HHS.

Addressing Medicare Trust Fund Issues/Social Insurance. HHS should continue to work with the Medicare Chief Actuary to lessen the variances of income and expenses reported on the SOSI and SCSIA between current law and the illustrative alternate scenario.

Reducing Improper Payments. HHS must also continue to pursue needed legislative remedies to develop and report an improper payment estimate for TANF. In addition, HHS must meet improper payments reduction targets and reduce improper payments to less than 10 percent for all programs.

Addressing Concerns About Contracts Management. CMS should improve coordination and collaboration across departmental staff with contract closeout responsibilities. CMS must also ensure that required acquisition strategies are completed. Further, CMS must strengthen its contracts oversight and performance measurement for benefit integrity contractors.

Implementing the DATA Act. HHS must ensure it has project plans that specifically detail how it implemented the Government data standards. HHS must also ensure the items entered into USASpending.gov under these standards are accurate and complete.

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 2015*, May 2016. (<https://oig.hhs.gov/oas/reports/region1/171652000.pdf>)
- OIG Report on Financial Statement Audit of Health and Human Services for Fiscal Year 2016, November 2016. (<https://www.hhs.gov/about/agencies/asfr/finance/financial-policy-library/agency-financial-reports/index.html>)
- OIG Report, *CMS Has Not Performed Required Closeouts of Contracts Worth Billions*, December 2015. (<https://oig.hhs.gov/oei/reports/oei-03-12-00680.pdf>)
- OIG Report, *CMS Did Not Identify All Federal Marketplace Contract Costs and Did Not Properly Validate the Amount to Withhold for Defect Resolution on the Principal Federal Marketplace Contract*, September 2015. (<https://oig.hhs.gov/oas/reports/region3/31403002.pdf>)
- OIG Report, *Report of Findings and Recommendations for HHS's DATA Act Implementation*, June 30, 2016. (<https://oig.hhs.gov/oas/reports/region17/171602018.pdf>)

Top Management Challenge #7: Protecting the Integrity of Public Health and Human Services Grants

Why This Is a Challenge

In FY 2016, HHS awarded more grants than any other Federal entity—more than \$100 billion in grants, excluding Medicaid. *(For information on challenges related to Medicaid, see TMCs #2 and #5.)* Recent legislation expands HHS's reach and increases expenditures through new grant programs. In passing the 21st Century Cures Act, Congress authorized (and subsequently appropriated) billions of dollars in new Federal spending to address national public health needs. This included \$1.8 billion for cancer prevention, diagnosis, and treatment; \$1.5 billion for neurological research; \$1.4 billion for the Precision Medicine Initiative;¹³ and \$1 billion in grants to States for opioid prevention and treatment. The Act also authorized funds for smaller grants to address other public health needs. For example, it authorized \$200 million over 4 years for grants for mental and behavioral health education training.

Key Components of the Challenge

- Ensuring effective grants management within the Department
- Ensuring program integrity and financial capability at the grantee level

Given the increased use of grant programs to address public health needs and crises—such as the opioid epidemic and emergency preparedness and relief efforts—it is crucial to safeguard these funds so they are used efficiently, effectively, and for their intended purposes. All grant programs are susceptible to fraud, waste, and abuse, and the challenges of mitigating these risks may be heightened in public health crisis situations.

The continued growth of Federal funding to State and local governments, including block grants for health and social programs, also creates challenges for HHS in verifying that appropriate controls are present and that reporting requirements are met. HHS plays a critical role in ensuring the integrity of public health and human services programs by maintaining transparency and accountability for Federal funds. Responsible stewardship of these funds while maintaining the desired flexibility is vital to public health and well-being as well as responsible use of tax dollars.

Key Components of the Challenge

Ensuring Effective Grants Management Within the Department. Because HHS awards funds to such a diverse variety of non-Federal entities, it faces a number of challenges to ensure proper administration and program integrity of its grants. Challenges include providing an infrastructure to best oversee grants across HHS, conducting effective antifraud activities, and overseeing States' compliance with reported activities in their State plans. HHS maintains multiple grant-awarding systems that do not interface. As a result, HHS lacks the ability to readily capture a grantee's performance and financial activities related to multiple HHS grant awards. OIG has found that the existing grants management and varying grant-oversight processes within each grant-awarding agency hinder HHS's ability to effectively oversee grantees during all aspects of the grants cycle. For example, HHS lacks a systematic method to share among its awarding agencies grantee information such as problematic grantees, risks posed by

¹³ The Precision Medicine Initiative is an emerging approach for disease prevention and treatment that takes into account people's individual variations in genes, environment, and lifestyle.

new grantees, and adverse information from audits of grantees. Further, while HHS maintains the Tracking Accountability in Government Grants System that awarding agencies can use to identify grantees they have in common, the system does not contain a detailed description of a grant award that might enable avoiding potential duplication and overlap of Federal funding from multiple HHS grants. OIG also found that because each HHS awarding agency uses different systems to manage their Federal grants, unintended consequences may result, such as increased administrative burden and costs and a hampered ability for HHS to effectively integrate program integrity into all aspects of its grants management activities.

HHS faces heightened challenges in overseeing grants in areas recovering from natural disasters. OIG has experience in reviewing grant oversight with the work we performed following Superstorm Sandy. For example, OIG found that after Superstorm Sandy guidance from ACF limited the effectiveness of State planning and hindered the use of funds for relief efforts. Improving ACF's guidance could enhance the response to future disasters.

Ensuring Program Integrity and Financial Capability at the Grantee Level. A common problem uncovered by our reviews of HHS grantees is a lack of accountability for Federal funds. This is often caused by inadequate financial management systems and internal controls. When these weaknesses are exploited, financial stewardship of these funds is greatly diminished or absent. Without sufficient internal controls, grants are vulnerable to financial mismanagement and fraud schemes, including embezzlement. As an example, a recent investigation found that a former chief executive officer of a HRSA grantee engaged in a fraudulent scheme to embezzle approximately \$17 million in Federal funds. The intended purpose of the grant was to provide quality health care for the homeless and low-income individuals. Instead, the funds were diverted to the individual's multiple corporations for personal use. The individual was convicted on 98 counts of fraud, including conspiracy, wire fraud, bank fraud, and money laundering, and sentenced to 18 years in Federal prison. In another example, we found that a grantee unlawfully spent nearly \$8 million in Head Start funds without maintaining its required enrollment level. Not only did the grantee not fulfill its program-enrollment obligations, it also misused an additional \$2 million of Head Start funds. The grantee did not monitor its partner agencies' operations to ensure that children at the partners' facilities in fact received Head Start services.

Weak program integrity and internal controls may also result in nonmonetary vulnerabilities. For example, audits of State agency oversight of childcare providers funded by the CCDF program highlighted the need to strengthen compliance with requirements for background screenings of individuals caring for children. We also found that States receiving CCDF grants sometimes failed to perform important program integrity and antifraud activities, such as reviewing provider records for potential fraud, identifying potential duplicate payments, performing verification checks (such as verifying addresses) of childcare providers, and conducting onsite visits.

Progress in Addressing the Challenge

HHS has worked to strengthen some program integrity efforts. To facilitate better information sharing about grantees, guidance has been issued to HHS awarding agencies that facilitates a review of prospective grantees prior to awarding grants. This information enhances HHS's assessment of prospective grant recipients' integrity and potential performance.

In addition, information provided via the Federal Awardee Performance and Integrity Information System (FAPIIS) database will improve HHS's access to information pertaining to entities applying for or receiving Federal funds. FAPIIS tracks contractor misconduct and performance by including information on contractor criminal, civil, and administrative proceedings in connection with Federal awards, suspensions and debarments, contracts terminated for fault, and past performance evaluations.

Further, HHS awarding agencies have begun to reach out to OIG regarding allegations of fraud. For example, HRSA officials referred allegations to OIG that resulted in significant criminal convictions and recoveries on behalf of HRSA's grant program and shut down a fraud scheme in which Federal funds were being stolen and diverted for personal use.

To combat fraud, waste, and abuse in its grant programs, HHS continues to pursue suspension and debarment actions (in addition to other administrative remedies). In addition, HHS has collaborated with OIG in presenting training on suspension and debarment and training for employees of HHS and Tribal facilities on how to identify and report potential fraud, waste, and abuse.

What Needs To Be Done

Effective grants administration depends on strengthening the use of data and technology to allow HHS to assess risk prior to making grants and to track grantee compliance and performance after an award. Specifically, HHS should develop interoperable grants management systems to share information across grant programs. HHS should also continue to work with States and other grantees to assess and strengthen their program integrity and fraud-fighting activities. When the Department identifies mismanagement, waste, or abuse, it must continue to pursue appropriate administrative remedies, such as suspension and debarment, as well as continue to refer suspected fraud to OIG. To fight fraud, OIG will continue to use all of our enforcement remedies, including a new enforcement tool authorized by the 21st Century Cures Act that empowers OIG to impose civil monetary penalties for fraudulent conduct in HHS grants, contracts, or other agreements.

Key OIG Resources

- OIG Report, *Newark Preschool Council, Inc., Did Not Always Comply With Head Start Requirements*, February 2017. (<https://oig.hhs.gov/oas/reports/region2/21402024.asp>)
- OIG Report, *HHS Oversight of Grantees Could Be Improved Through Better Information Sharing*, September 2015. (<https://oig.hhs.gov/oei/reports/oei-07-12-00110.asp>)
- OIG Report, *More Effort Is Needed to Protect the Integrity of the Child Care and Development Fund Block Grant Program*, July 2016. (<https://oig.hhs.gov/oei/reports/oei-03-16-00150.pdf>)
- OIG Report, *Cleveland Clinic Lerner College of Medicine Inappropriately Drew Down Hurricane Sandy Disaster Relief Act Funds and Did Not Always Implement Effective Internal Controls*, March 2017. (<https://oig.hhs.gov/oas/reports/region2/21502011.asp>)
- OIG Report, *Superstorm Sandy Block Grants: Funds Benefited States' Reconstruction and Social Service Efforts, Though ACF's Guidance Could Be Improved*, September 2016. (<https://oig.hhs.gov/oei/reports/oei-09-15-00200.asp>)

Top Management Challenge #8: Ensuring the Safety of Food, Drugs, and Medical Devices

Why This Is a Challenge

The FDA has a broad statutory mandate, and its responsibilities continue to grow. FDA protects the public health by ensuring the safety, efficacy, quality, and security of human and veterinary drugs, biological products, and medical devices, and by ensuring the safety of our Nation's food supply, cosmetics, and electronic products that emit radiation. FDA also regulates the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.¹⁴ FDA regulates products accounting for approximately 20 percent of all U.S. consumer spending. FDA has the continuing challenge of ensuring the safety and security of our Nation's foods and medical products (including drugs, biological products, and medical devices), which directly affect the health of every American. The expansion of FDA's authorities through legislation, including the 21st Century Cures Act in 2016, the Drug Quality and Security Act in 2013, and the Food Safety Modernization Act in 2010, add to the agency's mandate to protect the public health.

Key Components of the Challenge

- Ensuring food safety
- Ensuring the safety, efficacy, and quality of medical products
- Overseeing the complex drug and medical device supply

Key Components of the Challenge

Ensuring Food Safety. Each year roughly 48 million people get sick from a foodborne illness, 128,000 are hospitalized, and 3,000 die.¹⁵ FDA is responsible for ensuring the safety of almost all food products sold in the United States, with the exception of catfish, meat, poultry, and some egg products, which are regulated by the U.S. Department of Agriculture. Oversight is complicated by the immense diversity of the global food supply: 20 percent of vegetables consumed in the United States come from abroad, as does 50 percent of fresh fruit and more than 80 percent of seafood.¹⁶

FDA inspects food facilities to ensure food safety and compliance with regulations and may use various administrative tools and enforcement authorities as necessary to protect the public from unsafe or potentially unsafe food. However, OIG has consistently found that FDA does not always take action after it discovers significant inspection violations at food facilities. Additionally, OIG has found that FDA's actions are not always timely nor do they always result in the correction of these violations. For example, in 2016 OIG issued an Early Alert based on a review of a judgmental sample of 30 food recalls with a preliminary finding that FDA lacked an efficient and effective process to ensure that firms initiate prompt, voluntary food recalls.

Ensuring the Safety, Efficacy, and Quality of Medical Products. FDA's responsibility to ensure safe, effective, and quality medical products begins long before a product is brought to market and continues after FDA approval. FDA oversees more than 13,000 drug facilities and 25,000 medical device facilities.

¹⁴ See <https://www.fda.gov/aboutfda/whatwedo/>

¹⁵ Centers for Disease Control and Prevention, Food Safety, "Foodborne Germs and Illnesses." Available at <https://www.cdc.gov/foodsafety/foodborne-germs.html>

¹⁶ U.S. Food and Drug Administration, Global Engagement. Available at <https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/ucm298578.pdf>

FDA is also responsible for authorizing the use of investigational medical products as well as ensuring the safety and efficacy of all prescription medical products before marketing in the United States. In 2016, FDA approved 22 novel drugs, 73 first-time generic drugs, and 91 novel medical devices. FDA also oversees compounded drugs, which are not subject to FDA's premarket approval process, and continues to identify issues with the development of compounded products.

FDA must also ensure that medical products remain safe and of acceptable quality once on the market. In 2016, OIG released a report concerning FDA's oversight of drug sponsors' compliance with postmarketing requirements. Some drug sponsors may be required to carry out postmarketing studies or clinical trials to assess known or potential serious risk. OIG found that most sponsors are completing their studies according to schedule, although some studies were delayed at the time of our study. OIG recommended that FDA address limitations in its data management system that can hinder FDA's ability to track studies.

Overseeing the Complex Drug and Medical Device Supply Chain. The drug and medical device supply chain is growing increasingly complex, not only domestically but globally. Intricate global supply chains present FDA with many challenges as medical products move through the supply chain and are at risk of diversion, theft, counterfeiting, and adulteration. To enhance the security of the drug supply chain, the Drug Supply Chain Security Act (DSCSA) requires trading partners in the drug supply chain to exchange certain information with each other in each drug product transaction and to identify and investigate suspect and illegitimate drug products.¹⁷ FDA can then use such tracing and investigational information to further investigate suspect and illegitimate drug products and potential diversion. In 2017, OIG found that selected wholesalers were exchanging drug product tracing information and that about half of them—including the three largest wholesalers that account for more than 80 percent of drug distribution revenues—exchange all information required under the DSCSA. However, some wholesalers were missing a few of the required tracing information elements.

Progress in Addressing the Challenge

Ensuring Food Safety. In response to OIG's June 2016 Early Alert on FDA's food-recall initiation process, FDA announced the establishment of the Strategic Coordinated Oversight of Recall Execution, a team of FDA senior leaders that examines cases that present a significant hazard to human health and makes decisions during the most challenging high-risk food-recall cases. FDA also designed and implemented a plan to audit and monitor FDA's recall program across all regulated product areas. Lastly, FDA implemented a strategic plan to identify priorities that optimize FDA's policies and procedures for recall of FDA-regulated products that pose a public health risk.

In 2017, FDA also implemented many longstanding OIG recommendations targeted at ensuring that structure and function claims made by dietary supplements are truthful and not misleading. FDA educated the dietary supplement industry about registration and labeling and improved the accuracy of the information in the dietary supplement registry by publishing updates to three guidance documents and developing additional resources. FDA improved its notification system for dietary supplement structure/function claims by developing an e-portal system that allows for an organized, complete, and

¹⁷ Drug Quality and Security Act, P.L. No.113-54, Title II.

accurate accounting of health benefit claims. FDA also expanded its market surveillance of dietary supplements to enforce the use of disclaimers.

Ensuring the Safety, Efficacy, and Quality of Medical Products. In response to recommendations OIG made related to postmarketing requirements for drug sponsors, FDA followed up with sponsors to ensure they are carrying out these requirements. Through this followup, FDA enhances public safety and quality of care as well as compliance and accountability.

Overseeing the Complex Drug and Medical Device Supply Chain. FDA continually engages in efforts to enhance drug and device traceability. For example, FDA published guidance that outlines general parameters for the interoperable exchange of drug product tracing information, issued revised guidance on product tracing requirements for dispensers, and issued draft guidance on identifying trading partners pursuant to requirements of the DSCSA.

FDA also continues to implement the unique device identification (UDI) system for medical devices. FDA's UDI system for medical devices should facilitate better detection of adverse events, improve product recalls, and enable robust postmarket surveillance.¹⁸ In 2013, FDA promulgated a final rule establishing a UDI system designed to adequately identify medical devices through distribution and use.¹⁹ In 2016, FDA supported capturing certain UDI information on Medicare claim forms to help identify safety concerns with medical devices.

What Needs To Be Done

Ensuring Food Safety. FDA must ensure the safety of the Nation's food supply by continuing to monitor food facilities and effectively using its administrative and enforcement tools. FDA must establish timeframes to discuss with a firm the possibility of a voluntary recall of its violative products. In addition, FDA must finalize its mandatory recall procedures and agency guidance to include the factors that staff should consider when determining whether there is a reasonable probability that a food could cause serious adverse health consequence or death.

Ensuring the Safety, Efficacy, and Quality of Medical Products. In addition to continuing its implementation of DSCSA, FDA must also implement the 21st Century Cures Act, which requires FDA to, among other things, establish new programs to accelerate innovation and increase access to medical products, increase patient involvement in the research and medical product development process, and operationalize its new hiring authority for scientific staff. FDA must also continue its commitment to improving both its postmarket reporting processes and its technical oversight capacity.

Overseeing the Complex Drug and Medical Device Supply Chain. FDA must continue to implement requirements of the DSCSA to enhance drug and device traceability. To ensure that all trading partners comply with this law, OIG recommends that FDA offer technical assistance where appropriate.

¹⁸ Food and Drug Administration Amendments Act of 2007, P.L. No. 110-85 (enacted Sept. 27, 2007).

¹⁹ 78 Fed. Reg. 58786 (Sept. 24, 2013) and 21 CFR part 803.

Key OIG Resources

- OIG Report, *Challenges Remain in FDA's Inspections of Domestic Food Facilities*, September 2017. (<https://oig.hhs.gov/oei/reports/oei-02-14-00420.pdf>)
- OIG Report, *Early Alert: The Food and Drug Administration Does Not Have an Efficient and Effective Food Recall Initiation Process*, June 2016. (<http://oig.hhs.gov/oas/reports/region1/11501500.asp>)
- OIG Report, *FDA Is Issuing More Postmarketing Requirements, but Challenges With Oversight Persist*, July 2016. (<https://oig.hhs.gov/oei/reports/oei-01-14-00390.asp>)
- OIG Report, *Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information*, August 2017. (<https://oig.hhs.gov/oei/reports/oei-05-14-00640.pdf>)

Top Management Challenge #9: Ensuring Program Integrity and Quality in Programs Serving American Indian and Alaska Native Populations

Why This Is a Challenge

In FY 2016, HHS administered 45 percent of all Federal funds that serve American Indian and Alaska Native (AI/AN) communities—a total of \$7 billion. A number of HHS agencies administer programs for AI/ANs throughout the United States. With an annual budget of approximately \$6 billion, the Indian Health Service (IHS) is the largest of these programs and, in partnership with Tribes, provides or funds health care to approximately 2.2 million AI/ANs who are members of the 567 federally recognized Tribes located in 36 States served by 662 health care facilities. Other HHS agencies provide grants to Tribes for human services programs, ranging from Head Start to the Low Income Home Energy Assistance Program (LIHEAP). HHS faces significant challenges to ensuring effective delivery of crucial services to AI/ANs and protecting funds from fraud, waste, and abuse.

Key Components of the Challenge

- Improving IHS quality of care, management, and infrastructure
- Combating fraud and misuse of funds
- Ensuring adequate internal controls and staff training for HHS grant programs in Indian Country

Key Components of the Challenge

Improving IHS Quality of Care, Management, and Infrastructure. AI/ANs often face health disparities in comparison to the national population. For example, the infant mortality rate for AI/ANs is about 25 percent higher than the national rate, and AI/ANs are almost twice as likely as the overall population to have diabetes. Additionally, AI/ANs have disproportionately high rates of suicide and death from unintentional injuries. IHS operates health care facilities to help meet these needs, including 26 Federal acute-care hospitals, many of which are in remote locations. However, some IHS hospitals face longstanding challenges that affect their ability to provide quality care and comply with Medicare standards. These challenges include recruiting and retaining essential staff, ensuring access to needed care and training resources, maintaining the clinical proficiency of professional staff serving a diverse caseload, and maintaining and upgrading outdated buildings and equipment. Further, OIG has found that IHS has few systematic sources of information on its hospitals' performance and a limited capacity to provide clinical support. As a result, IHS may be missing opportunities to improve the quality of care at its hospitals. In addition, we found that IHS monitors hospitals through its Area Offices, which have varying access to information about the quality of care and degree of oversight at hospitals. Shortages of staffing and funding at Area Offices also limit the clinical support and guidance they can provide. Hospitals with limited resources struggle to implement IT improvements and update EHR systems. In addition, IHS faces challenges in combating the opioid abuse epidemic. *(For more information about curbing the opioid epidemic, see TMC #3.)*

Combating Fraud and Misuse of Funds. OIG has identified instances of fraud that put Federal funds and AI/AN communities at risk. OIG investigations have revealed that some Tribes and Tribal organizations have not adequately protected funds provided under the Indian Self-Determination and Education Assistance Act (ISDEAA). (ISDEAA provides Tribes with the option to assume IHS program funds to administer programs, services, functions, and activities themselves rather than having them be administered by IHS.) In some cases, the funds were misappropriated or misused by individuals. In the most egregious cases, funds had been converted to personal use, leaving the Tribes with dangerous shortages in health care funding for their members.

In the resolution to one alarming case of fraud, in 2017 a business owner in Montana was sentenced in Federal court to 2 years in prison for multiple criminal offenses related to HHS and IHS programs. The business owner was convicted of conspiracy, wire fraud, and bribery, all of which were associated with “pay to play” kickback schemes related to HHS and other Federal programs on a Montana Indian reservation. The business owner was ordered to pay \$4.58 million in criminal restitution and fines.

OIG investigations have also found that some IHS pharmacies are particularly vulnerable to fraud and abuse related to controlled substances, including diversion and trafficking by employees, contract providers, and patients. For example, in 2016 one IHS employee in Montana was sentenced to 3 years of Federal probation after admitting to stealing controlled substances from two IHS pharmacies as well as tampering with a consumer product by replacing the controlled substance the employee had stolen with tablets containing other substances.

In addition, OIG has pursued cases against Tribes and Tribal organizations for submitting false claims and violating the civil monetary penalties law. For example, in 2017 a Washington State Tribe entered into a settlement to resolve allegations that it had submitted false claims to Medicaid for mental health counseling services that the Tribe’s behavioral health unit did not actually provide.

Ensuring Adequate Internal Controls and Staff Training for HHS Grant Programs in Indian Country.

Insufficient internal controls and inadequate staff training create vulnerabilities for agencies, grantees, and beneficiaries. OIG has uncovered insufficient internal controls, lack of documentation relating to employee misconduct, and prohibited personnel practices, including the hiring of excluded individuals to provide items or services to Federal program beneficiaries. For example, we found that of the \$5.7 million in LIHEAP grant funds that the ACF awarded to one North Dakota Tribal organization for Federal FYs 2010 through 2014, \$1.2 million was not administered by the Tribal organization in compliance with Federal laws, regulations, and guidance. The errors occurred because the Tribal organization did not have sufficient internal controls in place to prevent the errors and because their staff circumvented existing internal controls. These funds could have been used to provide additional benefits to eligible LIHEAP beneficiaries. *(For more information about protecting the integrity of public health and human services grants, see TMC #7.)*

Progress in Addressing the Challenge

Improving IHS Quality of Care, Management, and Infrastructure. IHS recently reported to OIG a broad range of efforts toward improvement. IHS noted that it revised leadership and staffing for implementing its new Quality Framework and Office of Quality, with the goal of tracking compliance and quality efforts through a new accountability dashboard under development. IHS has awarded a national hospital accreditation contract and is developing a formal governance structure within the IHS Director’s office to oversee compliance throughout the agency. With regard to internal oversight, IHS has made strides in establishing standards and expectations for how Area Offices and governing boards oversee and monitor hospitals and monitor adherence to those standards. The agency now requires a standardized governance process for use by IHS hospital governing boards. In addition, IHS has finalized agency-wide standards for patient wait times and is developing plans for system-wide monitoring by the end of 2017. In addition, IHS has increased its focus on addressing the opioid epidemic, including carrying out activities related to the following priorities: provide treatment and recovery services, promote broader use of overdose reversal drugs, monitor opioid prescribing data, and support appropriate pain management.

IHS is also providing opportunities for leadership training internally and through coordination with the Partnership to Advance Tribal Health, the Quality Improvement Organization (QIO) for IHS. Additionally, IHS awarded a contract for a national provider credentialing system in 2017 and is updating its credentialing policy to reflect current standards and use of the new system. IHS also implemented a global recruitment strategy that allows applications to be considered for multiple locations. IHS is coordinating with CMS to implement the IHS and CMS Quality Improvement Network, QIO, and Hospital Engagement Network programs. Further, IHS has begun planning for an agency-wide needs assessment for quality of care and compliance. Finally, HHS created an Executive Council on Quality Care in 2016, led by the Deputy Secretary to identify opportunities from across the department that could be leveraged to support IHS in improving quality and safety. The Council includes health quality experts from across HHS and is working collaboratively to identify opportunities to assist IHS in its improvement efforts.

Protecting the Integrity of Programs Serving AI/ANs. OIG is engaging in ongoing efforts to provide technical assistance to Tribal recipients of HHS funds. For instance, OIG negotiated in 2017 the first-ever Voluntary Tribal Compliance Agreement with the Washington State Tribe mentioned earlier as part of the Tribe's efforts to resolve allegations that it had submitted false claims to Medicaid for children's mental health services. With this type of agreement, OIG is helping the Tribe to implement a compliance program that includes retaining a compliance officer, establishing a compliance committee and relevant policies and procedures, providing pertinent training to employees, and appropriately screening employees upon hiring and then regularly thereafter. Also, OIG conducted a training program for IHS and Tribal officials on health care and grants management compliance in South Dakota, with a focus on quality of care and service delivery, compliance programs and other tools for combating fraud and abuse, and internal controls and single audits. In addition, in August 2017 OIG provided IHS headquarters managers training to mitigate grant fraud. OIG is also working with Offices of Inspector General from other Federal departments to identify common risks and opportunities to strengthen program integrity across Federal programs serving AI/ANs.

What Needs To Be Done

Improving IHS Quality of Care, Management, and Infrastructure. IHS should continue its efforts to improve oversight and quality of care at IHS hospitals. This includes implementing a compliance program that provides internal controls to govern IHS's ethics and business policies and helps create a culture that promotes prevention, detection, and resolution of unlawful or unethical conduct. Also, IHS should implement OIG's recommendation to conduct a needs assessment and continue its recent efforts to develop an agency-wide strategic plan with actionable initiatives and target dates. In addition, IHS should establish standards for oversight activities by Area Offices and governing boards and should continue maturing its hospital performance metrics for the accountability dashboard. IHS's plans for improvement are extensive, but these plans are early in implementation and contingent on the agency's ability to establish and staff new executive-level national oversight functions, including the new Office of Quality and Office of Strategic Workforce Development. In addition, IHS should continue to take actions to curb opioid abuse, including periodically analyzing and reporting on purchasing and prescribing data for controlled substances within IHS facilities.

Further, HHS must continue to harness expertise from across its agencies and stakeholder community to address IHS's challenges. The HHS Executive Council on Quality Care should lead an examination of the

quality of care delivered in IHS hospitals and use the findings to identify and implement innovative strategies to mitigate IHS's longstanding challenges. In addition, CMS should conduct more frequent surveys of nonaccredited IHS hospitals.

Protecting the Integrity of Programs Serving AI/ANs. To ensure that HHS funds are protected and that AI/AN communities receive maximum value and benefit from services, Tribes and Tribal organizations should develop and implement policies, procedures, and internal controls to detect and prevent fraud, mismanagement of funds, and improper billing. HHS reported that it is using annual audits to assess these issues. In addition, programs serving AI/ANs should ensure that their staffs are adequately trained to comply with Federal requirements and Tribal policies and controls.

Key OIG Resources

- OIG Report, *The Three Affiliated Tribes Improperly Administered Low-Income Home Energy Assistance Program Funds for Fiscal Years 2010 Through 2014*, July 2017. (<https://oig.hhs.gov/oas/reports/region7/71604230.asp>)
- OIG Training Session, "Protecting Indian Health and Human Services Programs and their Beneficiaries: The Basics of Health Care and Grants Management Compliance," Crazy Horse, South Dakota, April 2017. (<https://oig.hhs.gov/conference/>)
- OIG Companion Reports, *Indian Health Service Hospitals: More Monitoring Needed to Ensure Quality Care in Indian Health Service Hospitals: Longstanding Challenges Warrant Focused Attention to Support Quality Care*, October 2016. (<https://oig.hhs.gov/oei/reports/oei-06-14-00010.asp> and <https://oig.hhs.gov/oei/reports/oei-06-14-00011.asp>)
- OIG Report, *Expenses Incurred by the Rocky Boy Health Board Were Not Always Allowable or Adequately Supported*, March 2016. (<https://oig.hhs.gov/oas/reports/region7/71504221.asp>)
- OIG Alert to Tribes and Tribal Organizations To Exercise Caution in Using Indian Self-Determination and Education Assistance Act Funds, November 2014. (<https://oig.hhs.gov/compliance/alerts/guidance/20141124.pdf>)
- Podcasts, "Voluntary Tribal Compliance Agreement," February 2017, and "What Is OIG's Work in Indian Country?", August 2016. (<https://oig.hhs.gov/newsroom/podcasts/>)

Top Management Challenge #10: Protecting HHS Data, Systems, and Beneficiaries From Cybersecurity Threats

Why This Is a Challenge

Data management, use, and security are essential to the effective and efficient operation of HHS and its programs. As HHS works to leverage the power of data, the Department will maintain and use expanding amounts of sensitive data. So, too, will individuals and entities—such as States, contractors, providers, grant recipients, and beneficiaries—involved in delivering or receiving benefits from the many HHS programs.

Cybersecurity incidents and breaches pose a significant risk to the confidentiality, integrity, and availability of sensitive data. This could cause a myriad of problems including impeding HHS's ability to offer essential programs and services, threatening major elements of our country's critical infrastructure, and placing the health and safety of patients at risk. The Department must ensure that it takes appropriate actions to protect all HHS data and systems from cybersecurity threats. Similarly, HHS must protect its beneficiaries by fostering a culture of cybersecurity among its partners and stakeholders.

Key Components of the Challenge

- Protecting HHS's data and systems
- Fostering a culture of cybersecurity beyond HHS

The environment in which the Department must achieve these imperatives is complex. For example, the sheer volume of data grows at an extremely rapid rate, which means there are significant and ever-increasing amounts of data to protect. Relatedly, data reside in many places and in the possession of private individuals and organizations who have a wide range of cybersecurity knowledge, experience, and resources. The continuing expansion of the Internet of Things, including networked medical devices, further increases potential attack vectors. These factors all impact the threat ecosystem.

Additionally, data—particularly health care data—are extremely valuable to cyber criminals. Media reports have identified the value of electronic health records (EHRs) to be as much as 10 times that of a credit card number. The threat facing the Department comes not just from individual actors, but also from organized groups representing or acting on behalf of criminal organizations and foreign nation states with sophisticated tools and resources. Furthermore, many public and private individuals, organizations, and agencies operate aging equipment and outdated software, which can create challenges in terms of keeping up with technological advances and evolving cybersecurity threats. For example, the WannaCry ransomware that critically impacted the United Kingdom's National Health Service in May 2017 and the NotPetya malware that halted a pharmaceutical company's production of some of its drugs in June 2017 offer cautionary warnings. The Department and its public and private partners and stakeholders have taken some steps to address coordination and information sharing concerning cybersecurity threats, but they must continue to work to enhance capabilities.

Key Components of the Challenge

Protecting HHS's Data and Systems. HHS must continually undertake efforts to protect its data and information systems and make certain that the Department is prepared to respond in the event of an incident. Meanwhile, the Department is under constant attack as criminals attempt to infiltrate or disrupt HHS systems.²⁰ OIG has identified cybersecurity vulnerabilities in multiple HHS systems and State Medicaid systems, including inadequacies in access controls, patch management, configuration management, encryption of data, and website security. Such weaknesses could affect the Department's ability to protect against unauthorized access to sensitive information. HHS is also responsible for complying with [Executive Order 13800](#) (Strengthening the Cybersecurity of Federal Networks and Critical Infrastructure) as well as implementing the [Continuous Diagnostics and Mitigation program](#) in conjunction with the U.S. Department of Homeland Security (DHS). When implementing technology, HHS must use modern IT practices, such as those highlighted by the [Digital Services Playbook](#). Additionally, more and more of the Department's programs, such as the [All of Us Research Program](#), are becoming technology dependent. Ensuring the protection of the confidentiality, integrity, and availability of participants' personal information—and the systems the initiatives rely on—is paramount.

Fostering a Culture of Cybersecurity Beyond HHS. To protect the privacy and safety of those served by HHS programs, the Department must foster a culture that prioritizes cybersecurity among its partners and stakeholders.²¹ The Department can encourage such a culture through policy and partnerships. With respect to policy, the Department must determine when and how to appropriately use existing policy levers—such as regulations, contract or grant requirements, financial incentives, or guidance—to encourage cybersecurity efforts without creating undue burden. For example, FDA has opportunities to promote cybersecurity in fulfilling its responsibility to ensure the safety and effectiveness of medical devices. Similarly, CMS has opportunities in the design and operation of its programs to further cybersecurity among participants.

The Department must collaborate with public and private partners and stakeholders to further cybersecurity goals. HHS is the Sector-Specific Agency for the Healthcare and Public Health Sector (HPH) and the Co-Sector-Specific Agency for the Food and Agriculture Sector. In those roles, HHS is tasked with, among other things, coordinating with Federal partners, collaborating with critical infrastructure owners and operators, and offering support in identifying vulnerabilities and mitigating incidents.²² These sectors face many cybersecurity-related issues, including those identified in the [Health Care Industry Cybersecurity Task Force Report](#) (the Task Force Report), released in June 2017. The Department must determine how best to support partners' and stakeholders' efforts to enhance cybersecurity while being mindful of the wide diversity in the infrastructure and resources available to prepare for, detect, and respond to cybersecurity threats.

²⁰ See, for example, Chase Gunter, *Federal Computer Week (FCW)*, "CIO: HHS faces 500 million hack attempts per week," June 20, 2017. Available at <https://fcw.com/articles/2017/06/20/hhs-cio-cyber-attacks.aspx>.

²¹ Executive Order 13636, Improving Critical Infrastructure Cybersecurity, and Presidential Policy Directive (PPD) 21, Critical Infrastructure Security and Resilience.

²² Ibid.

Progress in Addressing the Challenge

Protecting HHS's Data and Systems. HHS has made progress in strengthening the privacy safeguards and security of its systems and information. For example, HHS adopted DHS's Continuous Diagnostics and Mitigation program and is currently working on final implementation of Phase Two. Additionally, HHS has taken steps to address vulnerabilities identified in OIG cybersecurity reports, including those referenced above.

Fostering a Culture of Cybersecurity Beyond HHS. Similarly, HHS made progress in fostering a culture of cybersecurity among public and private partners and stakeholders. In 2016, FDA published final guidance addressing postmarket cybersecurity vulnerabilities for medical devices. In addition, in 2016 FDA entered into a new Memorandum of Understanding with the National Health Information Sharing and Analysis Center (NH-ISAC) and the Medical Device Innovation, Safety, and Security Consortium to share information on cybersecurity threats and foster the development of risk assessment frameworks. Further, HHS has undertaken efforts to increase communication within the Department and across the HPH Sector by developing its new Healthcare Cybersecurity and Communications Integration Center (HCCIC). According to the Department, the HCCIC is a necessary resource for health care providers and a sector-specific response to cybersecurity threats that will supplement DHS's [National Cybersecurity and Communications Integration Center](#) and provide direct benefits for health care cybersecurity. Additionally, HHS awarded cooperative agreements to the NH-ISAC totaling \$350,000 to support cybersecurity efforts by HPH Sector partners through the sharing of information and threat indicators. Finally, the Department continued its efforts as a Sector-Specific Agency to improve sector-specific communication by, among other things, sharing important information with health care providers and associations during the May 2017 WannaCry incidents.

What Needs To Be Done

Protecting HHS's Data and Systems. Cybersecurity threats are evolving, as evidenced by the recent rise of ransomware, and HHS must remain vigilant. While HHS continues to undertake efforts to protect its own data and systems, more remains to be done. To protect its data and systems, the Department must continue to take steps to address vulnerabilities previously identified by OIG and others. OIG's work will continue to focus on HHS systems' privacy and security to support HHS's efforts to mitigate the risk of unauthorized access or changes to or theft of its sensitive information. In addition, across HHS, several key mission areas rely on aging or outdated technology. These systems pose a risk to the successful execution of the HHS mission if they fail or are compromised. As the Department updates or acquires new technology, HHS must also ensure that it aligns with technology priorities defined in legislation and administration policy. This includes the full implementation of the Federal Information Technology Acquisition Reform Act, modernization of legacy systems, and adoption of modern IT management practices.

Fostering a Culture of Cybersecurity Beyond HHS. To further foster a culture of cybersecurity among partners and stakeholders to protect beneficiaries, HHS must use available policy levers to address Health IT security issues. Ongoing work will continue to consider security issues related to networked medical devices, and future work may consider additional security issues that arise from the continuing expansion of the Internet of Things. Furthermore, the Department must complete its review of recommendations included in the Task Force Report and determine how best to address those recommendations.

Key OIG Resources

- OIG Report, *HealthCare.gov: Case Study of CMS Management of the Federal Marketplace*, February 2016. (<https://oig.hhs.gov/oei/reports/oei-06-14-00350.pdf>)
- OIG Report, *Hospitals Largely Reported Addressing Requirements for EHR Contingency Plans*, July 2016. (<https://oig.hhs.gov/oei/reports/oei-01-14-00570.asp>)
- OIG Summary Report, *Wireless Penetration Test of Centers for Medicare & Medicaid Services' Data Centers*, August 2016. (<https://oig.hhs.gov/oas/reports/region18/181530400.asp>)
- OIG Summary Report, *Information Technology Control Weaknesses Found at the Commonwealth of Massachusetts' Medicaid Management Information System*, March 2017. (<https://oig.hhs.gov/oas/reports/region6/61500057.asp>)
- OIG Summary Report, *Virginia Did Not Adequately Secure Its Medicaid Data*, May 2017. (<https://oig.hhs.gov/oas/reports/region4/41505066.asp>)
- OIG Summary Report, *Information Technology Control Weaknesses Found in the New Mexico Human Services Department's Medicaid Eligibility Systems*, August 2017. (<https://oig.hhs.gov/oas/reports/region6/61605000.asp>)
- OIG Summary Report, *The State of North Carolina Did Not Ensure That Federal Information System Security Requirements Were Met for Safeguarding Its Medicaid Claims Processing Systems and Data*, August 2017. (<https://oig.hhs.gov/oas/reports/region7/71600469.asp>)