

2016

Top Management & Performance Challenges Facing HHS

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

Top Management and Performance Challenges Facing the Department

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, including, Medicare, Medicaid, the Public Health Service, and the Indian Health Service. These challenges cover critical HHS responsibilities that include delivering quality services and benefits, exercising sound fiscal management, safeguarding public health and safety, and enhancing cybersecurity. OIG maintains a list of recommended solutions to address vulnerabilities detected in its audits and evaluations and identifies the top unimplemented recommendations that, if implemented, are likely to garner significant savings and improvements in efficiency and effectiveness. Unimplemented recommendations may be found on our website at <https://oig.hhs.gov/reports-and-publications/compendium/index.asp>.

2016 OIG Top Management and Performance Challenges Facing HHS

1. Ensuring Program Integrity in Medicare Parts A and B
2. Effectively Administering the Medicaid Program to Improve Oversight of Managed Care, Address High Improper Payments, and Strengthen Program Integrity
3. Health Information Technology and the Meaningful and Secure Exchange and Use of Electronic Information
4. Improving Financial and Administrative Management
5. Ensuring the Proper Administration of HHS Grants for Public Health and Human Services Programs
6. Curbing the Abuse and Misuse of Controlled and Non-controlled Drugs in Medicare Part D and Medicaid
7. Ensuring Quality of Care and Safety for Vulnerable Populations
8. Operating and Overseeing the Health Insurance Marketplaces
9. Managing Delivery System Reform and Strengthening Medicare Advantage
10. Ensuring the Safety of Food, Drugs, and Medical Devices

In this presidential transition year, HHS must address these challenges while undertaking the additional important responsibility of conducting a well-orchestrated transition to new leadership, consistent with the executive order on “Facilitation of a Presidential Transition” and other requirements. The transition will require heightened focus on effective coordination across HHS operating divisions, continuity of operations, and emergency preparedness. This transition must be accomplished while maintaining and strengthening HHS’s many complex programs and protecting and serving its beneficiaries.

Top Management Challenge #1: Ensuring Program Integrity in Medicare Parts A and B

Key Components of the Challenge

- Reducing improper payments
- Preventing, detecting, and responding to fraud
- Fostering prudent payment policies

Why This Is a Challenge

Spending under Medicare Parts A and B is expected to increase significantly over time due to the growth in the number of beneficiaries and the increase in per capita health care costs. The 2016 Annual Report by Medicare's Board of Trustees estimates that the Trust Fund for Part A will be depleted by 2028. The report also projects Part B spending growth of almost 7 percent over the next 5 years, outpacing the projected 5 percent growth of the U.S. economy during that time. Further, the Part B payment system for providers is undergoing substantial changes through the Medicare Access and CHIP Reauthorization Act of 2015 and other reforms. *(For more information on Medicare payment and delivery reform, see TMC #9.)* HHS faces challenges—and opportunities—in each of the key areas addressed below.

Key Components of the Challenge

Reducing Improper Payments. In FY 2015, the Centers for Medicare & Medicaid Services (CMS) reported an improper payment rate of 12.1 percent, corresponding to \$43.3 billion, for Medicare Fee-for-Service (Parts A and B). These measures include payments that were paid at an incorrect amount (including both overpayments and underpayments), as well as payments for unnecessary services, services not rendered, billing or coding errors, and claims that did not meet documentation or other Medicare coverage requirements. *(For more information on improper payment rate measurement and reporting, see TMC #4.)*

While OIG reviews all areas of improper payments, OIG efforts in recent years have focused on specific provider areas based on risk and program size. Our reviews of hospitals' compliance with and risk of not complying with Federal and State requirements have served an important role in highlighting vulnerabilities in hospital billings and returning improper payments to the Medicare Trust Fund. OIG has also focused attention on improper payments in home health and hospice care due to concerns about vulnerabilities in these areas. Through compliance audits of home health agencies, OIG has uncovered improper payments across a number of risk areas, such as insufficient documentation, medical necessity, and homebound determinations. With respect to hospice, OIG found that one-third of stays for hospice general inpatient care in 2012 did not meet Medicare requirements, costing \$268 million. *(For more information on the quality of care in home health and hospice, see TMC #7.)*

In addition, OIG has focused efforts on improper payments to Part B providers, such as chiropractors, physical therapists, and certain durable medical equipment (DME) suppliers (e.g., power mobility device suppliers). Historically, these providers have had high improper payment rates, and OIG has identified error rates exceeding 50 percent in its reviews of them.

Preventing, Detecting, and Responding to Fraud. Curbing fraud is vital to protecting beneficiaries and conserving scarce health care resources. Fraud schemes can shift over time, but certain Medicare services have been consistent targets. Program areas susceptible to widespread fraud include home health and hospice services and DME. Common schemes include billing for unnecessary services or services not provided and kickbacks to recruiters and patients. Other concerns include aggressive and

illegal DME telemarketing and social targeting of Medicare beneficiaries, which can result in financial loss to Medicare and beneficiaries being put at risk of medical identity theft.

To help prevent fraud, Medicare must have accurate information about the individuals and entities with which it does business and must take appropriate steps to avoid doing business with, and exposing beneficiaries to, those who are untrustworthy. To this end, CMS must fully and effectively deploy all available program integrity tools, including those provided under the Patient Protection and Affordable Care Act, such as enhanced screening of provider enrollments. However, OIG found weaknesses in Medicare contractors' administration of provider enrollments that could leave Medicare vulnerable to billing by ineligible providers and beneficiaries vulnerable to seeking care from substandard providers. The weaknesses included gaps in the verification of key information, inconsistencies in site visit procedures, and failures to use site visit results for enrollment decisions. Further, CMS's Provider Enrollment, Chain and Ownership System (PECOS) is incomplete and, in some cases, inaccurate. The information in PECOS is intended to aid CMS in tracking enrollment and revalidation trends and to help determine whether CMS contractors are meeting requirements.

Fostering Prudent Payment Policies. In certain contexts, Medicare pays significantly different amounts for the same services provided to similar patients in different settings. For example, we estimated that during calendar year 2010 swing-bed services provided at 90 percent of the critical access hospitals (CAHs) we reviewed could have been provided at other nearby facilities that are paid under the Skilled Nursing Facility (SNF) Prospective Payment System. We believe that Medicare could have saved \$4.1 billion over 6 years if payments for swing-bed services at CAHs were made to other facilities at SNF rates. Medicare and beneficiaries also typically pay more for a physician service provided in a "provider-based facility" (i.e., one owned by a hospital) than for the same service provided in an independent facility. OIG has highlighted weaknesses in CMS's management of these payment policies.

CMS is implementing a significant overhaul of the payment system for clinical laboratory tests pursuant to the Protecting Access to Medicare Act of 2014. The new system, which seeks to better align Medicare reimbursement for lab tests with market rates, takes effect on January 1, 2018. Before then, CMS must complete numerous tasks associated with collecting private payer data from labs and using it to establish the new reimbursement rates for lab tests. Timeframes for some of these tasks are tight, e.g., completing sub-regulatory guidance before the data-reporting period begins on January 1, 2017. Further, OIG has raised concerns about risks to payment accuracy on the basis of CMS's plans to rely on labs to self-identify whether they meet the criteria for reporting private payer data and CMS's plans to rely on reporting labs' self-attestations of the data's completeness and accuracy.

Some payment systems create financial incentives that may negatively affect patient care and drive up Medicare costs. For example, Medicare's payment policies for SNFs gives these facilities incentives to bill for higher levels of therapy than beneficiaries need. OIG work showed that SNFs have billed for the highest level of therapy at increasing rates that were not supported by patient needs. Additionally, hospices provided care much longer and received much higher Medicare payments for beneficiaries in inpatient assisted living facilities (ALFs) than for beneficiaries in other settings, creating incentives for hospices to target these patients. OIG found that Medicare payments for hospice care in ALFs more than doubled in 5 years, totaling \$2.1 billion in 2012.

Progress in Addressing the Challenge

Through the Health Care Fraud and Abuse Control (HCFAC) Program, OIG, HHS, and the Department of Justice have made substantial strides in fighting fraud, waste, and abuse in Medicare (all parts) and Medicaid and recovering stolen and misspent funds. From 2013 to 2015, the HCFAC Program has

returned \$6.10 for every \$1 invested. In FY 2015, HCFAC-funded audits and investigations resulted in expected recoveries of \$2.4 billion. To combat Medicare fraud, waste, and abuse, HHS has also taken steps to implement additional program integrity tools and many of OIG's recommendations. Specifically, in FY 2015, OIG reported potential savings of more than \$18.4 billion from legislative, regulatory, and administrative actions taken by HHS and that were supported by OIG recommendations.

CMS is implementing prior authorization models and demonstrations in certain areas to help make sure items and services are provided in compliance with Medicare coverage, coding, and payment rules. CMS has established or is implementing prior authorization processes in certain locations that cover the following: power mobility devices, repetitive scheduled non-emergent ambulance transport, and certain durable medical equipment, prosthetics, orthotics, and supplies. CMS has also begun implementing a demonstration project in five States requiring home health agencies to submit required documentation for pre-claim review to help reduce and prevent improper payments. OIG has noted reductions in Medicare billing and payments for certain services and geographic areas known for fraud risks. For example, following law enforcement activities and CMS administrative actions, billing and payments for home health services and community mental health services declined significantly from 2009 to 2014 in fraud hot spots.

Furthermore, CMS has performed actions to improve provider enrollment safeguards to protect the integrity of the Medicare program. CMS has expanded its temporary provider enrollment moratoria for home health agencies to Statewide moratoria in certain geographic locations known for significant fraud. CMS has also proposed new regulations that would use its provider and supplier information more effectively to keep out or remove providers who pose risks to Medicare and its beneficiaries. In FY 2016, CMS reported that it has enhanced the address verification software in PECOS to better detect vacant or invalid addresses or commercial mailing reporting agencies. Further, CMS has reported improvements in its oversight and measurement of its contractors' performance and its corrective actions regarding improper payment vulnerabilities that contractors identify.

With respect to clinical laboratory services, CMS reports significant progress in several key areas, including promulgating regulations, establishing the Advisory Panel, publishing most of the sub-regulatory guidance, and building the data collection system. Finally, CMS is working to implement new legislation that would restrict the higher payment rates for provider-based facilities to "on-campus" facilities (those within 250 yards of the main provider) and to "off-campus" facilities that were designated as such before November 2, 2015.

What Needs To Be Done

Despite progress in some key areas, more must be done to protect Medicare from fraud, waste, and abuse and extend the solvency of the program. CMS could do more to ensure that fraudulent or abusive providers are not allowed to enroll or remain in Medicare in order to help prevent inappropriate payments, protect beneficiaries, and reduce the need for collection efforts against fraudulent providers who abscond with ill-gotten Medicare funds. CMS must continue improving its oversight and the performance of contractors in implementing Medicare provider enrollment safeguards, ensuring payment accuracy, and identifying and recovering overpayments in a timely manner. CMS should also improve the completeness, accuracy, and timeliness of its provider ownership data (maintained in PECOS) to support effective oversight.

HHS should continue to address and resolve program integrity weaknesses identified. OIG has recommended numerous actions, which remain unimplemented, to reduce improper payments for

specific services. For example, OIG has recommended that CMS increase its oversight of hospice general inpatient claims, ensure that a physician is involved in the decision to use this level of care, and conduct prepayment reviews for lengthy stays. OIG has also recommended strengthened safeguards to ensure that Medicare pays for home health services only when the beneficiary meets the applicable homebound requirement and the home health agency has provided reasonable and necessary skilled services that are supported by and documented in the physician's certification plan.

OIG has also recommended changes to promote more prudent payment policies, including payments to hospital outpatient departments and ambulatory surgical centers, SNFs, and hospices. Many of these changes would require new statutory authority, and HHS's role is to develop legislative proposals for consideration by the Administration and Congress. Concurrently, OIG has recommended numerous actions that CMS can take within its existing authorities to mitigate the financial and quality of care risks under the current systems. For example, OIG recommended that CMS analyze billing data to identify SNFs that appear to be overbilling for therapy and expand its oversight reviews of those SNFs.

For laboratory tests, CMS must maintain focus on key remaining tasks, including completing the data collection system, ensuring completeness and accuracy of reported data, and establishing new Medicare payment rates after labs report data in 2017. CMS should monitor labs' reporting to ensure that all required labs' report data are accurate and complete. In the longer term, CMS should monitor the new system to ensure that it is meeting its cost savings goals.

Key OIG Resources

- OIG Testimony, "Medicare and Medicaid Program Integrity: Combatting Improper Payments and Ineligible Providers," May 2016. (<https://oig.hhs.gov/testimony/docs/2016/maxwell-testimony05242016.pdf>)
- OIG Report, "Medicare Hospices Have Financial Incentives to Provide Care in Assisted Living Facilities," January 2015. (<https://oig.hhs.gov/oei/reports/oei-02-14-00070.pdf>)
- OIG Report, "Medicare Compliance Review of Sea View Health Care Services, Inc.," May 2016. (<https://oig.hhs.gov/oas/reports/region2/21401027.pdf>)
- 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, "Nationwide Analysis of Common Characteristics in OIG Home Health Fraud Cases," June 2016. (<https://oig.hhs.gov/oei/reports/oei-05-16-00031.pdf>)

Top Management Challenge #2: Effectively Administering the Medicaid Program to Improve Oversight of Managed Care, Address High Improper Payments, and Strengthen Program Integrity

Key Components of the Challenge

- Oversight of Medicaid managed care
- Reducing improper payment rates
- Strengthening program integrity to protect against fraud, waste, and abuse

Why This Is a Challenge

With over 72 million enrolled individuals, Medicaid serves more enrollees than any other Federal health care program and represents one-sixth of the national health economy. Effectively administering the Medicaid program takes on heightened urgency as the program expands under the Patient Protection and Affordable Care Act (Affordable Care Act) and undergoes other significant modernization reforms. The Centers for Medicare & Medicaid Services (CMS) reported that Federal and State Medicaid expenditures are projected to increase at an average annual rate of 6.4 percent and reach \$921 billion by 2024.

Effectively administering Medicaid continues to be a top management challenge for HHS, given the needs of the beneficiaries served and longstanding vulnerabilities related to oversight of Medicaid managed care; high improper payment rates; and harnessing program integrity tools, including data, to protect the program from fraud, waste, and abuse.

Key Components of the Challenge

Oversight of Medicaid Managed Care. The vast majority of Medicaid beneficiaries are enrolled in managed care. OIG has identified challenges to ensuring that these beneficiaries have access to high-quality care and that Medicaid funds are expended properly. For instance, OIG has found that varying State standards for access (e.g., States range from requiring one primary care provider for every 100 to 2,500 enrollees) and limited appointment availability may limit beneficiary access to services. OIG has also found that CMS does not have complete and timely managed care data from State Medicaid agencies. These data are necessary to identify and address possible fraud, waste, and abuse.

Improper Payment Rates Are High. Reducing improper payments to providers is a critical element in protecting the financial integrity of the Medicaid program. In FY 2015, HHS did not meet its established improper payment target for Medicaid. HHS set a FY 2015 target of 6.7 percent for Medicaid. However, the actual improper payment rate for FY 2015 was 9.8 percent. Although not all improper payments are fraud, all improper payments pose a risk to the financial security of the Medicaid program.

Program Integrity Needs Strengthening. CMS and State Medicaid agencies have a shared responsibility to ensure that Medicaid expenditures are spent appropriately and also to protect the program from fraud, waste, and abuse. However, OIG has found that the Affordable Care Act's screening tools designed to strengthen provider enrollment were not fully implemented by State Medicaid agencies. In addition, OIG has found that CMS's national Medicaid database—essential to effective program oversight—is incomplete and additional data are needed to enhance national program integrity activities. (*For more information on improving the flow of complete, accurate, and timely information, see TMC #3.*) Finally, OIG identified significant and persistent vulnerabilities related to personal care services (PCS), including ineffective program safeguards to ensure that beneficiaries are not exposed to

unsafe or suboptimal care and Medicaid is not exposed to high improper payments. (For more information on ensuring quality in PCS and other services, see TMC #7.)

Progress in Addressing the Challenge

New Medicaid Managed Care Regulations. In May 2016, CMS issued a Medicaid Managed Care Final Rule. The rule addressed numerous OIG recommendations and will strengthen oversight of managed care entities by improving accountability and transparency. For example, the rule expanded requirements for managed care organizations to report data related to utilization and quality of services. The rule also requires State Medicaid agencies to develop and implement provisions ensuring that beneficiaries have adequate access to Medicaid covered services. Once provisions are implemented, State Medicaid agencies will be required to annually validate network adequacy.

Improper Payment Rate Corrective Action Plans. CMS determined that the primary reasons for the high FY 2015 improper payment rate errors were related to State Medicaid agencies' difficulties coming into compliance with new requirements. These include enrolling all referring or ordering providers, screening providers under the Affordable Care Act risk-based screening process, and including the attending provider National Provider Identifier on all electronically-filed institutional claims. CMS has engaged with State Medicaid agencies to develop State-specific corrective action plans that address these reasons for the high improper payment rate. CMS has also facilitated national best practice calls to share ideas across States, offered ongoing technical assistance, and provided additional guidance, as needed, to address the root causes of these improper payments.

CMS Working with States to Implement Program Integrity Measures. CMS indicated that it is taking actions to address provider enrollment vulnerabilities identified by OIG. CMS recently released guidance, "Medicaid Provider Enrollment Compendium," to assist State Medicaid agencies in implementing disclosure requirements and the Affordable Care Act's screening and enrollment requirements. Furthermore, CMS's final rule on managed care requires State Medicaid agencies to screen and enroll all network providers. This new requirement is a significant step in addressing a large number of providers previously exempt from State Medicaid agencies' screening and enrollment requirements. CMS continues to work with States to improve Medicaid data. Specifically, CMS works with all State Medicaid agencies to submit complete, accurate, and timely data. In addition, CMS conducted focused reviews of State Medicaid agencies' high-risk program integrity areas, including State Medicaid agencies' implementation of provider enrollment and screening provisions of the Affordable Care Act. Finally, CMS is assessing what actions it can implement to address the longstanding and persistent PCS vulnerabilities identified by OIG.

What Needs To Be Done

Full Implementation of the Medicaid Managed Care Regulation. CMS's issuance of the Medicaid Managed Care Final Rule is a positive step in addressing the managed care vulnerabilities identified by OIG. The final rule is the first major update to Medicaid managed care regulations in more than a decade. To facilitate full implementation of the final rule, CMS should continue to provide guidance to State Medicaid agencies in a timely manner and work closely with them to develop effective strategies to meet new requirements.

Reduce the Improper Payment Rate. CMS should continue its engagement with State Medicaid agencies to develop corrective action plans. Moreover, CMS should ensure that State Medicaid agencies are implementing and monitoring the effectiveness of their corrective action plans. Finally, CMS should continue innovative approaches, such as the creation of the Program Integrity Board, which leverages multiple CMS resources to identify payment vulnerabilities.

Ensure States Fully Implement Program Integrity Measures. CMS should continue to work with State Medicaid agencies to fully implement Affordable Care Act-required program integrity tools. Full implementation of these tools is critical to safeguarding the Medicaid program. CMS must ensure that State Medicaid agencies rigorously screen providers and make accurate beneficiary eligibility determinations. CMS should also continue to work with State Medicaid agencies to ensure that the submission of all required Medicaid data is complete, accurate, and timely. Finally, CMS must do more to address vulnerabilities in home- and community-based services, such as PCS. OIG recommends that CMS take a more active role to promote program integrity in PCS by promulgating regulations to, among other things, establish minimum qualifications and require attendants to undergo background checks and enroll in Medicaid or register with State Medicaid agencies.

Key OIG Resources

- OIG Testimony, “Medicare and Medicaid Program Integrity: Combatting Improper Payments and Ineligible Providers,” May 2016. (<https://oig.hhs.gov/testimony/docs/2016/maxwell-testimony05242016.pdf>)
- OIG Report, “Personal Care Services: Trends, Vulnerabilities and Recommendations for Improvement – A Portfolio,” November 2012. (<http://oig.hhs.gov/reports-and-publications/portfolio/portfolio-12-12-01.pdf>)
- 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, “Providers Terminated from One State Medicaid Program Continued Participating in Other States,” August 2015. (<https://oig.hhs.gov/oei/reports/oei-06-12-00030.asp>)

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

Key Components of the Challenge

- Ensuring privacy and security of information
- Improving the flow of complete, accurate, and timely information
- Delivering on the promise of Health IT

Why This Is a Challenge

In support of its mission and operations, HHS maintains and uses expanding amounts of sensitive information. Complete, accurate, and timely data can help ensure efficient operations of HHS and its programs, as well as support proactive program oversight. Similarly, the American health care system increasingly relies on health information technology (health IT) and the electronic exchange and use of health information. Health IT, including electronic health records (EHRs), offers opportunities for improved patient care, more efficient practice management, and improved overall public health. However, HHS continues to face a number of significant challenges in this information-rich environment.

Key Components of the Challenge

Ensuring Privacy and Security of Information. Safeguarding privacy and ensuring data security—both physical and cyber security—are, and should remain, top priorities for HHS. HHS must ensure that the data it creates and maintains are protected. Equally important is the need to ensure appropriate protection of health information when considering and implementing policies related to the adoption of health IT and the exchange, storage, and use of electronic health information. The rapid pace at which technology evolves, the continuing expansion of the Internet of Things (including networked medical devices), and the rise of mobile health technology contribute to the complexity of the privacy and security challenges facing HHS.

The frequency of notable data breaches has increased significantly, and ransomware has emerged as a considerable threat in the health care space. Data breaches can have serious consequences for the health care industry, HHS, and those whom HHS serves. Threats to the confidentiality, integrity, and availability of data can result in a range of harms, including financial harm (to individuals and the public), identity theft, and physical patient harm. Frequently-identified weaknesses include inadequacies in access controls, patch management, encryption of data, and website security vulnerabilities at HHS, health care providers, States, and other entities that do business with HHS. Such weaknesses could impact the Department's ability to protect against unauthorized access to sensitive information. HHS is also responsible for implementing certain provisions of the Cybersecurity Act of 2015, as well as the Continuous Diagnostics and Mitigation program in conjunction with the Department of Homeland Security (DHS). When implementing technology, including complex, interoperable IT systems, HHS must utilize modern IT practices, such as those highlighted by the [Digital Services Playbook](#).

Improving the Flow of Complete, Accurate, and Timely Information. To capitalize on growing amounts of data in the health care context,¹ there must be meaningful access, subject to appropriate privacy and security safeguards, to complete, accurate, and timely data, where and when needed. However,

¹ Sources of relevant health care data, including patient-generated data, are ever increasing, particularly as the Internet of Things continues to expand.

enabling and encouraging the flow of information remains a challenge for HHS. Several factors may impede the flow of information. These include technical barriers (e.g., lack of interoperability), the complex nature of Federal and State privacy and security laws, financial considerations (e.g., the cost of health IT acquisition), and behavioral issues—such as information blocking² and consumer confidence—that relate to a willingness to share information.

Impediments to information sharing can present patient safety concerns. For example, a patient could be subjected to additional invasive testing that could have been avoided had information about prior results held by a different provider been shared. Improving the appropriate flow of health information among providers, patients, and those delivering related services is also critical to the success of many delivery reform and other initiatives, including the President’s [Precision Medicine Initiative](#) (PMI) and the [Cancer Moonshot](#). Without appropriate information sharing, those who participate in the initiatives may face challenges in achieving initiative goals. *(For more information on health care delivery reforms, see TMC #9.)*

The flow of information is also important between HHS and others, including providers. For example, data created, maintained, or transmitted using EHRs or other health IT are used to ensure correct Medicare and Medicaid payments, including value-based payments. Participants in certain initiatives also receive Departmental data for their use in improving the care they furnish. Additionally, HHS increasingly uses and shares data as part of its program operations and program integrity efforts. HHS must continue to find ways to leverage the vast amounts of data at its disposal to enhance decision-making, including streamlining and accelerating internal data exchange. Similarly, it is critical that HHS ensure that the systems on which it relies, including Medicare and Medicaid systems, are developed and operate in a way that ensures that the data are complete, accurate, timely, and appropriately protected. Prior OIG work has raised concerns about, for example, the completeness and accuracy of Transformed Medicaid Statistical Information System (T-MSIS) data.

Delivering on the Promise of Health IT. HHS has made significant investments in health IT.³ However, HHS faces challenges in ensuring that the goals associated with investing in the widespread adoption and use of EHRs and other health IT are fulfilled, and that the promise offered by health IT is realized. These challenges are in addition to the challenges of ensuring privacy and security and improving the flow of complete, accurate, and timely information. They include preventing inappropriate payments to participants who do not meet program requirements; ensuring that the beneficial characteristics of EHRs, including efficiency and ease of storage and access, are not used as tools for fraud; encouraging adoption and use of health IT by those who are not eligible for existing incentive programs; ensuring that patient safety benefits are realized; and encouraging the use of data that are exchanged.⁴ Connecting the entire continuum of those involved in health care, as well as human services, is

² For more information on the topic of information blocking, see The Office of the National Coordinator for Health Information Technology’s (ONC) Report to Congress, “Report on Health Information Blocking,” April 2015. (https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf).

³ For example, in connection with the PMI, the National Institutes of Health (NIH) issued \$55 million in grants, some of which will be used to establish a data and research support center and a participant technologies center. (<https://www.nih.gov/news-events/news-releases/nih-awards-55-million-build-million-person-precision-medicine-study>)

⁴ ONC noted the need to improve the use of exchanged information by non-Federal acute care hospitals. ONC, Data Brief, No. 36, “Interoperability among U.S. Non-federal Acute Care Hospitals in 2015,” May 2016. (https://www.healthit.gov/sites/default/files/briefs/onc_data_brief_36_interoperability.pdf)

important to leveraging the benefits of health IT in a value-driven health care system. *(For more information on health delivery reforms, see TMC #9.)* Also important is ensuring that the underlying data are robust enough to be leveraged for important research and regulation.⁵ When addressing these challenges, HHS must ensure coordination among internal agencies, as well as other Federal partners, with overlapping responsibility for various aspects of health IT to avoid potential gaps in policy and oversight that could undermine the promise of the health IT in which HHS has invested.

Progress in Addressing the Challenge

HHS has made progress with respect to privacy and security of its systems and information. Last year, HHS participated in the U.S. Chief Information Officer's [30-day Cybersecurity Sprint](#). More recently, HHS adopted DHS's Continuous Diagnostics and Mitigation program and is in the process of implementing [EINSTEIN 3A](#).

Similarly, HHS has made progress regarding the privacy and security of external health information. For example, HHS participated in the development of the PMI: [Data Security Policy Principles and Framework](#); the Food and Drug Administration (FDA) held a [public workshop](#) with DHS concerning medical device cybersecurity; HHS's coordination with the Federal Trade Commission led to the issuance of [new resources for health IT developers](#), including some related to privacy and security; HHS, in conjunction with other Federal agencies, issued [ransomware guidance](#) discussing best practices; and the Office for Civil Rights (OCR) released a [Fact Sheet](#) on the Health Insurance Portability and Accountability Act (HIPAA) and ransomware. Further, HHS has taken steps to implement portions of the Cybersecurity Act of 2015, including convening a [health care industry cybersecurity task force](#).

HHS has made great strides in developing a nationwide health IT infrastructure that supports the appropriate flow of complete, accurate, and timely information. As of September 2016, more than 599,000 eligible professionals, eligible hospitals, and critical access hospitals were actively registered in the EHR incentive programs.⁶ Additionally, HHS has made a concerted effort to empower patients with respect to accessing their electronic health information.⁷ HHS continues to focus on liberating health data in order to improve patient outcomes and health care delivery as well as social services. A sample of some of HHS's data initiatives include the Centers for Medicare & Medicaid Services' (CMS) release of new and updated public use files related to physician payment data and interactive online tools (such as the Medicare Part D Opioid Drug Mapping Tool and Mapping Medicare Disparities Tool); NIH's Genomic Data Commons platform to store, analyze, and distribute cancer genomics data; FDA's openFDA now allows direct downloads of data (openFDA offers access to medical device reports, enforcement reports, and drug adverse event reports); and Centers for Disease Control and Prevention's publically available

⁵ FDA, for example, issued draft guidance concerning the use of real-world evidence to support regulatory decision-making for medical devices, which notes that "[real-world data] and associated [real world evidence] could constitute valid scientific evidence, depending on the characteristics of the data." (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf>)

⁶ CMS "[State Breakdown of Registration by Medicaid and Medicare Providers through September 30, 2016](#)," September 2016.

⁷ OCR issued a Fact Sheet (<http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>); ONC and OCR released [educational videos](https://www.healthit.gov/access) (<https://www.healthit.gov/access>); and ONC issued a patient engagement playbook (<https://www.healthit.gov/playbook/pe/>).

data repository related to the ongoing Zika epidemic. The year 2016 also marked the 7th Annual Health Datapalooza, which brought together startups, academics, Government agencies, and individuals.⁸

With respect to information blocking, HHS established a hotline to receive complaints concerning potential information blocking practices and issued a final rule implementing related attestation requirements under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Further, HHS obtained [commitments](#) from providers of hospital EHRs, large private health systems, and leading professional associations and stakeholder groups to make EHRs work better for patients and providers. One of the areas of commitment relates to avoiding information blocking.

HHS's participation and leadership in the Healthcare Fraud Prevention Partnership (HFPP) continues to improve the flow of information to address program integrity issues. The HFPP, a public-private partnership, brings interested parties—including private insurers, public payors, law enforcement agencies, and others—together to share and use data and analytic tools to proactively address health care fraud, waste, and abuse. Further, HHS continues to work with States to improve Medicaid data that are essential for protecting program integrity. Specifically, CMS issued a final rule in December 2015 authorizing the withholding of a subset of Federal funds for Medicaid administration from States until T-MSIS data are reported as required and information systems meet operability standards. In addition, CMS has established standards for the completeness, accuracy, and timeliness of T-MSIS data. According to CMS, it is in the process of implementing T-MSIS with all states, and there are 18 states in production as of September 2016. CMS also reports that it anticipates T-MSIS data to be available for the various stakeholders in early 2017 subject to state T-MSIS transition timelines.

HHS has continued to oversee the Medicare and Medicaid EHR incentive programs and has endeavored to advance the national conversation about important health IT issues to ensure that the potential benefits of health IT investments are realized.⁹ HHS has also finalized a rule to implement the MACRA provisions that replace the Medicare EHR Incentive Program for eligible professionals with the Advancing Care Information Performance Category of the Merit-based Incentive Payment System (MIPS).

⁸ HHS also collaborated with Health Datapalooza to add a post-conference day devoted to health IT privacy and security. (<https://www.healthit.gov/buzz-blog/privacy-and-security-of-ehrs/new-health-datapalooza-2016-day-devoted-privacy-security/>)

⁹ Last year, ONC issued a document entitled "Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure" (<http://healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf>) (10-Year Vision Paper), which describes plans to expand the sharing of information for health beyond EHRs and identifies privacy and security protections for health information as a building block for a nationwide interoperable health information infrastructure. More recently, ONC issued a document entitled "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0," (<https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>) which supports the vision laid out in the 10-Year Vision Paper. ONC has also issued an information-blocking report to Congress. (https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf), 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).

What Needs To Be Done

Threats to information privacy and security are evolving, as evidenced by the recent rise of ransomware, and HHS must remain vigilant. While HHS has made progress with respect to protecting its own information, as highlighted in OIG work and a [congressional report](#) from 2015, more remains to be done. OIG work will continue to focus on HHS systems' privacy and security to support HHS's efforts to mitigate the risk of unauthorized access to its sensitive information. HHS must also use available policy levers to address health IT privacy and security issues. OIG work released in 2016 examined HIPAA-required contingency planning for hospitals' EHRs and discussed the role contingency plans can play in preventing and mitigating disruptions caused by ransomware and other problems. Phase 2 of OCR's HIPAA Audit Program, which it launched in 2016, and OCR's efforts to increase investigations of smaller breaches (those involving fewer than 500 individuals)¹⁰ are additional activities that will bring attention to health IT privacy and security. OIG work will continue to focus on privacy and security issues in the regulated community and on the related agencies to address concerns about similar risks for health information. Ongoing work is considering privacy and security issues related to networked medical devices, and future work may consider additional privacy and security issues that arise from the continuing expansion of the Internet of Things.

To reach HHS's goals, including goals related to achieving the learning health system identified in ONC's 10-Year Vision Paper and those associated with the PMI and Cancer Moonshot, HHS must do more to improve the flow of complete, accurate, and timely information, subject to appropriate privacy and security safeguards. This includes ensuring that HHS's data systems are developed and operated in a way that delivers complete, accurate, and timely data. HHS must also find ways to remove potential barriers to leveraging health IT and related data to advance public health initiatives and to facilitate sharing and use of information along the entire continuum of care (beyond just those who are eligible for EHR incentives).

Finally, to deliver on the promise of health IT, and given the magnitude of the investment in EHRs and other health IT programs, it will become increasingly important to measure the extent to which EHRs and health IT have achieved HHS's goals, which include improved health care and lower costs. As HHS develops policies, such as those related to the development and implementation of meaningful use stages and implementation of the Advancing Care Information Performance Category of MIPS created in MACRA, it should continue to consider feedback from stakeholders to ensure that adopted policies advance the Nation toward HHS's stated goals, while appropriately reflecting the rapidly changing health IT landscape and balancing privacy and security considerations. Additional guidance and technical assistance should be issued to address adoption, meaningful use, interoperability barriers, and program integrity safeguards. It is also essential that privacy, security, and fraud prevention remain at the forefront of health IT efforts of HHS, ONC, OCR, and CMS. Ongoing OIG work is examining the accuracy of Medicare and Medicaid EHR incentive payments for meaningful use and health IT interoperability across providers participating in accountable care organizations. Future work may also examine health IT interoperability across HHS and between providers and patients as well as outcomes from health IT investments.

¹⁰ OCR listserv email from August 19, 2016, entitled "OCR Announces Initiative to More Widely Investigate Breaches Affecting Fewer than 500 Individuals," available at <https://list.nih.gov/cgi-bin/wa.exe?A2=OCR-PRIVACY-LIST;65d278ee.1608>.

Key OIG Resources

- 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 Report, “Hospitals Largely Reported Addressing Requirements for EHR Contingency Plans,” July 2016. (<https://oig.hhs.gov/oei/reports/oei-01-14-00570.asp>)
- OIG Report, “Not All States Reported Medicaid Managed Care Encounter Data as Required,” July 2015. (<https://oig.hhs.gov/oei/reports/oei-07-13-00120.asp>)
- OIG Report, “CMS and Its Contractors Have Adopted Few Program Integrity Practices To Address Vulnerabilities in EHRs,” January 2014. (<https://oig.hhs.gov/oei/reports/oei-01-11-00571.asp>)
- OIG Report, “Not All Recommended Fraud Safeguards Have Been Implemented in Hospital EHR Technology,” December 2013. (<https://oig.hhs.gov/oei/reports/oei-01-11-00570.asp>)

Top Management Challenge #4: Improving Financial and Administrative Management

Key Components of the Challenge

- Addressing weaknesses in financial management systems
- Reducing improper payments
- Improving contracts management
- Implementing DATA Act standards.

Why This Is a Challenge

HHS is the largest civilian agency within the Federal Government. In FY 2015, HHS reported total costs of approximately \$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

Financial Management Systems. We continue to report a material weakness in HHS's financial management systems related to inadequate internal controls over segregation of duties, configuration management, and access to HHS financial systems. HHS still does not substantially comply with financial management system requirements due to these issues. Under the Federal Financial Management Improvement Act of 1996, Federal agencies must establish and maintain financial management systems, and Inspectors General must determine 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.

Improper Payments. Reducing improper payments is a critical element in protecting the financial integrity of HHS programs. Although not all improper payments are 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 its most recent Agency Financial Report (AFR), HHS reported improper payments totaling \$89.7 billion overall for FY 2015 (excluding Superstorm Sandy programs). Our audit of HHS's FY 2015 AFR, published in May 2016, found that HHS did not meet all IPIA requirements. Specifically, we found that HHS did not report an improper payment rate for the Temporary Assistance for Needy Families (TANF) program, reported that the improper payment rate exceeded 10 percent for the Medicare Fee-for-Service program, reported four other risk-susceptible programs that did not meet their FY 2015 target error rates, and did not perform a risk assessment of payments to employees and charge card payments. HHS does not have the statutory authority to collect data from States that is necessary for calculating a TANF improper payment rate.

Contracts Management. HHS is one of the largest contracting agencies in the Federal Government. Given the high dollar amount and complexity of 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 Health Insurance Marketplaces operated by the Centers for Medicare & Medicaid Services (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. 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 its benefit integrity contractors.

Digital Accountability and Transparency Act. The Digital Accountability and Transparency Act (DATA Act) required the Office of Management and Budget (OMB) and Department of the Treasury to establish Governmentwide data standards for reporting financial and payment information by May 2015.

Broadly, the DATA Act requires HHS to begin using the Governmentwide data standards to enter information into USA Spending by May 2017 in an effort to ultimately increase transparency and accountability. Our readiness review of HHS's implementation of the DATA Act as of June 30, 2016, found that although HHS made progress, they have 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 is 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, we determined that HHS will face challenges implementing these uniform data standards within the required timeframe.

Progress in Addressing the Challenge

HHS has taken corrective actions to resolve the information technology-related deficiencies reported in the AFR. In FY 2015, senior leadership placed additional focus on this area, which has remediated a number of deficiencies related to HHS financial management systems identified in past audits. HHS reviewed and updated critical entitywide governance documentation, such as authorities that allow systems to operate, plans to account for and improve system security, and configuration management. HHS also updated application-level contingency plans and backup policies and procedures and performed testing to improve redundancy and availability of the supporting information technology infrastructure and financial application system.

HHS has stated that when legislation is considered to reauthorize TANF, HHS plans to work with Congress to address a set of issues related to accountability and how funds are used, and to craft statutory changes that would allow for reliable error rate measurement, if appropriate. HHS also stated that it would perform risk assessments of payments to employees and charge card payments in FY 2016 and publish the results in the FY 2016 AFR.

In November 2015, HHS published a final rule that updated the HHS Acquisition Regulation (HHSAR) to supplement the Federal Acquisition Regulation. The HHSAR provides additional policy and procedural guidance to foster financial integrity and accountability across the acquisition lifecycle, from the concept of need through contract closeout. Additionally, CMS reported that it has prioritized closing out contracts. Since February 1, 2014, CMS reported that it has closed 4,909 contracts with an obligated value of \$2.2 billion and de-obligated \$82.49 million.

HHS has established a DATA Act Project Management Office within the Office of the Assistant Secretary for Financial Resources. This encompasses representatives from all of its operating divisions. HHS expects that these actions will enable it to meet the May 2017 due date for implementing the Governmentwide data standards. The HHS DATA Act Program Management Office 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 recommendations to Congress 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

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.

In addition, HHS must meet improper payment reduction targets and reduce improper payments to less than 10 percent for all programs. HHS must conduct thorough root cause analyses of significant improper payments and develop robust corrective action plans that target identified causes. HHS also must conduct a risk assessment of payments made to employees and use of charge cards.

CMS should improve coordination and collaboration across departmental staff with contract closeout responsibilities. CMS must also ensure that acquisition strategies are completed as required. Further, CMS must strengthen its contracts oversight, including proper accounting for contract costs related to the Federal Marketplace.

HHS must implement the Governmentwide data standards established by OMB and Department of the Treasury in accordance with the timeframes established by the DATA Act. HHS must also ensure that any information provided to comply with the Governmentwide data standards is complete, accurate, and timely.

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.asp>)
- OIG Report on Financial Statement Audit of Health and Human Services for Fiscal Year 2015, November 2015. (<http://www.hhs.gov/sites/default/files/afr/fy-2015-hhs-agency-financial-report.pdf>)
- 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 on the DATA Act Readiness Review Audit of the Department of Health and Human Services," November 2016. (<https://oig.hhs.gov/reports-and-publications/oas/dept.asp>)

Top Management Challenge #5: Ensuring the Proper Administration of HHS Grants for Public Health and Human Services Programs

Key Components of the Challenge

- Misuse of grant funds
- Inadequate oversight of programs for children
- Inadequate oversight of preparedness and response to emergencies and infectious diseases.

Why This Is a Challenge

HHS is the largest grant-making organization in the Federal Government, with more than \$400 billion awarded in FY 2016. The Patient Protection and Affordable Care Act (Affordable Care Act) provided additional grants funding, adding to HHS's oversight responsibility. Responsible stewardship of these program dollars is vital to public health and well-being. Operating a financial management and administrative infrastructure that employs appropriate internal controls to minimize risk and protect resources remains a challenge for HHS.

Vulnerabilities exist in grants management throughout HHS. For example, awarding agencies lack effective mechanisms to share information about problematic grantees. Intra-department communication is critical, especially because awarding agencies are now required to assess risks posed by grant applicants. Additionally, awarding agencies' monitoring of grantee progress over the life of the grant continues to need improvement. Once funds are awarded, effective oversight is key in ensuring that grantees expend Federal funds properly and efficiently. Lastly, many HHS grantees lack effective internal controls, including robust financial management systems required to provide effective accountability for Federal funds. To fulfill grant responsibilities and ensure accountability of Federal funds, grantees are required to maintain internal controls that provide reasonable assurance that operations are effective and efficient, ensure reliable reporting for internal and external use, and comply with laws and regulations. In addition to its usual grants administration and oversight activities, HHS faces the challenge of updating its internal and external grants policies and systems in accordance with 45 CFR part 75, its new regulation governing grants administration and the establishment of cost principles.

Examples of specific vulnerabilities in HHS grant programs include misuse of funds, inadequate oversight of programs for children, and inadequate oversight of preparedness and response to emergencies and infectious diseases.

Key Components of the Challenge

Misuse of Grant Funds. Misuse of Federal funds poses significant risks to the integrity of HHS programs. For example, in 2015 the University of Florida entered into a \$19.875 million settlement agreement with OIG and HHS to resolve allegations that the University overcharged hundreds of HHS grants for the salary costs of its employees, charged some of these grants for administrative costs for equipment and supplies when those items should not have been directly charged to the grants under Federal regulations, and inflated costs charged to HHS grants. In another example, five individuals from Montana were convicted of fraud and sentenced in 2015 after improperly receiving Temporary Assistance for Needy Families (TANF) funds from the Blackfeet Tribe of the Blackfeet Nation in Montana and from the Federally funded State welfare program simultaneously. The Administration for Children and Families (ACF) worked with OIG to pursue a misuse of funds penalty against the Tribe for lack of oversight of HHS funds in its TANF program.

Oversight of Programs for Children. For HHS block grants, States are given broad flexibility to oversee and monitor funds and determine the fraud-prevention activities they will use to help ensure program integrity. OIG found that States differed in the scope and method of their program integrity and antifraud activities. For the Child Care and Development Fund (CCDF)—a \$5.7 billion program that services nearly 1.4 million children every month—OIG identified weaknesses in the fiscal controls over CCDF funds in various States and, in total, reported more than \$39.4 million in fund expenditures for FYs 2004–2010 that did not comply with Federal requirements. ACF has been working in the CCDF Block Grant structure to encourage States to adopt more uniform program integrity policies. The CCDF final rule, published on September 30, 2016, requires States to have effective procedures and practices to ensure integrity and accountability in the CCDF program. In addition, HHS oversees a variety of grantees providing for the care and services for unaccompanied children entering the United States from foreign countries and must maintain vigilance against fraud. For example, a grantee case manager in Florida defrauded more than 10 family members and/or potential sponsors of unaccompanied children who were in the custody of the Office of Refugee Resettlement by falsely representing that failing to send the case manager a requested amount of money might delay reunification with their children or result in the child’s deportation. The case worker was sentenced to 18 months of imprisonment and ordered to pay \$11,100 in restitution.

Oversight of Grants for Emergency Preparedness and Response and for Infectious Diseases. Effective protection against public health threats requires a well-coordinated public health infrastructure that can rapidly respond to emergencies at home and internationally. In dealing with infectious diseases such as Zika and Ebola, proper grant mechanisms need to be in place to foster effective response coordination with domestic and international partners. Once policies are in place, awarding agencies must also ensure that funds are effectively awarded and managed. OIG found that the Centers for Disease Control and Prevention (CDC) did not always adequately document its funding decisions to award \$1.9 billion in President’s Emergency Plan for AIDS Relief funds over a 5-year project period. OIG also found that CDC may have considered applications that it should not have or treated applicants inconsistently. HHS must also ensure that grant programs allow appropriate funding flexibility to best address response needs. For example, five States received almost \$475 million in Social Services Block Grant (SSBG) funding to help cover social service and reconstruction expenses resulting directly from Superstorm Sandy. Although Sandy SSBG funds assisted States’ recovery by supporting reconstruction and social service activities, ACF’s guidance limited the effectiveness of State planning and use of the funds.

Progress in Addressing the Challenge

HHS has worked to strengthen its grants program integrity efforts. New grant regulations were codified at 45 CFR part 75, implementing Office of Management and Budget’s Uniform Guidance requirements. Pursuant to those rules, the Assistant Secretary for Financial Resources (ASFR) is implementing a single audit resolution tracking system—scheduled for completion by September 30, 2017. These rules are intended to ensure that all grant closeout activities are completed within 270 days. *(For more information on the DATA Act, see TMC #4.)* Further, ASFR issued the Grants Policy Administration Manual in December 2015, which compiles all internal grants policies in a single location.

HHS has made efforts to assess grant program performance and improve grant oversight along with identifying and reporting potential fraud, waste, and abuse in its programs. For example, the Indian Health Service partnered with OIG to provide training for employees of HHS and tribal facilities on identifying and reporting potential fraud, waste, and abuse. HHS has increased its use of suspension and debarment authorities, resulting in an increase from 32 debarments and 7 suspensions in FY 2014 to 26 debarments, 28 proposed debarments, and 37 suspensions in FY 2015—thus preventing prohibited

businesses and individuals from receiving Federal funding. HHS is actively training awarding agencies on the suspension and debarment process. In addition, HHS has partnered with OIG in presenting suspension and debarment training.

What Needs To Be Done

HHS needs to take more aggressive action to identify poorly performing grantees and those at risk of misspending Federal dollars and either provide increased technical assistance and monitoring or prevent them from continuing to receive grant funds. Sustained focus and information sharing is needed to monitor and address vulnerabilities, and HHS must diligently continue efforts to ensure that recipients use funds consistent with legal requirements and Departmental policies and procedures.

As HHS moves forward to implement requirements related to the new grant regulations at 45 CFR part 75 and the DATA Act, it must ensure that the HHS awarding agencies have processes and appropriate internal controls in place to effectively award, monitor, and report on grants management activities. These include the development of:

- a framework to evaluate risks posed by grant applicants that is then included in funding opportunity announcements;
- a process to correlate grantee financial data to performance accomplishments to demonstrate effective practices and improve program outcomes; and
- a system to standardize grant data elements and publicly report financial spending data for grant awards.

In addition, HHS will need to successfully implement a system to track, monitor, and resolve single audit findings to effectively carry out new management responsibilities under 45 CFR part 75.

HHS should continue to provide training on identifying and pursuing misconduct in grants. Grant officers should more actively coordinate with and refer potential fraud to OIG for investigation. HHS should continue to pursue other avenues of training beyond the classroom setting, such as webinars or podcasts, to reach a broader range of HHS staff that are located domestically and internationally. HHS also needs to continue to refine its suspension and debarment procedures by streamlining the referral and decision process, to continue providing training and decrease the processing time of referrals. Moreover, HHS needs to implement a program to actively pursue fraud under the Program Fraud Civil Remedies Act.

Key OIG Resources

- 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, “Puerto Rico Improperly Claimed Some Child Care and Development Targeted Funds,” January 2016. (<https://oig.hhs.gov/oas/reports/region2/21202016.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.asp>)
- OIG Report, “CDC Did Not Award President’s Emergency Plan for AIDS Relief Funds for 2013 in Compliance with Applicable HHS Policies,” May 2016. (<https://oig.hhs.gov/oas/reports/region4/41404021.pdf>)
- OIG Report, “Link2Health Solutions, Inc., Budgeted Costs That Were Not Appropriate and Claimed Some Unallowable Hurricane Sandy Disaster Relief Act Funds,” March 2016. (<https://oig.hhs.gov/oas/reports/region2/21402013.asp>)

Top Management Challenge #6: Curbing the Abuse and Misuse of Controlled and Non-controlled Drugs in Medicare Part D and Medicaid

Key Components of the Challenge

- Questionable and inappropriate utilization of prescription drugs
- Abuse and misuse of controlled and noncontrolled substances

Why This Is a Challenge

The Centers for Medicare & Medicaid Services (CMS) oversees prescription drug coverage for 41 million Medicare Part D and more than 72 million Medicaid beneficiaries.¹¹ Part D is the fastest growing component of the Medicare program. Since its inception in 2006, Part D spending has more than doubled to \$137 billion in 2015. Medicaid expenditures for prescription drugs are also increasing, influenced by Medicaid expansion and increasing expenditures for expensive specialty drugs. In FY 2014, Medicaid spent approximately \$22 billion, 5 percent of total Medicaid spending, on prescription drugs. HHS's oversight of its prescription drug programs faces numerous challenges, affecting beneficiary and community safety and the integrity of the benefit itself.

Key Components of the Challenge

Oversight. The Part D and Medicaid prescription drug programs are large and complex. In Part D, CMS contracts with plan sponsors, which are responsible for paying claims, monitoring billing patterns, and establishing compliance plans, among other things. CMS also contracts with the Medicare Drug Integrity Contractor to detect and prevent fraud, waste, and abuse in Part D. OIG has identified challenges concerning all of the players charged with safeguarding the program. These challenges relate to (1) the need to more effectively collect and analyze program data to proactively identify and resolve program vulnerabilities and prevent fraud, waste, and abuse before it occurs; and (2) the need to more fully implement robust oversight to ensure appropriate payments, prevent fraud, and protect beneficiaries. *(For information on Medicaid's oversight challenges related to other services, see TMC #2.)*

Drug Abuse and Diversion. Pharmaceutical fraud and drug diversion continue to rise. In FY 2015, OIG had 571 investigative cases and pending complaints involving Medicare and Medicaid prescription drug fraud. In FY 2016, the number of investigative cases and pending complaints rose to 692. Medicaid Fraud Control Units also investigate drug diversion, and they reported to OIG that they had 553 open drug diversion cases, 117 related convictions, and \$4.3 million in recoveries related to drug diversion in FY 2015.

Abuse and Misuse of Controlled Substances. According to the Centers for Disease Control and Prevention, the use of opiates (drugs commonly used for pain relief) and other controlled substances has reached epidemic proportions, with more than 2 million people abusing or dependent upon prescription opioids. Nearly one in three Part D beneficiaries received commonly-abused opioids in 2015. Part D spending for these drugs reached \$4.1 billion in 2015, a 165 percent increase since the

¹¹ The Medicaid beneficiary total includes full and partial dual eligible recipients as well as the Children's Health Insurance Program (CHIP) recipients. Dual eligible recipients receive prescription drug benefits through Part D plans and may also be reflected in the Medicare total numbers. CHIP recipients receive drug benefits through the individual State programs.

program started in 2006. In addition to concerns this trend may raise around questionable and inappropriate utilization, novel abuse methods and refinement techniques present new challenges.

Several HHS operating divisions are responsible for programs related to the safety and efficacy of drugs and drug abuse prevention and treatment. Effectively coordinating all Departmental efforts and prioritizing initiatives are key to combating this complex epidemic. *(For more information on challenges for the Food and Drug Administration (FDA) and Medicaid, see TMCs #10 and #2.)*

Abuse and Misuse of Non-controlled Substances. It is often under-recognized that many non-controlled substances are abused along with opiates to enhance euphoria. These medically-inappropriate dosages and combinations contribute to adverse events, including respiratory depression (hypoventilation) and death. Additionally, Part D spending for compounded drugs (drugs that have been combined, mixed, or altered to create a medication tailored to the needs of an individual patient) increased significantly, particularly for topical medications that have risen by 3,400 percent since 2006. This rapid growth, along with a growing number of fraud cases involving medically-unnecessary compounded drugs, could indicate an emerging fraud trend. *(For more information on ensuring Medicaid quality of care, see TMC #2, and for more information on compounded drugs, see TMC #10.)*

Progress in Addressing the Challenge

Reducing Questionable and Inappropriate Utilization.

CMS has taken steps to improve the oversight provided by the key players tasked with safeguarding Part D. For example, CMS updated its audit process to ensure that sponsors' compliance programs addressed all of the required compliance program elements. When implemented successfully, a compliance plan that includes a comprehensive fraud, waste, and abuse program helps plan sponsors protect the integrity of Medicare funds and may also improve the operating efficiency and effectiveness of plan sponsors. CMS is also taking steps to prevent pharmacy billing fraud and overutilization of prescription drugs. Specifically, CMS has implemented a system to reject payments for Part D prescriptions written by providers who have been excluded from Federal health care programs.

In April 2015, CMS launched Predictive Learning Analytics Tracking Outcome (PLATO), a web-based tool to allow CMS, law enforcement, and plan sponsors to share information and coordinate actions against high-risk pharmacies and prescribers.

Reducing Abuse and Misuse of Controlled Substances.

CMS started publicly sharing data to raise community awareness among providers and local public health officials about regional opioid-prescribing habits. In November 2015, CMS released an interactive online mapping tool, which shows geographic comparisons at the State, county, and ZIP code levels of Medicare Part D opioid prescriptions (excluding private and personal information). HHS has also taken

Addressing the Rising Costs for Prescription Drugs

The effect of high and rising prices for drugs on beneficiary costs and access to medications is a significant challenge facing the Department and the entire health care system. Rising prescription drug prices also have a significant impact on the financial health of Federal and State programs that account for a significant portion of total prescription drug spending. In 2014, Medicaid paid \$22 billion for outpatient drugs. In 2014, Medicare Part B and its beneficiaries paid more than \$21 billion for prescription drugs, and Medicare Part D paid almost \$78 billion. HHS is considering a number of policy options for both Medicare and Medicaid to address the rising cost of prescription drugs. To assist with this challenge, OIG is committed to providing information about the impact of prescription drug prices on Federal programs and enrollees.

actions to restrict the manufacture, possession, or use of potentially dangerous controlled substances. For example, FDA published abuse deterrent guidelines for manufacturers to make tamper-resistant products. FDA also requires that drug manufacturers develop and implement Risk Evaluation and Mitigation Strategies (REMS) for certain drugs, including many controlled substances. Also, many State Medicaid programs reported savings linked to implementing lock-in programs, which restrict certain beneficiaries to certain pharmacies or prescribers.

CMS supports States' efforts to improve care for individuals with substance use disorders, including individuals with opioid use disorder. Over the past several years, CMS has provided States with information and program support to enhance coverage for behavioral health conditions. For example, CMS has been providing technical support to States regarding improvements to their substance use disorder systems through the Medicaid Innovation Accelerator Program, which seeks to improve health care for Medicaid beneficiaries by supporting States' ongoing payment and delivery system reform efforts.

Reducing Abuse and Misuse of Non-controlled Substances. OIG has performed educational outreach to pharmacists in all 50 States on the dangers of mixing non-controlled medications with opiates as part of the substance abuse spectrum. CMS updated its Drug Diversion Toolkit, which provides education on the diversion of controlled and non-controlled medications.

What Needs To Be Done

To fully protect Part D from fraud, waste, and abuse, CMS should take further action and implement OIG's unimplemented recommendations to improve program oversight. For example, OIG recommended that CMS require plan sponsors to report the number of instances of fraud, waste, and abuse in their Part D plans and the corrective actions they subsequently took. This information will enable CMS to monitor the effectiveness of Part D plans' efforts to protect the program. Prescription Drug Monitoring Programs (PDMP) can help curb excessive and inappropriate prescribing. State continuity on requirements for checking the database, and State access to the data for utilization reviews, would assist in strengthening the program. HHS should support efforts to integrate PDMP data into the broader health care system.

HHS should continue to prioritize efforts to reduce opioid misuse and abuse. In Part D, implementing a lock-in program for certain Medicare beneficiaries, the authority for which was recently granted by Congress, would help the program more effectively protect beneficiaries from the harm of inappropriate utilization and also protect the program from drug diversion. With respect to the misuse and abuse of non-controlled substances, CMS and plan sponsors should monitor beneficiary use of a wider range of drugs that are frequently abused. In particular, CMS should expand drug utilization review programs to include additional drugs susceptible to fraud, waste, and abuse, focusing particularly on non-controlled drugs that are abused in conjunction with opioids. Additionally, FDA should continue to assess how best to use the REMS program and other strategies to improve medication safety.

Key OIG Resources

- OIG Portfolio, "Ensuring the Integrity of Medicare Part D," June 2015. (<https://oig.hhs.gov/oei/reports/oei-03-15-00180.asp>)
- 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 Report, "Medicaid Fraud Control Units Fiscal Year 2014 Annual Report," April 2015. (<https://oig.hhs.gov/oei/reports/oei-06-15-00010.pdf>)

Top Management Challenge #7: Ensuring Quality of Care and Safety for Vulnerable Populations

Key Components of the Challenge

- Nursing home and hospice care
- Home- and community-based services
- Indian Health Services
- Programs serving children

Why This Is a Challenge

Programs operated and administered by HHS touch the lives of nearly all Americans. HHS faces special challenges in serving particularly vulnerable populations, including recipients of nursing home care, hospice care, and home- and community-based services (HCBS); Indian Health Service (IHS) beneficiaries; and children. People may also be especially vulnerable based on the type of conditions they have, such as mental health or substance abuse issues or multiple chronic conditions.

Key Components of the Challenge

Nursing Home Care. Problems continue with the quality of care and safety of people in nursing facilities, as well as concerns related to preventing abuse of nursing facility residents. For example, in a review of a nursing home's residents who were hospitalized with urinary tract infections, we found that providers did not always render services to residents in accordance with their care plans before the residents were hospitalized with urinary tract infections. Other problems OIG has identified include substandard care causing preventable adverse events, limited compliance with Federal regulations for reporting abuse and neglect, lack of monitoring of hospitalization rates, failure to correct deficiencies identified during the survey process, and employment of caregivers who do not meet relevant licensure requirements.

Hospice Care. Hospice care provides comfort for terminally ill beneficiaries and supports family and other caregivers. Problems include inadequate oversight of certification surveys and staff licensure requirements, care planning failures, inadequate medical and nursing care, fraudulent enrollments undertaken without beneficiary consent, and enrollment of beneficiaries who are not terminally ill.

Home- and Community-Based Services (HCBS). HCBS, including personal care services (PCS), help beneficiaries continue to live in their homes and avoid costly and disruptive facility-based care. PCS, a critical component of HCBS, serve several targeted populations, including people with mental illness or physical, cognitive, or developmental disabilities. PCS help promote beneficiary choice and preferences, but payment, compliance, and quality vulnerabilities persist and may serve to undermine HCBS goals of offering beneficiaries safe and high quality care outside of an institutional setting. *(For more information on vulnerabilities related to Medicaid PCS, see TMC #2.)* OIG and State Medicaid Fraud Control Units cite high amounts of PCS fraud, some of which involve the abuse or neglect of beneficiaries by PCS attendants that have resulted in deaths, hospitalizations, and less severe degrees of patient harm. Vulnerable beneficiaries may be unable to report the abuse and neglect because of limited communications skills or may be reluctant to report on PCS attendants whom they feel dependent.

Indian Health Service. IHS is the principal Federal health care provider for American Indians and Alaska Natives. HHS must ensure adequate access to care and quality of care for IHS beneficiaries. Recruiting

and retaining competent clinical staff, aging facilities, hospitals unable to render competent emergency or high-level care, and limited resources for referred care remain pressing challenges. *(HHS's challenge in combating diversion of opioids and other controlled substances as well as abuse and misuse of prescription drugs is addressed in TMC #6. HHS's challenge in ensuring appropriate use of grant funds is addressed in TMC #5.)*

Children. In partnership with the States, HHS operates Medicaid and the Children's Health Insurance Program to provide medical care for over 36 million children, including children from financially needy families, children in foster care, and children with 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 intended beneficiaries enjoy access to safely-delivered, high-quality services remains a longstanding challenge for HHS. OIG reviews revealed that many children covered by Medicaid do not receive required dental services, and many children in foster care do not receive required medical services. HHS also operates several programs that provide care for children arriving in the United States without legal status and who are unaccompanied by parents or guardians. *(HHS's challenge in adequately overseeing these programs is addressed in TMC #5.)*

Progress in Addressing the Challenge

Strengthening Processes to Promote Quality Improvement. HHS continues its efforts to improve the quality of nursing home, hospice, and HCBS programs; care for IHS beneficiaries; and services for especially vulnerable children. In July 2016, the Centers for Medicare & Medicaid Services (CMS) updated a booklet entitled "Preventing Medicaid Improper Payments for Personal Care Services." This guidance addresses problem areas identified by OIG and advises PCS agencies and attendants how to avoid improper payments in the following areas: (1) inadequate documentation for claims; (2) claims for ineligible services; (3) services without adequate supervision; (4) services rendered by unqualified providers or without adequate verification and documentation of qualifications; and (5) claims for home care services supposedly rendered to beneficiaries while the beneficiary was away from home and receiving institutional care.

In August 2016, CMS also issued an Informational Bulletin entitled "Suggested Approaches for Strengthening and Stabilizing the Medicaid Home Care Workforce" that discussed States' ability to implement basic training for home care workers in topics such as first aid and CPR certification.

HHS continues its efforts to incentivize improved quality of care by linking payment to value and promoting transparency. *(For more information on delivery system reform, see TMC #9.)* In September 2016, CMS published a final rule to improve the quality of nursing home care. The rule updates the requirements for long-term-care facilities that participate in Medicare and implements provisions of the Patient Protection and Affordable Care Act, including requirements for facilities to implement a quality assurance and performance improvement program to ensure that facilities continuously identify and correct quality deficiencies and promote and sustain performance improvement. CMS has also worked to improve the "Five Star Quality Rating System" to better inform beneficiaries and their families about nursing home options. In July 2016, CMS published a final rule on the Skilled Nursing Facility (SNF) Quality Reporting and Value Based Purchasing Programs. CMS continues to develop the SNF Quality Reporting Program (QRP) measures mandated by the Improving Medicare Post-Acute Care Transformation Act of 2014, including reviewing prescribed medication regimens and accounting for potentially preventable hospital readmissions. The rule also establishes penalties for SNFs that fail to submit required quality data to CMS.

HHS is also developing policies and procedures for public reporting of quality data. In July 2016, HHS updated the hospice Quality Reporting Program to include new quality measures and announced a plan to begin publicly reporting hospice quality measures via a Compare site in calendar year 2017. In August 2016, CMS directed State Survey Agency Directors to ensure that nursing homes do not misuse photography or recordings to compromise residents' right to privacy, confidentiality, and dignity. 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 elderly persons and to prosecute providers who subject them to abuse or neglect.

CMS has also been working to develop a new tool to improve person-centeredness of home- and community-based services. The Consumer Assessment of Healthcare Providers and Systems® HCBS Survey helps HCBS programs assess the experiences of beneficiaries. The Survey facilitates comparisons across the hundreds of State Medicaid HCBS programs throughout the country that target different adults with disabilities; including frail elderly, individuals with physical disabilities, people with developmental or intellectual disabilities, those with acquired brain injury, and persons with severe mental illness. The new tool is available for voluntary use in HCBS programs, including both fee-for-service programs as well as managed long-term services and support (LTSS) programs, as part of quality assurance and improvement activities. Aspects of LTSS covered by the survey are staff reliability, communication with staff, getting help from case managers, choice of services, personal safety, adequacy of medical transportation, and community inclusion and empowerment.

HHS has expressed its commitment to improving quality of care in IHS, especially in the Great Plains where recent reports of quality failures have been most pronounced. Recently, HHS created the Executive Council on Quality Care to improve patient safety at IHS hospitals and clinics. IHS' own quality improvement plans include development of a new Quality Framework and establishment of an Office of Quality in IHS Headquarters. IHS has also undertaken a survey initiative to assess IHS hospitals' compliance with conditions of participation and will track resulting performance data. IHS is also undertaking training initiatives for Area Office staff, service unit leaders, and hospitals, the latter with assistance from the Joint Commission. Additionally, IHS and CMS have committed to continue supporting IHS hospital improvement through the Quality Improvement Network – Quality Improvement Organization and Hospital Engagement Network programs.

In 2014, Congress reauthorized the Child Care and Development Block Grant Act. The Act sets basic health and safety standards for CCDF-funded childcare, requires staff background checks, and requires States to monitor childcare programs serving CCDF-funded children annually. HHS continues efforts to ensure that children enrolled in Medicaid can access Medicaid-covered services, including dental care. These efforts include assistance for States and requirements for States to establish access monitoring review plans.

Protecting Beneficiaries from Dishonest and Potentially Dangerous Providers. Successful enforcement activities continue to identify providers and grantees who violate program rules and prevent them from misappropriating additional funds or harming program beneficiaries. In June 2016, a national health care fraud takedown resulted in civil and criminal charges against 301 individuals, including numerous Medicaid HCBS providers. In July 2016, a national operation to combat CCDF fraud generated 18 prosecutions.

Sometimes, OIG determines that providers have rendered such inferior care that protecting the programs and beneficiaries going forward necessitates excluding those providers from serving program beneficiaries. In other situations, OIG determines that the programs and beneficiaries are better served by allowing the offending provider to continue serving beneficiaries but under close supervision to

ensure that future care meets safety and quality standards. To achieve this goal, OIG invests substantial efforts in helping providers improve. OIG has developed an innovative quality-oriented corporate integrity agreement (CIA) process to work with providers so they may better serve beneficiaries. OIG has placed nearly 40 nursing home companies (covering more than 900 facilities) under CIAs that include quality-monitoring provisions designed to ensure that beneficiaries receive the care they deserve. For example, one dental chain that targeted children enrolled in Medicaid was initially placed under a CIA to address substandard care. However, when the provider failed to meet the terms of the CIA and quality-of-care problems persisted, the CIA was terminated and the provider was excluded from further participation in the Federal health care programs.

What Needs To Be Done

HHS must strengthen procedures to ensure that providers and grant recipients comply with all relevant program rules and deliver safe and high-quality services to the programs' intended beneficiaries. Specifically, HHS should continue to prioritize quality of care in nursing homes and hospices as well as the care rendered as HCBS, with particular focus on PCS. 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. CMS should improve coordination with State agencies to ensure that care providers meet relevant licensure requirements. HHS should also 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.

Ensuring high-quality HCBS and enabling beneficiaries to avoid institutionalization relies heavily on appropriate PCS. CMS must do much more to address vulnerabilities in HCBS, such as PCS. As Medicaid expands, so too will beneficiaries' reliance on HCBS as they seek to avoid institutional care settings. As CMS continues its work to expand access to HCBS, it should also focus on strategies to prevent fraud, waste, and abuse and safeguard beneficiaries' safety. CMS should follow through on commitments to improve PCS program integrity by promulgating regulations and issuing clarifying guidance to States on the range of vulnerabilities that expose beneficiaries to risk of unsafe or suboptimal care.

HHS should ensure the integrity of Medicaid-funded PCS by establishing minimum Federal qualification standards for providers that are based on the needs of the individual being served; improving CMS's and States' ability to monitor billing and quality of care; and issuing operational guidance for claims documentation, beneficiary assessments, person-centered plans of care, and supervision of personal care attendants when hired by an agency. For self-directed programs in which a beneficiary directs his or her own PCS, CMS and the States should improve oversight of controls to ensure individual health and welfare and financial integrity. HHS should also issue guidance to States regarding adequate prepayment controls and help States access data necessary to identify overpayments.

HHS must better oversee IHS hospitals to identify and rectify quality issues and help hospitals implement data-driven quality improvement methods. Specifically, IHS should (1) implement a quality-focused compliance program, (2) establish standards for Area Office/Governing Board oversight activities, (3) set hospital performance metrics, and (4) better train hospital administrators and staff. In addition, CMS should conduct more frequent surveys of non-accredited hospitals.

The Administration for Children and Families must fully implement its new authorities to ensure safer CCDF-funded childcare. HHS should develop a comprehensive plan to ensure children’s access to Medicaid-covered dental services, such as by working with States to (1) develop and achieve service benchmarks, (2) identify areas of provider shortages and address barriers to Medicaid participation, and (3) analyze payment policies.

Key OIG Resources

- OIG Report, “Personal Care Services: Trends, Vulnerabilities and Recommendations for Improvement – A Portfolio,” November 2012. (<http://oig.hhs.gov/reports-and-publications/portfolio/portfolio-12-12-01.pdf>).
- OIG Report, “Indian Health Service Hospitals: Longstanding Challenges Warrant Focused Attention to Support Quality Care,” October 2016. (<https://oig.hhs.gov/oei/reports/oei-06-14-00011.asp>)
- OIG Report, “West Carrol Care Center Did Not Always Follow Care Plans for Residents Who Were Later Hospitalized with Potentially Avoidable Urinary Tract Infections,” June 2016. (<https://oig.hhs.gov/oas/reports/region6/61400073.asp>)
- 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, “Puerto Rico Child Day Care Centers Did Not Always Comply With Commonwealth Health and Safety Requirements,” September 2015. (<https://oig.hhs.gov/oas/reports/region2/21402001.asp>)

Top Management Challenge #8: Operating and Overseeing the Health Insurance Marketplaces

Key Components of the Challenge

- Payment accuracy
- Eligibility determinations
- Management and administration
- Security and privacy of information systems

Why This Is a Challenge

The Health Insurance Marketplaces (Marketplaces), also known as health insurance Exchanges, are critical components of the health care reforms enacted through the Patient Protection and Affordable Care Act. Implementation, operation, and oversight of the Marketplaces were among the most significant challenges for HHS in previous years and continue to present a top management and performance challenge.

The Marketplaces involve complex regulatory, operational, and technological challenges. Among these are effective communication and coordination between and among all internal and external parties with Marketplace responsibilities, including within HHS and with contractors, issuers, and partners in State and Federal Government. Effective coordination with the Internal Revenue Service (IRS) is particularly important for sound administration of the premium tax credit program—a refundable tax credit that helps eligible individuals and families with low or moderate income afford health insurance purchased through a Marketplace. In addition, the Centers for Medicare & Medicaid Services (CMS) is responsible for ensuring that State Marketplaces comply with Federal requirements and provide complete, accurate, and timely data used for Federal payments. Further, CMS must take appropriate steps to promote compliance by Qualified Health Plans (QHP) with Federal requirements, including network adequacy and non-discrimination requirements. CMS must also take appropriate steps to ensure that individuals are enrolled in the correct insurance program (e.g., Medicare, Medicaid, or private insurance) and to prevent the improper influence of individuals when choosing insurance.

Key Components of the Challenge

Payments. Ensuring sound expenditure of taxpayer funds for insurance affordability and other Marketplace purposes poses a substantial management challenge, and OIG found evidence of early deficiencies. For example, CMS's internal controls did not effectively ensure that payments for the advance premium tax credit program were made only for enrollees who paid their monthly premiums. Continued attention is warranted, especially given the introduction of an automated policy-based payment system at the Federal Marketplace and the continued use of interim solutions and manual systems at the State Marketplaces. Effective management of the premium stabilization programs is important because of these programs' impact on the private health insurance market. Attention also must be paid to expenditures of HHS funds used by State Marketplaces for grants and contracts.

Eligibility. Accurate eligibility determinations ensure that only eligible consumers are able to enroll in health plans and receive insurance affordability benefits during open and special enrollment periods. To appropriately determine eligibility, CMS must have effective internal controls and accurately and quickly resolve inconsistencies between applicant-reported information and Government databases. OIG and the Government Accountability Office have found vulnerabilities in CMS's eligibility verification and enrollment processes and resolution of inconsistencies.

Management and Administration. Management and administration of the Federal and State Marketplaces require, among other things, clear leadership, disciplined operations, and effective strategies and communication. An OIG review of the implementation of Healthcare.gov (the website consumers use to apply for insurance through the Federal Marketplace) identified management deficiencies that contributed to the initial breakdown of the website, as well as improved management afterwards. OIG identified lessons learned from this experience that HHS should continue to apply to the operation of the Federal Marketplace, including the automated policy-based payment system and other large-scale projects. OIG has also made recommendations to CMS to improve its acquisition planning and procurement, contract monitoring, and administration of payments for Marketplace contracts. *(For further information on contract administration, see TMC #4.)* In addition, some Consumer Oriented and Operated Plans (CO-OPs) have ceased operation, posing an additional challenge for HHS.

Security. Protecting the confidentiality and ensuring the integrity of consumers' personal information and Marketplace information systems is paramount. Effective operation of the Marketplaces requires rapid, accurate, and secure integration of data from numerous Federal and State sources, issuers, and consumers. HHS must vigilantly guard against intrusions and continuously assess and improve the security of Marketplace-related systems, including, among others, the Data Services Hub, a conduit through which a Marketplace sends and receives electronic data from multiple Federal agencies, and the Multidimensional Insurance Data Analytics System, a data warehouse and repository. *(For more discussion of information privacy and security, see TMC #3.)*

Progress in Addressing the Challenge

CMS implemented several core management principles identified in OIG's review that enabled the organization to improve the HealthCare.gov website as well as agency management and culture. In addition, CMS has reported progress in Marketplace operations, including implementing automated policy-based payments for the Federal Marketplace in May 2016; implementing parallel processing and multiple levels of review of financial assistance payments information; working to develop a strategic and unified view of Marketplace procurement and costs; and developing a strategy to improve Marketplace program integrity. As part of its strategy to improve program integrity, CMS has established standards for terminating or suspending agreements between agents and brokers and the Federal Marketplace in cases of fraud or conduct that may cause consumer harm. CMS is also developing outreach and education campaigns designed to inform consumers, agents, and brokers about the dangers of identity theft. CMS reports that it has taken steps to tighten eligibility standards and processes for special enrollment periods.

Additionally, CMS has coordinated with entities across and beyond HHS to improve the accuracy of eligibility and payment data. CMS reported that it updated its Standard Operating Procedures with additional directives to ensure that its Federal Marketplace eligibility support workers can resolve applicant inconsistencies of all types. Further, CMS has developed additional tools to help States report on their eligibility and enrollment processes and to oversee States' plans for addressing unresolved applicant inconsistencies. CMS also reported having regular communications with the IRS and the Department of the Treasury to validate payment information, conduct improper payment risk assessments to determine areas that might affect the accuracy of financial assistance payments, and provide technical and other support to the State Marketplaces. CMS also issued a request for information seeking public comment on concerns that some providers and organizations may be steering people eligible for Medicare and/or Medicaid into QHPs to obtain higher reimbursement rates.

What Needs To Be Done

HHS should continue to apply core management principles—including designating clear leadership, integrating policy and technology work, and continuously learning—to improve its operations and oversight of the Federal Marketplace, particularly the eligibility, administrative, and financial management functions. CMS should also address OIG recommendations to improve internal controls.

Vulnerabilities in CMS’s business processes must be addressed to ensure accurate and timely initial payments and reconciliations of payments. Additionally, CMS must focus on effective management and integrity of the premium stabilization programs. This includes validating information received from issuers to ensure that it is complete, accurate, and timely for payment purposes.

CMS must ensure that all pathways for enrollment operate with integrity, consumers are not improperly influenced in their selection of insurance, and consumers' personal information is secure. Vigilant monitoring and testing of systems and rapid mitigation of identified vulnerabilities are essential. CMS must also focus attention on the sound operation of financial assistance programs for beneficiaries. Consumers and issuers must receive accurate Marketplace information, including information relevant for tax purposes, such as Form 1095A tax forms. Furthermore, Marketplaces must continue to protect personally identifiable information and strengthen security controls.

CMS must also continue to work with States to improve State Marketplace operations, including payment systems, and to ensure compliance with Federal requirements for Marketplaces and health plans. HHS must continue to pay attention to the financial and operational challenges faced by CO-OPs. CMS must monitor for and address fraud, waste, and abuse risks in Marketplace programs. CMS must respond quickly and effectively to credible allegations of fraud, working with QHPs and with partners at the Federal and State level to hold those involved accountable.

Key OIG Resources

- For links to OIG’s portfolio of reports on the Federal and State Marketplaces, as well as OIG's Health Reform Oversight Plan, please see the Patient Protection and Affordable Care Act Reviews section on OIG’s website: <https://oig.hhs.gov/reports-and-publications/aca/>.

Top Management Challenge #9: Managing Delivery System Reform and Strengthening Medicare Advantage

Key Components of the Challenge

- Implementing Medicare’s Quality Payment Program
- Managing the CMS Innovation Portfolio
- Strengthening Medicare Advantage

Why This Is a Challenge

A paradigm shift is underway in the Nation’s health care system—both public and private—to improve patient care and reduce wasteful spending through heightened focus on quality of care rather than quantity of care. The pace of change is rapid and the magnitude substantial. New models are being introduced that focus on rewarding the delivery of high-value health care and promoting innovative care redesigns that provide patients with better coordinated care. These models are intended to incorporate new understandings of medicine, social science, population health, technology, data analysis, and behavioral incentives. Medical, mental health, and social services are being integrated in new ways.

For HHS, this shift—propelled by reforms under the Patient Protection and Affordable Care Act, Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), and other statutes—affects all parts of Medicare, as well as Medicaid and public health programs. Stakeholders include patients, providers, vendors, managed care organizations, private payers, administrative contractors, State agencies, and taxpayers. HHS is investing significant resources in developing evidence-based tools, realigning provider and beneficiary incentives, testing new coordinated and integrated care designs, promoting meaningful use of electronic health records (EHRs) and other technologies, and enhancing patient engagement and access to health information.

Delivery system reform in a highly complex environment requires concurrent, sustained, and multifaceted planning, execution, and oversight. To participate successfully in new models, providers and others must commit resources and reshape the delivery of care. Models often involve new types of caregivers as well as individuals and entities undertaking new roles and responsibilities in Federal health care programs. HHS must effectively educate and oversee both experienced participants and new entrants into these programs.

Key Components of the Challenge

Implementing Medicare’s Quality Payment Program. MACRA revamped Medicare’s physician reimbursement system, affecting physicians and other clinicians reimbursed under the Medicare Physician Fee Schedule. The new Quality Payment Program (QPP) introduces into physician reimbursement two new mechanisms linked to quality and efficiency: (1) a Merit-Based Incentive Payment System (MIPS) and (2) alternative payment models (APMs). To meet statutory deadlines, much must be accomplished quickly. This novel and complex program presents substantial policy, administrative, operational, logistical, and technological challenges. The Centers for Medicare & Medicaid Services (CMS) must consolidate three existing incentive programs into MIPS and craft advanced APMs suitable for physicians with various practice characteristics and levels of operational readiness. In so doing, CMS must be mindful of administrative burden. Notably, there is concern that small and rural providers may need assistance navigating the transition. Physicians must prepare for significant changes in reimbursement methodology, reporting, and, depending on circumstances, delivery of care and workflow. Quality measurement is a key component of the QPP. Challenges

highlighted in HHS's recent Quality Measure Development Plan¹² for the QPP include closing known measurement and performance gaps; harmonizing and aligning measures across programs, settings, and payers; and refining measure development. CMS has signaled plans to finalize measure sets in annual rulemaking.

Managing the CMS Innovation Portfolio. The diverse CMS innovation portfolio poses a significant management challenge for HHS. Comprising dozens of new models in various stages of development and implementation, the portfolio touches on virtually every aspect of health care delivery and experiments with a variety of payment structures, including shared savings, episode-based payments, population-based payments, capitation, and value-based purchasing. Many new payment structures are hybrids involving both traditional and new types of payments, giving rise to additional challenges in managing risk. Many models involve novel business arrangements among providers and new incentives to promote patient engagement in their own care. These arrangements and incentives also give rise to challenges for risk management. CMS operates both voluntary models and models that are mandatory in designated geographic areas; mandatory models pose unique challenges in ensuring provider readiness.

HHS must ensure that Medicare realizes benefit from the Government's substantial investment in designing, testing, and implementing new models, including the Center for Medicare & Medicaid Innovation's (CMMI) 10-year, \$10 billion budget. Perhaps equally challenging is ensuring that models are viable in light of providers' substantial investments in infrastructure and care redesign. Responsibility for administering and overseeing new models is shared across several CMS components, including CMMI and the Center for Program Integrity. CMS leverages expertise across HHS through partnerships with other HHS operating divisions. These collaborations within and outside CMS require shared vision, clear communications, and continuous coordination.

Strengthening Medicare Advantage. Approximately 30 percent of Medicare beneficiaries are enrolled in Medicare Advantage (MA), a three-fold increase since 2004. Ensuring a sound MA program is essential to meeting intended coverage, access, quality, and cost goals. OIG work has identified challenges in the MA program with respect to the precision and use of data, payment accuracy, and program integrity, including vulnerabilities at both the plan and provider levels. CMS estimated for FY 2015 that 9.5 percent of payments to MA organizations were improper, mainly due to insufficient documentation to support diagnoses submitted by MA organizations.¹³ Notwithstanding these vulnerabilities, MA organizations have the potential to increase efficiency and quality through better coordinated care, aligned incentives, and performance measurement. HHS is developing new models for MA, including a Value-Based Insurance Design model. (*For more information on improving the effectiveness of Medicaid managed care, see TMC #2.*)

Progress in Addressing the Challenge

Implementing the QPP. CMS is making steady early progress in implementing the QPP, including recently issued final program regulations. HHS has begun issuing other program policies and guidance, including the Office of the National Coordinator for Health Information Technology's guidance for measuring interoperability and health information exchange. CMS is deploying an integrated policy and

¹² <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Final-MDP.pdf>

¹³ GAO Report: <http://www.gao.gov/assets/680/676441.pdf>; Annual Financial Statement Audit <http://www.hhs.gov/sites/default/files/afr/fy-2015-hhs-agency-financial-report.pdf>

technology team to plan and execute the QPP. CMS is testing user-centered IT designs and planning education and technical assistance initiatives to promote clinician acceptance of, and readiness for, the QPP. In April 2016, CMS released a solicitation for direct technical assistance to support implementation of the QPP. CMS more recently announced a new, long-term initiative to increase clinician engagement, including an 18-month pilot program to reduce medical review for certain physicians practicing within specified alternate payment models with two-sided risk.

Designing and Assessing Models. CMS is compiling a growing roster on its website of early results from, and evaluations of, new programs and models. For example, CMS reported that Medicare accountable care organization (ACO) programs, comprising over 400 ACOs, generated total gross program savings of more than \$466 million for Medicare in 2015; CMS also reported improvements in quality performance.¹⁴ Further, CMS reported second-year results for the Independence at Home (medical home) Demonstration of an average savings of \$1,010 per beneficiary, with all participating practices improving quality from the first performance year in at least two of the six quality measures. Results vary across models, with some more promising than others.

CMS continues to test initiatives to speed adoption of best practices, accelerate development of new models, and reform Medicaid and the Children’s Health Insurance Program, among others. Models include multiple types of ACOs, primary care medical homes, and bundled payment initiatives. More recently, CMS has been developing and refining models that will qualify as advanced APMs under the QPP. HHS is supporting the Health Care Payment Learning and Action Network to collaborate on aligning reforms across health care sectors. CMS issued regulations for an expanded Medicare Diabetes Prevention Model. CMS continues to provide guidance and education to model participants, as well as to state Medicaid agencies engaged in reforms through CMMI’s Medicaid Innovation Accelerator Program, and has taken steps to include in new models program integrity safeguards, including transparency of data and monitoring for indicators of abuse or gaming.

In March 2016, HHS announced that it met, earlier than scheduled, its goal of tying 30 percent of traditional Medicare payments to APMs by the end of 2016. HHS aims to increase this amount to 50 percent by 2018.

Strengthening Medicare Advantage. CMS is using audits to oversee, among other things, MA organizations’ implementation of programs to detect, correct, and prevent fraud, waste, and abuse, which are required by their compliance plans. CMS has issued guidance on sharing information between CMS contractors and with other program integrity stakeholders, such as State agencies, to more effectively coordinate efforts to identify and investigate fraud. HHS has stated a goal of having all MA contracts audited annually. CMS has taken steps to incorporate recovery audit contractors into MA, as required by statute.¹⁵ CMS has enhanced the transparency of information about MA plans by publicly reporting on its website additional data, including information about grievances filed with plans and plans’ oversight of sales agents and brokers. CMS announced changes to the Star Ratings system, developed through a public process, aimed at better accounting for costs of caring for enrollees. Further, CMS has developed a Network Management Module to help assess network adequacy.

¹⁴ <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-08-25.html>

¹⁵ GAO Report: <http://www.gao.gov/assets/680/676441.pdf>

What Needs To Be Done

Continue Implementing the QPP. Physician payment reform under MACRA will require sustained focus. For a successful transition, CMS must address policy, infrastructure, data systems, oversight, and provider education needs. Physician representatives have identified challenges, including complexity of reporting and measurement, scope and availability of APMs, provider education, daunting timelines, infrastructure investments, new business requirements, and administrative burden. CMS should allocate sufficient resources to ensure issuance of timely and clear program regulations and guidance and to provide meaningful education and technical assistance. In addition to well-functioning, physician-oriented websites, CMS must ensure that it has fully operational back-end payment and data systems for the QPP. CMS must coordinate with the Office of the Assistant Secretary for Planning and Evaluation and the Physician-Focused Payment Model Technical Advisory Committee on the development of APM opportunities submitted by physicians. CMS needs to develop quality measures as outlined in the Quality Measure Development Plan and monitor for any unintended impacts the quality measures have on Medicare beneficiaries. CMS needs to ensure that its medical records review reduction pilot program operates in a manner that protects the Medicare program from fraud and abuse.

Effectively Manage and Oversee New Models. CMS must continue to manage its growing portfolio of complex models and innovations to ensure they achieve their intended quality of care and efficiency outcomes. CMS must issue clear guidance on program requirements; administer (or contract for) financial, beneficiary alignment, and other systems necessary for effective operations; and test, evaluate, and verify model progress and outcomes. Attention should be paid to the policy, evaluative, compliance, and practical day-to-day challenges for CMS and providers of concurrent participation in multiple models. Further, CMS must clearly define actionable and meaningful quality measures and ensure that they, in fact, measure what CMS intends them to measure to achieve desired quality goals.

CMS should carefully monitor for successes and benefits that can be scaled and replicated, as well as for potential problems—including inefficiencies and misaligned incentives. As the testing of multiple models matures, CMS will need to effectively manage the transition from testing a model to its expansion, as appropriate.

New models rely significantly on data, EHRs, and technology. CMS must ensure that data collected and provided for new payment models are complete, accurate, timely, and secure and that new technologies, such as telemedicine, achieve their intended results. Data from providers and others must be integrated and shared across models within HHS and with stakeholders, as appropriate. *(For more information on the challenges associated with electronic information and health IT, see TMC #3.)* To the extent that resource, 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.

CMS must monitor for program integrity risks in new models, incorporate safeguards tailored to specific risks in particular models, and assess the effectiveness of the safeguards it employs. Detected program integrity problems should be remediated promptly and safeguards strengthened to prevent program and patient abuse or gaming. Sharp attention to program integrity is especially important for models that introduce new payment incentives, which might lead to new fraud schemes, or for which waivers of payment or fraud and abuse laws may have been issued under sections 1899(f) or 1115A of the Social Security Act. As a critical element of program integrity, CMS must maintain accurate historical and real-time information about new models, including, for example, information about providers and beneficiaries. *(For more information on fraud and abuse in Medicare Parts A and B, see TMC #1.)*

Strengthen Medicare Advantage. CMS should continue to focus on ensuring that MA plan enrollees have access to and receive the services to which they are entitled and that those services are of appropriate quality. CMS must strengthen the MA program to ensure that benefits are provided only to eligible beneficiaries. Further, CMS must ensure that data and other information related to payment from providers and plans are available for fraud detection and prevention. CMS must use data effectively to ensure payment accuracy and to review MA organizations' performance. Ensuring the accuracy and integrity of risk-adjustment and other data used to establish payment rates is also critical to protect against gaming or abuse and reducing the payment error rate. HHS should take steps to address the obstacles to accurate risk-adjustment payments and recovery of improper payments recently identified by the Government Accountability Office.¹⁶ Finally, CMS will need to oversee new models within the MA program to ensure that they meet intended quality of care and cost-containment goals.

Key OIG Resources

- OIG Accountable Care Organization Resource Page: (<https://oig.hhs.gov/compliance/accountable-care-organizations/index.asp>)
- OIG Report, "Observations From our Review of CMS' Administration of the First Performance Year of the Pioneer Accountable Care Organization Payment Model," May 2016. (<https://oig.hhs.gov/oas/reports/region1/11300509.pdf>)
- OIG Report, "Medicare Improperly Paid Medicare Advantage Organizations Millions of Dollars for Unlawfully Present Beneficiaries for 2010 Through 2012," April 2014. (<https://oig.hhs.gov/oas/reports/region7/71301125.pdf>)
- OIG Report, "CMS Regularly Reviews Part C Reporting Requirements Data, but Its Followup and Use of the Data are Limited," March 2014. (<https://oig.hhs.gov/oei/reports/oei-03-11-00720.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>)

¹⁶ GAO Report: <http://www.gao.gov/assets/680/676441.pdf>

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

Key Components of the Challenge

- Food safety
- Drug compounding
- Complex drug supply chain
- Improper marketing

Why This Is a Challenge

HHS, through the Food and Drug Administration (FDA), must ensure the safety, efficacy, and security of our Nation's food supply, drugs, biologics, and medical devices. FDA is also responsible for regulating tobacco products. Areas of particularly high risk include food safety, drug compounding, a complex drug supply chain, and improper marketing activities.

Key Components of the Challenge

Food Safety. Foodborne illnesses, such as those caused by *Salmonella*, *Listeria monocytogenes*, and *E. coli*, pose a continuing public health threat. Oversight is complicated by the immense diversity of the global food supply: 20 percent of our vegetables come from abroad, as does 50 percent of our fresh fruit, and more than 80 percent of our seafood.¹⁷ When a problem with the U.S. food supply is identified, FDA must ensure that the problem is addressed using its various administrative tools and enforcement authorities. After reviewing 30 recalls selected on the basis of their risk factor, OIG recently alerted FDA that consumers remained at risk of illness or death for several weeks after FDA was aware of a potentially hazardous food in the supply chain.

Drug Compounding. The potential danger of improperly compounded drugs drew national attention in 2012 when drug injections meant to be sterile were contaminated during the compounding process and resulted in a deadly fungal meningitis outbreak. Compounded drugs are not subject to FDA's premarket approval process, in which FDA evaluates the safety and efficacy of conventionally-manufactured drugs. FDA continues to identify serious problems at facilities that compound drugs, the vast majority of which do not register with the FDA.¹⁸ (*For information on rising costs and potential fraud involving compounded drugs, see TMC #6.*)

Complex Drug Supply Chain. The drug supply chain is growing increasingly complex, not only domestically but globally. This makes it difficult to track products to their sources in case of a recall and complicates FDA's task of ensuring the integrity of these products. Multiple manufacturers may be involved in the various stages of production. Currently, about 40 percent of prescription drugs sold in the United States and 80 percent of active ingredients used in drugs are made in other countries.¹⁹ Once drugs are produced, multiple parties may distribute or repackage the finished product. Drugs from

¹⁷ <http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/> (accessed October 26, 2016).

¹⁸ <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm>

¹⁹ <http://www.fda.gov/NewsEvents/Testimony/ucm271073.htm>

unapproved sources can also enter the U.S. drug supply chain. Disruptions in the supply chain can lead to problems with patient access to needed prescription drugs.²⁰

Improper Marketing Activities. FDA approves the marketing of drugs, biologics, and medical devices for specific uses after determining that the products are safe and effective for those uses. Once approved, qualified medical practitioners may prescribe them for any use, including uses not approved by the FDA. However, individuals and manufacturers are prohibited from marketing products for unapproved uses. In general, the Federal health care programs do not cover unapproved products. Improper marketing activities can put patients at risk of receiving inappropriate or harmful care and lead to fraudulent claims for payment from Federal health care programs. *(For more information on drug diversion and utilization of prescription drugs, see TMC #6.)*

Progress in Addressing the Challenge

Food Safety. FDA continues to implement its enhanced food-safety authorities statutorily granted in 2011 by the Food Safety Modernization Act. In 2015 and 2016, the Agency finalized rules on preventative controls for human food, current good manufacturing practices and preventative controls for animal food, produce safety, accredited third-party certification, sanitary transportation of human and animal food, protection against intentional adulteration, and the foreign supplier verification program. FDA's food scientists have also worked to further develop and broaden the use of whole genome sequencing technologies to better differentiate between organisms and strains to identify and prevent foodborne illnesses. FDA continues collaboration with State regulatory and public health partners to establish an integrated national food safety system and has initiated new efforts to incorporate produce safety. Additionally, as part of FDA's effort to leverage the comparable food safety oversight conducted by foreign partners, FDA entered into food safety systems recognition agreements with New Zealand in December 2012 and Canada in May 2016.

Drug Compounding. In 2013, the Compounding Quality Act clarified and amended FDA's authority to oversee compounding, including providing a new pathway for compounders to register with FDA as outsourcing facilities. Outsourcing facilities that compound drugs in accordance with the conditions set forth in the Compounding Quality Act are eligible for exemptions from certain FDA requirements, but are held to manufacturing quality standards similar to those applicable to conventional drug manufacturers. FDA continues to work to fully implement the Compounding Quality Act, and the Agency has issued numerous policy and guidance documents applicable to outsourcing facilities and other compounders. FDA also continues to inspect compounding facilities; oversee recalls of compounded drugs for contamination or lack of sterility assurance; and issue warning letters to compounders that violate the law.

Complex Drug Supply Chain. The Drug Supply Chain Security Act created the basis for building an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States, whether they originate in this country or not. FDA has issued guidance to establish initial standards for the interoperable exchange of product tracing information and also created a publicly available database of authorized wholesale distributors of traceable prescription drugs. OIG is reviewing wholesale distributors' and dispensers' early experiences in exchanging product tracing information.

²⁰ <https://aspe.hhs.gov/sites/default/files/pdf/108986/ib.pdf>

Improper Marketing Activities. To protect patients and reduce the waste of Federal health care program money, OIG, FDA, and their law enforcement partners have pursued numerous enforcement actions against manufacturers for improperly marketing drugs, biologics, and devices. In addition, FDA has engaged in both outreach and enforcement actions on unapproved drugs and devices, including unapproved products from foreign sources. FDA has also undertaken efforts to warn consumers, medical practitioners, and others about the medical risks associated with importing unapproved drugs. FDA, OIG, and their law enforcement partners continue to investigate and prosecute physicians and suppliers that distribute unapproved drugs and devices. FDA collaborates with international partners and has introduced improved border screening to enhance oversight of imported products.

What Needs To Be Done

Implementation. FDA must continue taking steps to fully implement its statutory authorities and develop robust policies and procedures to ensure that problems with the Nation's food supply are addressed in a timely manner. OIG has recommended that FDA remedy identified weaknesses in recall procedures and better ensure that recalls are promptly initiated, monitored, and closed out. FDA must continue to implement its new authorities to enhance oversight of drug compounders and better ensure the safety of compounded products, including by inspecting drug compounders and pursuing regulatory action when deficiencies are identified. FDA must also continue to implement its new authorities in tracking drugs through the supply chain.

Oversight. FDA must ensure that drug supply chain partners comply with product tracing requirements. FDA has twice delayed its enforcement of certain product tracing requirements for wholesale distributors and dispensers due to their requests for additional time to implement product tracing requirements. FDA must also continue combating improper marketing practices and importation of unapproved drugs for commercial distribution in the United States. OIG, in cooperation with the Department of Justice and other law enforcement partners, will continue to employ investigative and enforcement authorities to protect Federal health care programs and beneficiaries from these potentially-dangerous products.

OIG will continue monitoring the changing legal landscape, legislative developments, and FDA's oversight of food, drugs (both prescription and over-the-counter), biologics, dietary supplements, medical devices, and tobacco, and adjust priorities as needed.

Key OIG Resources

- 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, "High Part D Spending on Opioids and Substantial Growth in Compounded Drugs Raise Concerns," July 2016. (<https://oig.hhs.gov/oei/reports/oei-02-16-00290.asp>)
- OIG Report, "High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them," April 2013. (<http://oig.hhs.gov/oei/reports/oei-01-13-00150.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>)