

U.S. Department of Health and Human Services
Office of Inspector General



2019
TOP MANAGEMENT AND PERFORMANCE
**CHALLENGES
FACING
HHS**

CHALLENGES FACING HHS

Introduction

The 2019 Top Management and Performance Challenges Facing HHS is an annual publication of the Department of Health and Human Services (HHS or the Department) Office of Inspector General (OIG). In this edition, OIG has identified six top management and performance challenges (TMCs) facing the Department as it strives to fulfill its mission “to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.” This year, OIG synthesized new and past challenges and reorganized them into six TMCs. These top six challenges reflect overarching issues that affect multiple HHS programs and responsibilities. These are not the only challenges that face HHS, and OIG reports are a key resource that highlight specific opportunities to improve HHS programs and operations.

HHS is responsible for a portfolio of more than \$1 trillion, and its programs impact the lives of virtually all Americans. To identify the six TMCs, we integrated OIG’s oversight, risk analysis, data analytics, and enforcement work. For each TMC, we describe the dimensions of the challenge, highlight the progress that the Department has made in addressing the challenge, and identify what remains to be done.

Management and performance challenges are inherently cross-cutting and the TMCs reflect how multiple HHS Operating Divisions (OpDivs) may be affected by these pressing issues. For example, the challenge of financial integrity highlighted in TMC 1 has natural intersections with the challenge of delivering value, quality, and improved outcomes in Medicare and Medicaid, the subject of TMC 2. This document identifies those intersections. Given that challenges cross both internal HHS boundaries and sometimes externally across Departments at the Federal and State levels, coordination among HHS agencies and across Government is integral to addressing these challenges.

In addition to this annual publication, OIG maintains a list of significant unimplemented OIG recommendations, including legislative recommendations, to address vulnerabilities. These recommendations are drawn from OIG’s audits and evaluations. OIG identifies the top unimplemented recommendations that, in OIG’s view, would most positively affect HHS programs in terms of cost savings, program effectiveness and efficiency, and public health and safety.¹

More information on OIG’s work, including the reports mentioned in this publication, is available on our website at <https://oig.hhs.gov>.

CHALLENGES FACING HHS

1 Ensuring the Financial Integrity of HHS Programs

4 Safeguarding Public Health

2 Delivering Value, Quality, and Improved Outcomes in Medicare and Medicaid

5 Harnessing Data To Improve Health and Well-Being of Individuals

3 Protecting the Health and Safety of HHS Beneficiaries

6 Working Across Government To Provide Better Service to HHS Beneficiaries

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Acronyms

ACF	Administration for Children and Families	HHA	Home Health Agency
ACO	Accountable Care Organization	HHS	Department of Health and Human Services
AI/AN	American Indian/Alaska Native	HUD	Department of Housing and Urban Development
API	Application Programming Interface	IHS	Indian Health Service
AHRQ	Agency for Healthcare Research and Quality	IT	Information Technology
ARPO	Appalachian Regional Prescription Opioid	MA	Medicare Advantage
ASPR	Office of the Assistant Secretary for Preparedness and Response	FY	Fiscal Year
CCDF	Child Care and Development Fund	GAO	Government Accountability Office
CDC	Centers for Disease Control and Prevention	MAC	Medicare Administrative Contractor
CHIP	Children’s Health Insurance Program	MAO	Medicare Advantage Organization
CMS	Centers for Medicare & Medicaid Services	MAT	Medication-Assisted Treatment
CY	Calendar Year	MCO	Managed Care Organization
DATA	<i>Digital Accountability and Transparency Act of 2014</i>	NIH	National Institutes of Health
DEA	Drug Enforcement Agency	OCR	Office of Civil Rights
DHS	Department of Homeland Security	OIG	Office of Inspector General
DME	Durable Medical Equipment	OMB	Office of Management and Budget
DOJ	Department of Justice	ONC	Office of the National Coordinator for Health Information Technology
ED	Emergency Department	ORR	Office of Refugee Resettlement
EHR	Electronic Health Record	OS	Office of the Secretary
FAR	Federal Acquisition Regulation	ODD	Opioid Use Disorder
FBI	Federal Bureau of Investigation	PCS	Personal Care Services
FDA	Food and Drug Administration	TMC	Top Management Challenge
FEMA	Federal Emergency Management Agency	SAMHSA	Substance Abuse and Mental Health Services Administration
FFS	Fee-For-Service	SNF	Skilled Nursing Facility
FPS	Fraud Prevention System	TANF	Temporary Assistance for Needy Families
FHIR	Fast Health Interoperability Resource	T-MSIS	Transformed Medicaid Statistical Information System
FSMA	<i>Food Safety Modernization Act</i>	UAC	Unaccompanied Alien Children
HIPAA	<i>Health Insurance Portability and Accountability Act of 1996</i>		
HRSA	Health Resources and Services Administration		

1: Ensuring the Financial Integrity of HHS Programs

The Department of Health and Human Services (HHS or the Department) is the largest civilian agency in the Federal Government, with a \$1.2 trillion budget in fiscal year (FY) 2019, representing more than one-third of the total Federal budget. HHS's Medicare program is the Nation's largest health insurer, handling more than 1 billion claims per year. Medicare and Medicaid, the Department's largest programs, comprise 49 percent of the U.S. health care insurance economy. More than 136 million beneficiaries, or more than 40 percent of Americans, rely on these programs for their health insurance, including senior citizens, individuals with disabilities, low-income families and individuals, and patients with end-stage renal disease.² CMS bears the responsibility at HHS for administering these programs. Federal Medicare expenditures totaled \$644.8 billion in FY 2019; Federal Medicaid spending totaled \$418.7 billion in FY 2019 (with an additional \$18.6 billion for the Children's Health Insurance Program (CHIP)).³

RELEVANT OPDIVS

All HHS

KEY ELEMENTS

- Controlling costs by ensuring proper payment for goods and services
- Reducing improper payments
- Combating fraud, waste, and abuse in HHS programs
- Monitoring and reporting on the integrity of HHS programs

HHS is also the largest grant-making and fourth-largest contracting agency in the Federal Government. In FY 2018, HHS awarded \$109 billion in grants (excluding CMS) and \$25 billion in contracts. Responsible stewardship that ensures the transparency and accountability of HHS funds is paramount to making sure that HHS beneficiaries and the American public get the true benefit of this substantial financial investment.

The Department must protect the fiscal integrity of HHS funds and ensure that beneficiaries have access to the services they need, especially in light of looming financial shortfalls in the Medicare program,^{4, 5} the expansion of Medicaid services to a larger population, and the increased use of grants as funding tools to achieve program results. HHS should take steps to control costs by ensuring proper pricing for goods and services; reducing improper payments; and preventing, detecting, and prosecuting fraud in HHS programs. The Department must not only manage both the efficient and effective use of funds internally but also oversee the thousands of external funding recipients' use of Federal funds to fulfill HHS's mission.

Controlling costs by ensuring proper payment for goods and services

Whether HHS is paying for medical services, prescription drugs, or complex information technology (IT) solutions, managing what the Department pays and recognizing and remedying payment policies that inadvertently incentivize improper billing or inflate prices are critical to controlling costs.

Medicare

Medicare should act as a prudent payer on behalf of taxpayers and beneficiaries, including instituting payment policies delivering greater value. (See TMC 2 for more information on value-based payment models.) In certain contexts, Medicare payment policies, which are generally set by statute, result in Medicare and beneficiaries paying more for care provided in certain settings than for the same care

provided in other settings. For example, Medicare could have potentially saved \$4.1 billion over a 6-year period if swing-bed services at critical access hospitals had been paid for at the same rates as at skilled nursing facilities (SNFs).⁶ Likewise, Medicare pays hospitals different amounts for the same care depending on whether the hospital admits beneficiaries as inpatients or treats them as outpatients. Some payment policies create financial inequities that actually may drive up Medicare costs without improving care for beneficiaries.^{7, 8} For example, the OIG found that Medicare payments to SNFs for therapy greatly exceeded SNFs' costs for that therapy, creating an environment that provides incentives to bill for unnecessary therapy.⁹

Prescription drug programs

Vulnerabilities exist in HHS's payment strategies for prescription drugs and biologicals. HHS programs accounted for 40 percent (\$136 billion) of the total U.S. prescription drug expenditures in 2017. Increases in prescription drug prices have contributed to the growth in total prescription drug spending. Increases in drug prices may limit patients' access to needed prescription drugs if the out-of-pocket costs become unaffordable. The way that Medicare and Medicaid pay for drugs, in addition to fundamental differences in how the Medicare Part B and Part D programs are structured, can result in additional costs for programs and their beneficiaries. In the Part D program, for example, OIG found that although there was a 17-percent decrease in Medicare Part D prescriptions for brand-name drugs from 2011 to 2015, there was a 77-percent increase in total reimbursement for these drugs, leading to greater overall Part D spending and higher beneficiary out-of-pocket costs.¹⁰ In the Part B program, OIG found that Medicare would have saved millions of dollars if dispensing fees for several drugs had been aligned with the rates that Part D and State Medicaid programs paid.¹¹ In addition, CMS includes prices for higher-cost versions of drugs that are not covered under Medicare Part B when setting Part B payment amounts. OIG found that, because CMS included noncovered versions when setting payment for two Part B drugs, Medicare and beneficiaries paid an extra \$366 million from 2014 through 2016.¹² HHS must endeavor to limit the impact of high prices on programs and beneficiaries while protecting access to medically necessary drugs. Additionally, the Department should be prepared to address coverage and reimbursement challenges of emerging technologies, such as biosimilars and gene therapies like chimeric antigen receptor T-cell therapy.

Contracts

Better controls in HHS's contracting process could strengthen competition and pricing for HHS-purchased goods and services. OIG has identified vulnerabilities in acquisition planning and monitoring of procurement and contracts. For instance, key HHS contracts may not always undergo Contract Review Board oversight before being awarded, and when awarding contracts, CMS has not always performed thorough reviews of contractors' past performance.¹³ Similarly, in the past, CMS and other OpDivs have frequently chosen contract types that place the risk of cost increases solely on the Government.¹⁴

Reducing improper payments

Due to their size, HHS programs account for some of the largest estimated improper payments in the Federal Government. Medicare, Medicaid, and CHIP accounted for \$86.1 billion, or 99.6 percent, of the \$86.4 billion in improper payments that HHS reported in its FY 2018 Agency Financial Report.¹⁵ Furthermore, insufficient HHS oversight of grant programs and contracts poses risks of significant improper payments and payments for unallowable costs.

Medicare

Traditional Medicare fee-for-service (FFS) accounted for \$31.6 billion, or about 37 percent, of the improper payments that HHS reported. Notably, this improper payment rate decreased from 9.5 percent, or \$36.2 billion, in FY 2017 to 8.1 percent in FY 2018.¹⁶ This represents positive momentum upon which the Department and CMS can build. However, some types of providers and suppliers pose heightened risk to the financial security of Medicare.¹⁷ For instance, OIG and CMS have identified especially high rates of improper payments for home health, hospice, and SNF care, durable medical equipment (DME), chiropractic services, and certain hospital services.¹⁸ HHS and CMS have taken corrective actions for the Medicare FFS program focusing on specific service areas with high improper payment rates. Although this year's reduction in the improper payment rate was driven by a reduction in improper payments for home health and SNF claims, CMS should take further action to reduce improper payments among certain provider and supplier types and in geographic locations that present a high risk to the financial security of Medicare. Further, CMS should ensure that it is prepared to detect and prevent improper payments in burgeoning areas, such as telemedicine and genetic testing.

Medicaid

Medicaid is a Federal-State financing partnership with the 50 States, 5 territories, and the District of Columbia, each offering its own program variations reflecting State and local needs and preferences. CMS's Payment Error Rate Measurement (PERM) program measures improper payments in Medicaid and CHIP in all 50 States and the District of Columbia using a 17-State 3-year rotation. In FY 2018, the improper payment rate for the Medicaid program was 9.8 percent.¹⁹ OIG audits have identified substantial improper payments to providers across a variety of Medicaid services, including school-based, non-emergency medical transportation, targeted case management, and personal care services.²⁰ CMS has engaged with State Medicaid agencies to develop corrective action plans that address State-specific reasons for improper payments identified through the PERM program. OIG work has also identified that States are not always correctly determining eligibility of individuals to receive Medicaid benefits, resulting in potential improper payments. Given that CMS will resume the Medicaid eligibility component measurement and report updated national eligibility estimates for FY 2019, the improper payment rate may significantly increase for this fiscal year.

Grants and contracts

Administering grant programs and contracts requires HHS to implement internal controls to ensure program goals are met and funds are used appropriately. For grant programs, this includes oversight and guidance to award recipients. HHS is responsible for providing up-to-date policies to grant recipients and helping States and other grantees address their own financial management and internal control issues. Without proper internal controls, funds may be misspent, duplication of services may occur, and sub-recipients may not be adequately monitored. OIG has identified grantee-level concerns in several HHS programs, including some Office of Refugee Resettlement (ORR) Unaccompanied Alien Children (UAC) Program grantees reporting unallowable costs and lacking effective systems for administering program funds;²¹ and States not sufficiently overseeing their Child Care and Development Fund (CCDF) program payments.²²

As a critical element of ensuring that grant funds are used appropriately, HHS must track and report improper payment rates for its risk-susceptible grant programs, in keeping with the *Improper Payments Information Act of 2002*.²³ However, since the inception of these reporting requirements, HHS has not

reported an improper payment estimate for the Temporary Assistance for Needy Families (TANF) program. States receive block grants (\$16.5 billion annually) to design and operate TANF programs. HHS has stated that it does not believe it has the statutory authority to collect from States the data necessary for calculating an improper payment rate for the TANF program. The Office of Management and Budget (OMB) has identified TANF as a risk-susceptible program that must report estimated rates and amounts of improper payments. HHS must continue to pursue needed legislative remedies to develop an appropriate methodology for measuring TANF payment accuracy and report an improper payment estimate for TANF.

In terms of the Department's oversight of contracts, HHS has taken steps to enhance its acquisition systems and better monitor contract closeouts and contract payments. Moreover, CMS has increased its efforts in examining workload statistics for benefit integrity contractors and improving performance outcomes. However, OIG has identified problems with the Department's processes for contract closeouts. CMS relies extensively on contractors to carry out its mission and spends billions of dollars each year in contracts. Because improper payments may be identified and recovered during the closeout process, it is imperative that contracts are closed in accordance with Federal Acquisition Regulation (FAR) requirements. The closeout process, generally, is the last chance for improper contract payments to be detected and recovered, and delayed closeout poses a financial risk to agency funds. OIG found that a large backlog of unfinalized indirect cost rates may have contributed to the untimely closeout of CMS contracts totaling \$25 billion.²⁴ Although CMS has taken steps to improve its closeout and contract management processes, the Department needs to take additional actions to ensure that it is meeting FAR requirements.

Combating fraud, waste, and abuse in HHS programs

Fraud, waste, and abuse divert needed program resources to inappropriate, unauthorized, or illegal purposes. Effectively fighting fraud, waste, and abuse requires vigilance and sustained focus on preventing problems from occurring in the first place, detecting problems promptly when they occur, and rapidly remediating detected problems through investigations, enforcement, and corrective actions. To accomplish this, HHS must have controls to ensure the proper use of resources and to detect and prevent fraud. The Department should also apply a robust program integrity strategy to protect current and future HHS programs.

Program integrity strategies

HHS programs must be designed with program integrity in mind. These strategies must take into account the various methods that HHS uses to implement its programs, including how public and private partners can help in meeting the Department's mission. Additionally, these strategies must include systems and processes to detect and prevent fraud, as well as plans for addressing fraud when it occurs.

Systems and processes for detecting and preventing fraud

With respect to detecting and preventing fraud and improper payments, CMS's Fraud Prevention System (FPS) serves as an important tool that should be improved to increase its effectiveness. Since 2011, the

FRAUD SCHEMES

- **Billing for Services Not Provided**
- **Identity Theft**
- **Kickbacks**
- **Improper Prescribing**
- **Deceptive Marketing**
- **Money Laundering**

FPS has continuously run predictive algorithms and other sophisticated analytics nation-wide against Medicare FFS claims prior to payment to identify, prevent, and stop fraudulent claims. However, OIG found that the FPS is not as effective in preventing fraud, waste, and abuse in Medicare as it could be and recommended that CMS should make better use of the performance results within its FPS to refine and enhance its predictive analytic models.²⁵

In the Medicare and Medicaid programs, States must keep bad actors intent on committing fraud from participating in the programs. With respect to Medicaid in particular, significant problems remain for ensuring all high-risk Medicaid providers undergo criminal background checks. Further, States are not sharing provider enrollment data with Federal and State partners to streamline the Medicaid enrollment process. Sharing these data would reduce the chance for error within any one of the State and Federal databases and help in identifying fraud schemes and other vulnerabilities that cross State lines.²⁶ CMS should continue to work directly with States to implement tools such as fingerprint-based criminal background checks for high-risk providers. Further, CMS should develop a central repository or “one-stop shop” with provider information that all States and Medicare can use.

Medicare and Medicaid

Schemes to steal money from Medicare and Medicaid take many forms and vary depending on setting and services provided. These fraud schemes can be as simple as billing for services not provided and identity theft or as complex as kickbacks, improper prescribing, deceptive marketing, and money laundering. The perpetrators of fraud schemes range from highly respected physicians to individuals with no prior experience in the health care industry to organized criminal enterprises.

Managed care continues to play an increasingly important role in Medicare and Medicaid. Unlike in FFS, where CMS (Medicare) or the State (Medicaid) pays providers directly for each covered service received by a beneficiary, under managed care, CMS or the State pays a population-based fee to a managed care plan for each person enrolled in the plan. In turn, the plan pays providers for services a beneficiary may require that are included in the plan’s contract with CMS or the State. Managed care is the primary delivery system for Medicaid, covering at least some services for more than 80 percent of all enrollees.²⁷ In Medicare, one-third of beneficiaries are enrolled in Medicare Advantage organizations (MAOs). HHS faces a significant challenge in protecting managed care programs and other non-traditional models against fraud, waste, and abuse.

OIG has found weaknesses in MAOs’ and Medicaid managed care organizations’ (MCOs) efforts to identify and address fraud and abuse by their providers.²⁸ CMS requires MAOs and Medicaid MCOs to implement compliance plans that include measures to prevent, detect, and correct instances of fraud, waste, and abuse and non-compliance with CMS’s program requirements. However, these plans vary widely among the MAOs, as does the detection of suspected fraud. In Medicaid managed care, program integrity responsibilities are even more dispersed, as they are shared among CMS, States, and MCOs. This makes effective oversight by CMS more complex and challenging.

CMS is working to validate the completeness and accuracy of MAO and Medicaid MCO encounter data and recently has released best practices guidance for MAOs to improve encounter data submission. CMS is also working with States to provide technical assistance and education to identify and share best practices for improving Medicaid MCO identification and referral of cases of suspected fraud or abuse.

CMS should take further actions to ensure the completeness, validity, and timeliness of Medicaid encounter data. Further, CMS should work with its contractors and with States to make improvements in efforts to identify and address fraud and abuse. Additionally, CMS should work to ensure that appropriate information and referrals are sent to law enforcement.

Grants and contracts

Without adequate oversight and internal controls, grants and contracts are vulnerable to fraud schemes, including embezzlement.²⁹ HHS has worked to strengthen some of its program integrity efforts focused on grant programs. For instance, it issued guidance to HHS awarding OpDivs about facilitating a review of prospective grantees prior to awarding grants.³⁰ This information enhances awarding OpDivs' assessment of prospective grant recipients' integrity and potential performance.

Fraud involving prescription opioids

Opioid-related fraud encompasses a broad range of criminal activity, from prescription drug diversion to addiction treatment schemes. OIG investigations show that opioid drug diversion (the redirection of legitimate drugs for illegitimate purposes) is on the rise. Diverted opioid drugs are at high risk to be used inappropriately and create significant harm, including increased risk of overdose. Also at high risk for diversion are potentiator drugs (drugs that exaggerate euphoria and escalate the potential for misuse when combined with opioids) and drugs indicated to treat opioid use disorders (OUDs) (particularly buprenorphine).

OpDivs should improve efforts to identify and investigate potential fraud and abuse in prescription drug programs. For instance, CMS should collect comprehensive data from Medicare Part D plan sponsors. CMS should ensure that national Medicaid data are adequate to detect suspected fraud or abuse. The lack of reliable national Medicaid data hampers enforcement efforts. (See TMC 5.) CMS and States should follow up on prescribers with questionable prescribing patterns to ensure that Medicare Part D and Medicaid are not paying for unnecessary drugs that are being diverted for resale or recreational use. OIG has also recommended that the Indian Health Service (IHS) improve its internal controls against opioid-related fraud, including controls at entry points to sensitive areas of its hospitals to protect its pharmacy inventory from unauthorized access.³¹ In addition, the Department must guard against fraud in OUD treatment programs, including, for example, the submission of fraudulent insurance claims for purported OUD treatment and testing services.³²

Monitoring and reporting on the integrity of HHS programs

HHS must ensure the completeness, accuracy, and timeliness of financial and program information provided to other entities, both internal and external to the Federal Government. Responsible stewardship of HHS programs is vital to operating a financial management and administrative infrastructure that employs appropriate safeguards to minimize risk and provide oversight for the protection of resources. Although HHS continues to maintain a clean opinion on their basic financial statements that culminate the results of their programs, addressing weaknesses in financial management systems and meeting the requirements of the *Digital Accountability and Transparency Act (DATA Act) of 2014* remain challenges for HHS.

Addressing weaknesses in financial management systems

Financial management systems help OpDivs ensure operational effectiveness and efficiency, financial reporting reliability, and compliance with applicable laws and regulations. OIG continues to find

significant deficiencies in internal controls over segregation of duties, configuration management for approved changes to HHS financial systems, and access to HHS financial systems.³³ HHS must take additional actions to address and resolve these issues, including continuing to work to control user access, ensuring proper approval of and documentation supporting system changes, and ensuring appropriate segregation of duties so that no one employee can both enter and approve information entered into HHS financial management systems.³⁴

Meeting the requirements of the DATA Act of 2014

The DATA Act required agencies to use Government-wide data standards to report financial and award information into [USAspending.gov](https://www.usaspending.gov). For FYs 2017, 2019, and 2021, the DATA Act also requires the Inspector General of each agency to determine the accuracy, completeness, timeliness, and quality of these data. In FY 2018, OIG performed an additional audit to follow-up on prior issues and monitor and provide feedback on the progress made by the Department. For FY 2018, OIG's audit of compliance with the DATA Act found that HHS complied with data standards but continued to rely on a manual, labor-intensive process.³⁵ HHS needs to continue to automate the standardization and transmission of data to the Department of Treasury.

2: Delivering Value, Quality, and Improved Outcomes in Medicare and Medicaid

The transition to innovative, value-based, consumer-empowered care is a top Administration³⁶ and Departmental priority. HHS continues to enact reforms in Medicare and Medicaid to promote quality, efficiency, and value of care. These reforms come with an array of operational and program integrity challenges, as well as promising opportunities for better health outcomes, lower costs, improved transparency and choices for consumers, and reduced administrative burden on providers.³⁷

Medicare and Medicaid, the two largest programs in the Department, are also among the most complex. Both programs offer benefits in multiple formats (FFS, managed care, and newer payment models); cover a broad array of health conditions, providers, services, and settings; and operate pursuant to intricate statutory directives and regulatory schemes. Increasingly, beneficiaries are enrolling in Medicare and Medicaid managed care options.

The transition to value in the Medicare and Medicaid programs is well underway, with continued growth expected. The Health Care Payment Learning & Action Network, an HHS-sponsored public-private partnership, estimated that for FY 2017, 90 percent of providers in Medicare FFS were paid based, at least in part, on quality and value, with 38 percent being paid under an alternate payment model or a population-based payment; the comparable numbers for Medicaid were 32 percent and 25 percent, respectively.³⁸ HHS has introduced, and continues to introduce, a range of new models, including accountable care organizations (ACOs), medical homes, bundled payment models, primary care models, and others. Many of these models are designed as all-payer models to align with developments in the private sector. Most recently, HHS announced a major set of initiatives to reform payment and delivery of kidney care, including new payment models, technologies, and care options for patients.

Both Medicare (FFS, Part C, and Part D) and Medicaid have proven susceptible to fraud, waste, and abuse, with estimates of improper payments ranging from 8.1 percent (Medicare FFS) to 9.8 percent (Medicaid) of total expenditures, totaling \$86 billion in FY 2018.³⁹ For the past 16 years, the Government Accountability Office (GAO) has included both programs on its list of high-risk Government programs. OIG work has long demonstrated a range of vulnerabilities in both Medicare and Medicaid:

- Flaws in program design and administration (e.g., improper payments) (see TMC 1),
- Misaligned program incentives and confusing or insufficient program guidance,
- Deficiencies in how providers deliver care to beneficiaries (e.g., poor quality and unsafe care (see TMC 3) or inappropriate utilization),
- Gaps in provider enrollment systems and available data needed for proper oversight (see TMCs 1 and 5), and

RELEVANT OPDIVS

CMS, ONC, OS

KEY ELEMENTS

- Aligning program incentives with health outcomes
- Addressing integrity problems across models
- Delivering on the promise of innovative technology to improve health outcomes

- Problems in ensuring that eligible beneficiaries have adequate access to covered services in both FFS and managed care.

There are three specific elements of this challenge: (1) aligning program incentives with improved health outcomes, (2) strengthening program integrity, and (3) delivering on the promise of innovative technology. Each element is integral to delivering greater value (including savings), quality, and improved outcomes for Medicare and Medicaid, their beneficiaries, and taxpayers.

Aligning program incentives with health outcomes

Developing effective incentives and policies to drive better health outcomes is difficult given the complexities of medicine, the programs themselves, and the populations served by these programs. HHS faces obstacles in correctly measuring the value of care. Designing measures that effectively incentivize high-quality care without being overly prescriptive or burdensome to providers is challenging, and the science of quality measurement continues to evolve.

The Department is undertaking initiatives to streamline, improve, and target quality measures more precisely and to move from process measures to outcome measures. Through its *Meaningful Measures* initiative, CMS reports it rolled back 20 percent of measures because they were topped out, duplicative, or overly burdensome.⁴⁰ Where applicable, CMS must clearly define actionable and meaningful quality measures and ensure their reliability, accuracy, and utility. CMS and other OpDivs currently using quality measurements should continue to align efforts to reduce unnecessary provider burden and strengthen quality measurement. Moving forward, HHS will need to ensure that its programs use effective, evidence-based measures for quality improvement. Under the new Executive Order on Health Care Price Transparency and Quality, HHS is producing a health quality roadmap in coordination with the Secretaries of Defense and Veterans Affairs that will include a strategy for developing common quality measures, aligning inpatient and outpatient measures, and eliminating low-value quality measures. The Department is also exploring—via a Regulatory Sprint to Coordinated Care led by the Deputy Secretary—whether better care coordination and value-based care can be fostered through changes to existing regulations that some view as barriers to care coordination, including certain fraud and abuse regulations administered by CMS and OIG, as well as certain Substance Abuse and Mental Health Services Administration (SAMHSA) and Office for Civil Rights (OCR) regulations.

OIG work examining the Medicare Shared Savings Program over the first 3 years of the program revealed that ACOs participating in the Medicare Shared Savings Program reduced Medicare spending and achieved a net spending reduction of nearly \$1 billion for 9.7 million beneficiaries. ACOs improved their performance on most (82 percent) of the individual quality measures and outperformed FFS providers on most (81 percent) of the quality measures. ACOs participating in the program longer were more likely to reduce spending and by greater amounts than other ACOs. This suggests that more established ACOs can achieve greater cost savings and quality over time.⁴¹ OIG conducted site visits to successful ACOs and identified strategies used by ACOs to reduce Medicare spending and improve quality of care. Examples of these strategies include engaging beneficiaries in improving their health outcomes, managing beneficiaries with costly or complex care needs, reducing avoidable hospitalizations, controlling costs and improving quality in skilled nursing and home health care, addressing behavioral health needs and social determinants of health, and using technology to increase information sharing among providers.⁴² Based on this work, OIG recommended—and CMS concurred—that CMS take steps to support and share successful ACO strategies. These strategies may be adaptable in other value-based models.⁴³

New payment structures, business arrangements among providers, and incentives all give rise to risk-management challenges. In pursuing innovative models to improve the health care system—whether in FFS or managed care—CMS must take steps to prevent unintended consequences, such as misaligned incentives or abusive practices. Moreover, notwithstanding identified successes, CMS must maintain a steady focus on quality. For example, an OIG review of Medicare Part B dialysis services at a health care group in Puerto Rico found noncompliance with Federal requirements for which the deficiencies could have had a significant impact on the quality of care provided to Medicare beneficiaries and could have resulted in the provision of inadequate or unnecessary dialysis services. OIG provided recommendations for strengthening policies and procedures to meet quality requirements.⁴⁴ (See TMC 3 for further discussion of quality-of-care challenges.)

Addressing integrity problems across models

The transition to a value-driven health system could mitigate some of the fraud and abuse vulnerabilities resulting from volume-based incentives and poorly coordinated care. However, familiar risks will continue to exist and new risks will likely emerge. Examples of risks in a value-based system (e.g., one where providers assume financial risk for patients' cost of care) could include providers inappropriately reducing costs by stinting on care, discriminating against expensive patients, or manipulating or falsifying data used to measure performance, outcomes, or acuity. Managed care suffers from similar program integrity problems. More will need to be done across FFS and managed care programs to assess and identify emerging risks so that they can be mitigated.

As health care transitions from paying for procedures to paying for outcomes, the programs will concurrently face risks associated with volume-driven and value-driven payment and care. Indeed, many providers will be paid under models that combine multiple types of incentives, such as a shared savings payment in combination with FFS payments, and some providers will continue to be paid primarily or exclusively on a volume-basis. Managed care programs also are not immune from risks created by mixed incentives. OIG's oversight and enforcement work addressing program integrity in managed care demonstrate the opportunities for "downstream" fraud and abuse, such as by providers paid on an FFS basis, notwithstanding that the Government pays on a population basis (e.g., a capitated payment). (See TMC 1 for further discussion of program integrity in managed care.)

A further, significant program integrity concern arises in connection with services furnished in home- and community-based settings, which patients often prefer and can be less costly. Value-based care models are expected increasingly to promote care in these settings through home visits by practitioners and care managers, remote monitoring, and other technologies. CMS is expanding beneficiaries' access to telehealth. OIG work in areas such as hospice care, home health, and personal care services consistently demonstrates that patients and the programs may be vulnerable to fraud and abuse in home- and community-based settings. Moreover, there is heightened risk that new technologies, when misused, could enable wrongdoers to commit broader and new types of fraud.

Managing and mitigating multifaceted risks to ensure that patients, providers, and taxpayers realize the full benefits of innovative value-based care will require sustained effort, resources, flexibility, and continual prioritization by CMS and the Department. In testing and implementing value-based care models, CMS must continue to focus on program integrity risks, incorporate safeguards to reduce them, and promptly correct identified issues. Focusing on these risks is especially important for models that introduce new payment incentives, which might lead to new fraud schemes, and for models for which waivers of payment, coverage, or fraud and abuse laws may have been issued.

Across Medicare and Medicaid, whether in the traditional FFS, managed care, or emerging new models, CMS must remain attentive to tailoring effective program integrity strategies that prevent and detect problems and hold wrongdoers accountable. Attention must be paid to the range of fraud, waste, and abuse risks, including improper payments, compliance with program requirements, provider eligibility and qualifications, data integrity and availability, transparency and accuracy of information available to consumers, patient safety, substandard care, and access to care. These risks are covered in more detail in TMCs 1, 3, and 5.

Delivering on the promise of innovative technology to improve health outcomes

Leveraging digital and health technology to foster efficient, high-quality, safe care is critical to a value-driven health care system, as is ensuring the appropriate flow of complete, accurate, timely, and secure information. For example, recent OIG work examining how Medicare Shared Savings Program ACOs use health IT showed that, although ACOs have used health IT to aid in care coordination in a variety of ways, the full potential of health IT has not been realized.⁴⁵

HHS faces challenges in achieving a connected health care system to support better coordinated and value-based care in which patients' data—including conventional health care data and newer types of data related to social determinants, demographics, and personal trackers—flow freely across provider settings, with appropriate privacy and security protections. As health-related apps and technologies proliferate with the delivery of care, beneficiaries will need access to new and integrated information. This information should enable them to choose reliable apps and technologies to assure themselves that providers they may be engaging with via an app or technology are trustworthy. (See TMC 5.)

HHS also faces challenges in ensuring that evolving technologies achieve their intended results, enhancing patient access to quality care and providers' ability to furnish such care. The recent billion-dollar law enforcement action known as Operation Brace Yourself illustrated how telehealth technology used for remote physician consultations can make a familiar fraud scheme—charging Medicare for DME that patients do not need—bigger with less effort. HHS must provide appropriate oversight of rapidly evolving technologies, such as telehealth, networked medical devices, robotics, genomic testing, and remote monitoring. In many cases, new technologies and apps are being developed by individuals and entities—often engineers or scientists—unschooled in the complex regulations governing health care and unaware of the range of program integrity risks their inventions may face. These new participants in the health care ecosystem will need education, guidance, and appropriate oversight.

HHS faces a growing challenge in understanding and, as appropriate, overseeing providers' use of artificial intelligence and machine learning in the delivery of health care, such as in diagnostics, as well as for administrative functions, such as coding and claims submission. Artificial intelligence and machine learning are introducing new paradigms that will likely require fresh thinking about compliance and fraud prevention. Relatedly, HHS will need to assess how it can use artificial intelligence, machine learning, and other technologies to foster program integrity, value, and quality of care in Medicare, Medicaid, and other HHS programs. Finally, HHS will need to ensure that rural beneficiaries and underserved populations are not left out of a technology-enriched, value-driven health system. (See TMC 4 for further information about the Food and Drug Administration's (FDA's) role in emerging technology.)

Artificial intelligence and machine learning are introducing new paradigms that will likely require fresh thinking about compliance and fraud prevention.

Realizing the promise of value-based care and payment structures

To achieve better care at lower cost, HHS must maintain a steady focus on developing and refining effective, innovative, evidence-driven models while being proactive in preventing and detecting fraud, waste, and abuse. HHS must pay special attention to effectiveness and program integrity in nascent areas such as the intersection of health care with social determinants of health and new uses of digital technology. This is vitally important given the current and anticipated growth in the cost and number of beneficiaries in Medicare and Medicaid. Meeting this challenge will enable the Department to expand the reach of dollars devoted to these programs, thereby abating some of the anticipated rise in cost of these programs over the next decades and improving the lives and health outcomes of the beneficiaries they serve.

3: Protecting the Health and Safety of HHS Beneficiaries

HHS programs provide critical services to diverse populations across a broad range of care settings. Some such services are directly provided by HHS personnel, some delivered via HHS grant programs and others rendered by professionals of the beneficiary's choosing, who then claim reimbursement from Federal programs. Services include health care services, educational services, child care services, and even physical custody for select populations. Ensuring that intended beneficiaries receive appropriate services and are not subjected to abuse or neglect represents a major challenge for the Department.

RELEVANT OPDIVS

ACF, CMS, IHS, SAMHSA

KEY ELEMENTS

- Ensuring safety and quality of health care paid for by Federal health insurance programs
- Protecting the health and safety of children served by HHS programs
- Preventing abuse and neglect

Ensuring safety and quality of health care paid for by Federal health insurance programs

HHS operates the Medicare program to insure about 60 million elderly or disabled Americans. In partnership with the States, the Medicaid and CHIP programs insure about 75 million and 7 million beneficiaries, respectively. IHS serves about 2.6 million members of 573 federally recognized Tribes. These programs cover specific health care services, which may include hospital care, physician services, prescription drugs, hospice care, home and community-based care, DME, and skilled nursing care.

Delivering covered services

Ensuring access to care that meets quality and safety standards remains a challenge. Even when Federal health care programs cover care, many beneficiaries do not actually receive the care they need. For example, OIG found that over 500,000 children with attention deficit hyperactivity disorder (ADHD) who were Medicaid-enrolled did not receive timely follow-up care, and that over 50,000 such children did not receive behavioral therapy as recommended by professional guidelines.⁴⁶ At the other end of the life cycle, OIG found that more than 80 percent of hospice providers, a growing sector of health care serving beneficiaries and their families at an extremely vulnerable time near end-of-life, had quality-of-care deficiencies.⁴⁷ Additionally, fixed daily payment structures may incentivize hospices to enroll beneficiaries for longer time periods but scrimp on care. Oversight work also revealed that patients experience significant rates of adverse events (patient harm as a result of medical care) in health care facilities. Specifically, OIG found that 27 percent of Medicare beneficiaries were harmed during their stays in acute care hospitals, and that harm rates were even higher for post-acute settings: 29 percent in rehabilitation hospitals, 33 percent in skilled nursing facilities, and 46 percent in long-term-care hospitals.⁴⁸ In addition to the high harm rates, OIG found that hospitals did not identify when harm occurred in their facilities, in part due to confusion over HHS and other Government guidance regarding how to define and report adverse events.⁴⁹ OIG is currently conducting a study to update the harm rate for Medicare beneficiaries in hospitals. This review will assess progress made in reducing harm in the decade since the prior study was released in 2010.⁵⁰ OIG also has work underway to measure the rate of adverse events for patients at IHS Hospitals. (See TMC 6 for more information on challenges associated with adverse events.)

The Department continues efforts to improve the quality of covered services. The Department has worked to improve information available to beneficiaries and their families when selecting a care provider. One example is CMS's efforts to improve nursing home care. CMS's Five-Star Quality Rating System facilitates informed comparison of nursing homes. CMS has announced plans to revamp its Hospital Quality Star Rating System to enable better informed decision-making for beneficiaries seeking hospital care.

Also, CMS enforcement actions have stopped some poor-performing nursing homes from rendering worthless services. One nursing home chain charged with rendering grossly substandard care to Medicare and Medicaid beneficiaries agreed to repay \$18 million and abide by the terms of a Corporate Integrity Agreement to ensure that it delivers appropriate care going forward.⁵¹ Further, after a series of OIG reports about quality of care problems in IHS-operated hospitals,⁵² IHS created a new Quality Framework and Office of Quality to provide better guidance and oversight to its facilities and clinical staff.⁵³

Although the Department has made progress, more work remains to be done to improve access to and quality of all types of care. Among the top priorities as identified by OIG work are improving hospice care, including strengthening the survey process and better educating beneficiaries and their families and caregivers,⁵⁴ and improving the health and safety of nursing home residents by ensuring facility correction of deficiencies.⁵⁵ To continue improvements at IHS, OIG has recommended that IHS prioritize developing and implementing a staffing program to ensure sufficient qualified staff, including those at remote facilities; enhance training for staff and hospital leaders; intervene quickly and effectively when quality problems are identified; and establish better procedures, including improved external communication.⁵⁶

Protecting the health and safety of children served by HHS programs

HHS operates or funds many programs providing additional services beyond health care for children, including child care, education, and residential care. The Head Start program promotes school readiness for nearly 1 million children from low-income families and the CCDF provides child care for about 1.3 million children from low-income families. The importance of properly vetting staff for these programs is discussed below.

Operating the UAC Program

Through the UAC Program, ORR assumes custody of children who enter the United States without immigration status and have no parent or guardian in the United States able to provide for their physical and mental well-being. The child may have arrived in the United States alone, or in certain circumstances, may have been separated from their parents or legal guardians at the border. This program merits specific discussion, as it uniquely tasks the Department with assuming physical and legal custody for children, and the comprehensive responsibility for their welfare thus entailed. Through the UAC Program, ORR places unaccompanied or separated children in shelters and other facilities operated by grantees or contractors. These facilities provide food and shelter, as well as medical and mental health care and other services. Children remain in these placements until a sponsor (usually a parent or family member) is found to whom the child may be safely released, the child's immigration status is resolved, or the child turns 18 years old and ages out of the program. Since ORR began operating the UAC Program in 2002, it has served more than 175,000 children.

In recent years, ORR has been called upon to care for more children, including children who did not come to the United States alone but were separated from their parent or guardian at or after arrival. HHS

reported to a court as part of a lawsuit that 2,737 children had been separated by the Department of Homeland Security (DHS) and remained in ORR care as of June 2018. OIG reported in January 2018 that possibly thousands of children had been separated and released by ORR before the court order and that children had been separated from their parents for longer than had previously been reported. ORR had not been tracking this figure and the exact number of separated children is still not known, although HHS and DHS are now working to identify all of the children separated from their parents since July 2017. OIG also reported that children continue to be separated by DHS from their parents, and ORR does not always receive adequate information.⁵⁷ Lack of data about separated children complicates HHS's ability to ensure appropriate placement and reunite children with their families in a timely manner. These factors may cause children to spend more time in HHS custody. Issues related to identifying and vetting appropriate sponsors may also prolong children's time in HHS care facilities. Also, at one influx care facility, OIG found failures in conducting required staff background checks and insufficient clinical staff to serve children's mental health needs.⁵⁸

The Department must work to ensure that UAC Program-funded facilities meet all safety requirements and provide adequate medical and mental health care. As discussed further below, HHS must also enhance efforts to ensure that all staff with access to children have passed required background checks.

Preventing abuse and neglect

HHS funds and oversees many types of services for a broad range of beneficiaries. Countless HHS-funded providers are in a position of trust and in close contact with beneficiaries, often behind closed doors and at especially-vulnerable times in the beneficiary's life. The vast majority of providers seek to serve beneficiaries' best interests. However, some providers may cause beneficiaries harm and HHS must protect its beneficiaries from abuse and neglect. For example, a former IHS pediatrician is currently in prison in one State and standing trial in another State for sexually assaulting boys he treated as patients. That incident commanded extensive attention and the Department has committed to collaborating with a Presidential Task Force on Protecting Native American Children in the IHS system established in March 2019.⁵⁹ The Task Force is charged with examining IHS systems that may have failed in the past and recommending improvements to better protect children from abuse. Better attention to protecting vulnerable beneficiaries of all ages in all HHS care settings is also needed.

Vetting providers and staff

Although even the most thorough vetting cannot completely prevent all potential predators from abusing Federal programs to gain access to victims, background checks are a useful tool. OIG identified failure to conduct required background checks for UAC facility staff whose jobs entail access to children.⁶⁰ Failure to conduct adequate background checks has been a problem in domestic child care programs as well. OIG found that some States have not fully implemented CCDF requirements to conduct comprehensive criminal background checks on current and prospective staff.⁶¹ Implementation of background checks for long-term-care providers remains a challenge as well.⁶² Along with demonstrating job-specific competency and qualifications, ensuring that staff pass all required background checks is an important safety measure.

The Department should improve efforts to ensure staff pass required background checks before they have access to patients in various health care settings and to children in the UAC Program, Head Start, and CCDF. The Department is also working to support States' implementation of the CCDF background check

requirements. The Department should continue to work with States to ensure that implementation of the *Child Care and Development Block Grant Act of 2014* background check requirements align with the statutorily required effective dates and the allowable timelines described in the CCDF Final Rule.

Identifying and reporting abuse and neglect

Beneficiaries in many care settings are at risk of abuse and neglect. About 1.8 million Medicare beneficiaries receive care in SNFs each year.⁶³ Home and community-based services allow many Medicaid beneficiaries the opportunity to avoid undesired facility care. However, some beneficiaries have been abused or neglected by individuals, including some family members that Federal health care programs paid to care for the beneficiary at home. Group homes provide care to many especially vulnerable people, including adults with developmental disabilities. OIG work found extensive failures to properly handle critical incidents, including suspected abuse and neglect, of group home residents.⁶⁴ OIG has also identified substantial failures to report incidents of potential abuse or neglect of Medicare beneficiaries living in SNFs who require treatment in hospital emergency departments.⁶⁵ All States have enacted mandatory reporting laws that require certain individuals, like school teachers or nursing home staff, to report suspected abuse or neglect of vulnerable individuals. However, many instances of abuse and neglect go unreported, making it harder to help victims and hold wrongdoers accountable.⁶⁶

The Department has created several resources to better address abuse and neglect of residents of group homes. These resources include model practices for (1) State incident management and investigation, (2) State incident management audits, (3) State mortality reviews, and (4) State quality assurance.⁶⁷

It is important to prevent ongoing harm by identifying providers and facilities subjecting beneficiaries to abuse or neglect. States and other partners should use claims data to better identify unreported abuse and neglect. OIG created a resource guide to help accomplish this goal.⁶⁸ Additional efforts would help to improve reporting. For example, CMS should compile a list of diagnosis codes that indicate potential abuse or neglect, conduct periodic data extracts, and encourage States to better use data to facilitate compliance with mandatory reporting laws.

CMS should also work to ensure that Federal mandatory reporting laws suffice to protect beneficiaries in all care settings and are adequately enforced. Protecting beneficiaries from abuse and neglect is a critical responsibility requiring attention and cooperation from all stakeholders.

4: Safeguarding Public Health

As HHS pursues its mission of enhancing the health and well-being of all Americans, there are challenges to ensuring public health and safety. These include opioid abuse and misuse, risks associated with public health emergencies caused by communicable diseases and natural disasters, dangers from unsafe food, and medical devices vulnerable to cyberattacks. To best serve the American public, the Department must leverage the skills and tools it has at its disposal to reduce the ill-effects of opioid use disorders (OUDs) through prevention, treatment, and recovery support, prioritize emergency planning and response, and ensure that food, drugs, and devices are safe. Additionally, Americans rely on HHS to recognize and respond to emerging issues such as concerning trends and evidence of detrimental health impacts associated with the use of e-cigarettes and other electronic nicotine delivery systems (“vaping”). Because challenges to public health are often complex, the Department must ensure that operating divisions coordinate with each other, as well as partners within and outside of Government, to effectively promote public health and safety. (See TMC 6 for more information on the Department’s challenge of coordinating with internal and external partners.)

RELEVANT OPDIVS

ASPR, CDC, CMS, FDA, HRSA, IHS, SAMHSA

KEY ELEMENTS

- Tackling the opioid epidemic while ensuring access to treatment
- Strengthening emergency preparedness and response capabilities
- Safeguarding the Nation's food supply
- Providing adequate oversight of medical device safety and security

Tackling the opioid epidemic while ensuring access to treatment

The Nation is struggling with an opioid crisis that is, at least partially, fueled by opioids prescribed by licensed medical professionals, dispensed by licensed pharmacies, and paid for by Federal funds. Approximately 2 million people have an OUD,⁶⁹ and two out of three overdose deaths involve an opioid.⁷⁰ In 2017 alone, there were an estimated 47,600 opioid-related overdose deaths in the United States.⁷¹ Although the opioid epidemic is pervasive nationally, data suggest that the Appalachian region, in particular, has higher opioid prescribing rates and overdose death rates,⁷² and that the American Indian/Alaska Native (AI/AN) population is disproportionately harmed by opioid misuse^{73,74} and overdose deaths.⁷⁵ Additionally, synthetic opioids such as fentanyl and tramadol present a significant, growing threat and have been associated with more deaths than other types of opioids.⁷⁶

Two out of three overdose deaths involve an opioid.



In 2017, the President directed the Acting HHS Secretary to declare the opioid crisis a national public health emergency, authorizing the Department to use emergency authority to address the opioid epidemic. The Department plays a critical role in ensuring that opioids are prescribed and dispensed appropriately and according to program policies.⁷⁷ HHS developed a five-point strategy to combat the opioid crisis⁷⁸ and must continue working toward addressing the problem, adjusting its approach as appropriate. HHS OpDivs should continue to

use the tools available in their programs to address the opioid epidemic while being mindful of patients' needs to access appropriate pain management, which may include the use of opioid analgesics.

Although opioid misuse and abuse remains a problem, OIG found some potential improvements in utilization patterns and access to treatment for substance abuse in Medicare Part D, including a decrease in Medicare beneficiaries receiving opioids, an increase in beneficiaries receiving medication-assisted treatment (MAT) for OUD, and an increase in prescriptions for naloxone—a drug that can prevent overdose deaths.⁷⁹ Ensuring access to appropriate pain management therapies and combating opioid abuse remains a high priority. CMS and Part D sponsors should implement effective drug management programs for at-risk beneficiaries.

Further, IHS could improve the quality of care for prescribing and dispensing opioids to the AI/AN population by fully utilizing States' prescription drug monitoring programs. A 2019 OIG report⁸⁰ identified that IHS hospitals did not fully use the States' prescription drug monitoring programs when prescribing or dispensing opioids at certain IHS hospitals. In addition, the hospitals did not use available data to identify risks in their prescribing and dispensing practices, such as giving patients (1) opioid doses of as high as 500 daily morphine milligram equivalents; and (2) opioids and benzodiazepines at the same time, which puts patients at greater risk of a potentially fatal overdose. Making data-supported decisions and conducting data analysis will be crucial to identifying risks and reducing the occurrence of adverse events. (See TMC 5.)

Additionally, through the FDA, the Department approves new drugs before they are marketed in the United States and takes into account benefits and risks to assure safety and efficacy.⁸¹ FDA also monitors the safety of marketed drugs as new information becomes available. Through this framework, the FDA can encourage the development of abuse-deterrent formulations of opioids that may be less susceptible to abuse; employ tools, including the Risk Evaluation and Mitigation Strategy program, to mitigate risks associated with approved drugs; and pursue measures that include withdrawal from the market when there are serious safety concerns.⁸²

The treatment of OUDs is a priority. Only a fraction of the 2.1 million people with OUDs received specialty treatment in 2018 (19.7 percent).⁸³ It is important for the public to be able to access effective, quality treatments. Research suggests that MAT medications, in combination with counseling and behavioral therapies, can be an effective treatment for OUDs. Three drugs—methadone, buprenorphine, and naltrexone—are approved to treat OUDs. Access to MAT is a priority as patients suffering from an OUD are at risk for withdrawal and relapse and may seek out illicit opioids, such as heroin. As such, the Department must work diligently to ensure access to these medications.⁸⁴

The Department continues to manage and oversee investments to address OUDs. SAMHSA awarded more than \$930 million⁸⁵ through the State Opioid Response grants to support a comprehensive response to the opioid epidemic and expand access to treatment and recovery support services; HRSA awarded nearly \$400 million for community health centers, rural organizations, and academic institutions to establish and expand access to OUD treatment.⁸⁶ Although treatment must be prioritized nationally, the Department should ensure that resources are devoted to areas disproportionately affected by the opioid epidemic, including the AI/AN population and rural communities. Recognizing the potential danger of abrupt opioid withdrawal and the patient safety imperative of tapering or discontinuing opioids thoughtfully, the Department released a *Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*.⁸⁷

The Department can also help save lives through enabling people to access medications that reverse the effects of opioids and illicit drugs. Research shows policies that make it easier to access naloxone may be saving lives.⁸⁸ HHS is in the process of implementing the *SUPPORT for Patients and Communities Act of 2018* that proposes several strategies to combat the opioid crisis, including reducing improper opioid prescribing and expanding access to prevention, treatment, and recovery services. For example, it requires CMS to recommend ways to lower consumer prices for opioid overdose-reversal medications such as naloxone and requires HHS to establish a grant program to implement best practices regarding treatment for individuals who experience an overdose, including emergency treatment and the use of recovery coaches. (See TMC 1 for more information on program integrity considerations associated with grants.)

Strengthening emergency preparedness and response capabilities

HHS has a lead role in preventing, preparing for, and responding to the adverse health effects of public health emergencies. (See TMC 6 for more information about HHS's role in the Federal Government's emergency preparedness and response efforts.) Communicable diseases, outbreaks, and natural disasters constitute public health emergencies that can severely strain public health and medical infrastructure and lead to serious illness and loss of life. Prior to and during a public health emergency, it is important to have adequate planning (such as preparing for a medical surge) and mechanisms in place to efficiently and rapidly deploy assets and provide relief to those in need of vital health and human services resources in the aftermath of an emergency. Prior OIG work has identified gaps in emergency preparedness and response planning for health care facilities during disasters and pandemics.⁸⁹ The Department's continued efforts to improve preparedness and response are important as it is uniquely positioned with the opportunity to continuously assist communities throughout the United States so that they can respond to and deliver health services in the immediate aftermath of natural disasters, as well as support sustained recovery efforts.

Prior OIG work has identified gaps in emergency preparedness and response planning for healthcare facilities during disasters and pandemics.

Additionally, recent outbreaks of communicable diseases (e.g., measles, hepatitis, and Ebola) are an ongoing challenge and demonstrate the need for the Department to rapidly detect, diagnose, and assess these threats. A 2019 OIG report determined whether HHS's response efforts to the 2014 Ebola outbreak were effective and efficient and found that HHS (1) had no strategic framework in place to coordinate global health security at the international or departmental levels before the Ebola outbreak, (2) was not prepared to deploy the resources needed for such a large-scale international response, and (3) did not have in place internal or external communication channels for responding to an international public health emergency.⁹⁰ It is important for HHS to have the ability to readily develop, distribute, and administer medical countermeasures (i.e., vaccines, therapeutics, and diagnostics) to effectively prevent and treat infectious diseases. States and localities should ensure planning and preparedness in areas including medical surge and vaccine and antiviral drug distribution and dispensing.⁹¹

Safeguarding the Nation's food supply

An estimated 1 in 6 Americans get sick from contaminated foods each year, and 3,000 die.⁹² Individuals with weakened immune systems, such as older and younger populations, may be particularly susceptible to foodborne illnesses. Foodborne illnesses are largely preventable, and the American public relies on FDA, working with partners including the Centers for Disease Control and Prevention (CDC), to ensure that the food we eat is safe.⁹³ The passage of the *FDA Food Safety Modernization Act* (FSMA) placed renewed emphasis on the importance of preventing foodborne illnesses and FDA has made progress in implementing that statute. FDA has prioritized creating a more effective and efficient food safety system. One means by which it aims to do this is by increasing the role of the States in improving produce safety.⁹⁴ Still, with an increasingly global food supply, keeping food safe presents a constant challenge.

The Department must ensure that FDA continues to modernize the food safety system and responds effectively when issues are identified. FDA should use the array of tools at its disposal to protect the American public. It should conduct risk-based inspections of domestic and foreign food facilities within the timeframes required by FSMA, identify instances of failure to comply with good manufacturing practices, and take necessary steps when health risks are identified, including administrative and enforcement actions when warranted.⁹⁵ FDA has made organizational changes with the goal of improving incident response through, for example, instituting its Coordinated Outbreak Response and Evaluation Network, and should continue to optimize its ability to protect the public from outbreaks of foodborne illnesses.

Providing adequate oversight of medical device safety and security

FDA is responsible for approving new medical devices that it determines are safe and effective, and assuring that approved products remain safe and effective.⁹⁶ As technology advances, FDA performs this task in an increasingly complex environment. Beneficial aspects of innovative medical devices, such as the ability to communicate widely with other devices, may increase the risk of cybersecurity threats. (See TMC 5 for more information on cybersecurity.) FDA has the difficult task of staying at the forefront of emerging technology, amassing the technical knowledge to understand the science that supports advances in medical device function, and anticipating the potential impacts of new technologies. FDA reports that it has undertaken several initiatives to enhance the Agency's approach to medical device safety, and is working closely with patients, providers, and device developers to make sure that it is appropriately balancing risk and benefit.

The *21st Century Cures Act* (the Cures Act) aims to help accelerate medical product development and bring new innovations and advances to patients.⁹⁷ Among the expedited product development programs established by the Cures Act is the Breakthrough Devices program. Under that program, manufacturers of medical devices that meet certain criteria may obtain priority review by FDA. For example, a medical device designed to provide more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition may be eligible for "Breakthrough Device" designation.⁹⁸ Recently, FDA granted breakthrough status to an artificial intelligence-enabled medical device intended to diagnose and improve clinical management of patients with Type 2 diabetes with fast-progressing kidney disease.⁹⁹

The speed at which science and technology are evolving means that the development and regulation of medical devices presents new safety and effectiveness concerns. For example, artificial intelligence-enabled devices that communicate with other medical devices may be subject to cybersecurity risks¹⁰⁰ or interoperability difficulties, which could adversely affect patient safety and medical device performance. (See TMC 5.) One area of challenge for FDA thus will be to review medical device applications as expeditiously as possible while being mindful of

factors that could adversely affect the safety and effectiveness of medical devices. (See TMC 2 for HHS's challenges in overseeing evolving technologies in Medicare and Medicaid.)

Post-market surveillance of medical devices continues to be a management challenge for FDA.¹⁰¹ Each year, the agency receives several hundred thousand reports of medical devices suspected of being associated with death, injury or malfunction. By regulation, these reports must be submitted in a timely manner to FDA.¹⁰² In 2009, OIG reported that manufacturers and medical device user facilities often submitted tardy and incomplete adverse event reports and that FDA failed to employ adverse event reports in a systematic manner to detect and address safety concerns.¹⁰³ FDA reports that it is evolving beyond its current passive post-market surveillance system and moving to an active surveillance system that relies on real-world evidence and timely receipt of robust safety information, which it believes will better protect patients and help enable the Devices Program to act quickly with manufacturers and health care providers to make timelier decisions to keep patients safe. A key element of implementing this strategy will be the multi-stakeholder effort to establish the new national system for gathering real world evidence through the National Evaluation System for health Technology (NEST). Implementing a national surveillance system would also not be possible without the FDA's establishment in recent years of a unique device identification (UDI) system, in which medical devices are marked on their labels with a unique code that can be used to track the device through its distribution and use in patients.

5: Harnessing Data To Improve Health and Well-Being of Individuals

Improving how the Federal Government manages, shares, and secures its data is a priority for both Congress and the Administration.¹⁰⁴ HHS is prioritizing “Leveraging the Power of Data” as one of its six strategic shifts for its *ReImagine HHS* effort.¹⁰⁵ Collectively, these initiatives recognize the significant value of Federal data and the importance of having a coordinated approach to use “data to deliver on mission, serve the public, and steward resources while respecting privacy and confidentiality.”¹⁰⁶ Additionally, HHS’s authorities and influence that shape how an individual’s data are used and protected by other private and public entities are increasingly important in a technology-enriched health and human service delivery system. Failure to modernize HHS data practices will limit the capability of HHS and its OpDivs to fulfill their missions. HHS and its 11 OpDivs and associated programs have made progress in doing so, but challenges remain in how it manages, shares, and secures data.

RELEVANT OPDIVS

All HHS

KEY ELEMENTS

- Expanding HHS's capacity to use data in policy making, program management, and deployment of emerging technologies
- Providing data to HHS partners and promoting the public data access and sharing
- Protecting data from misuse or unlawful disclosure

Expanding HHS’s capacity to use data in policy making, program management, and deployment of emerging technologies

Data play a central role in every HHS program or policy mission.¹⁰⁷ HHS operations depend on the effective collection and use of a large amount of sensitive and important data about individuals, health care providers, key public health assets, and other entities and actors, which are vital to improving the health and welfare of individuals in the Nation. The Department and its programs are increasingly digitally oriented and able to generate, receive, and transmit data in large volumes associated with important programmatic functions.

However, having large amounts of data does not mean that the data can be used efficiently and effectively. HHS faces challenges in how it manages and leverages that data across its programs. Although most OpDivs primarily collect data to administer their own programs, the use of data across programs and OpDivs in remains a challenge. Data are often housed within a single OpDiv (“data silo”) and not easily shared with other parts of HHS even though OpDiv missions often overlap.¹⁰⁸ These silos may limit the capability of HHS to use data for evidence-based decision making and better manage its programs and OpDivs. Data silos may also impede deployment of emerging technologies, such as machine learning, that have enormous potential to improve the efficiency and effectiveness of the Department. When OpDivs and programs cannot access data from each other, they miss opportunities to improve the effectiveness of programs. For example, OIG recommended that CMS provide its Medicare Drug Integrity Contractor with centralized access to Medicare Part C encounter data to enable the contractor to more effectively and proactively identify potential fraud, waste, and abuse.¹⁰⁹ Eliminating or reducing data silos within the Department and increasing appropriate access across programs will be an essential step to improving program

management and evidence-based decision-making, as well as seeding the ground for HHS to benefit from emerging technologies.

Improving data governance to enhance program management

One critical step to improving HHS's capacity to utilize its data is the adoption of a better data governance approach. The need to improve data governance is not unique to the Department and is a priority and a requirement for Federal agencies.¹¹⁰ It is also part of HHS Strategic Plan and the Digital Strategy at HHS.¹¹¹ The Department is taking steps to improve its data governance and more effectively use the data it has. Under the *ReImagine HHS* "Leveraging the Power of Data" initiative and implementation of the Foundations for Evidence-Based Policymaking Act of 2018, the Department is developing an enterprise-wide data sharing strategy to increase combined analysis of disparate data sets to achieve better insights.¹¹² Although progress has been made, the Department's challenge will be to operationalize its plans notwithstanding the continued effect of data silos, restrictions related to the privacy and use of certain data, and legacy technology and data systems that do not easily support data sharing.

HHS must ensure any progress it makes on improving governance of its internally generated data must also apply to data that are generated by external entities but received and managed by the Department. Without quality data that can provide visibility on how its programs are operating, HHS will have limited capabilities to improve its program management. For example, OIG raised concerns about the national Medicaid data set named the Transformed Medicaid Statistical Information System (T-MSIS).¹¹³ CMS made progress by ensuring that all 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands report data and work with States to improve the quality of data submissions. However, concerns still exist about the completeness and reliability of the T-MSIS data. Most recently, OIG found a national review of opioid prescribing in Medicaid using T-MSIS is not yet possible because not all at-risk beneficiaries and providers can be identified. Because existing T-MSIS data do not allow identification of all at-risk beneficiaries and potentially inappropriate providers, data enhancements are needed to enable a national review of opioid prescribing in Medicaid.¹¹⁴ Further, limitations of T-MSIS data impede identification of individual beneficiaries for national opioid analysis.¹¹⁵ Similar data quality and governance challenges exist across other Departmental programs that collect external data from grantees or other organizations.¹¹⁶

Building Advanced Capacity To Use Data

Improving how HHS, its programs, and its employees use data is a critical component of the 2018 HHS's Data Strategy. Better use of data may improve evidence-based policy making, improve internal administrative functions, and support the deployment of emerging technologies, all of which are part of the larger Federal and Departmental strategies to promote efficient and appropriate data use.¹¹⁷

In certain areas, the Department made progress. For example, in response to OIG work related to improving Departmental oversight of grantees, HHS established the Audit Tracking and Analysis System, a Department-wide source of adverse information from grantee audits and facilitated Department-wide information sharing about grantees with past performance issues.¹¹⁸ However, HHS struggles to use and leverage its own data to improve its program management in several areas, such as financial and payment systems information and reporting operations. (See TMC 1.)

HHS's ability to use new technologies that can make the Department more effective and efficient is dependent on how well data can be gathered and curated from multiple OpDivs. Technologies such as machine learning and artificial intelligence must function on top of large data sets. To effectively deploy those tools, HHS will have to rely on data from across its programs, which will require complex technical

coordination among diverse types of data, some of which have technical limitations.¹¹⁹ The Department is making progress by exploring solutions through several recent pilots, demonstrations, and other limited scope projects.¹²⁰ These use cases can help HHS learn how data can be used in a short-time frame and that can serve as quick feedback loop to inform the next pilot or demonstration.

In December 2017, HHS hosted a “Opioid Code-a-Thon” to develop data-driven solutions to combat the opioid epidemic. The Code-a-Thon involved use and analysis of 10 HHS databases from 5 different OpDivs, and more than 70 data sets in total from other Federal agencies, State and local governments, and publicly available data. The competition resulted in the development of new tools to address the opioid crisis.¹²¹ According to HHS, the Code-A-Thon also provided insights into the data it has and what other steps it should take to improve its data governance that might facilitate development of other solutions to the opioid crisis.¹²²

The challenge for HHS will be to go from strategies and pilot tests to fully incorporating lessons learned into the Department’s operations. There are significant barriers—legal, cultural, and resource limitations—that strategies and pilots alone will not resolve. To overcome these barriers and fully harness data to improve the health and welfare of the Nation, the Department will need to undertake multiyear efforts and implement sustained change management across its OpDivs.

Increasing Data Access and Sharing with HHS Partners and the Public

There is an increasing recognition that Federal agency stakeholders¹²³ and the public can also use Federal data assets for the public good.¹²⁴ Much of HHS’s data are publicly available but may not be easy to use or may have other barriers that limit stakeholders’ and the public’s access or use. Those barriers present a challenge to providing increased access of HHS data that could lead to innovation and improvement in health and welfare. HHS also has significant authority, incentives, and influence to change the way data are shared in the health care system, public health, emergency preparedness and response, medical research, and other sectors that are vital to the Nation. Despite that significant influence, many of these sectors do not easily and regularly share data to the detriment of patients, individuals, and the public.

Expanding and Improving Access to HHS Data

Many HHS external stakeholders rely on effective dissemination of data collected by Departmental programs. However, most public access to HHS data does not benefit from contemporary approaches, such as the use of application programming interfaces (APIs). Although data might be available, they may not be well understood or in easily accessed formats. OpDivs are attempting to expand access to these important assets, but progress has been slow. In January 2018, FDA announced a pilot to provide more access to summary portions of the clinical study report for pivotal drug trials establishing the safety and effectiveness of the drug. However, only one drug sponsor agreed to participate in the FDA pilot program.¹²⁵ The CMS *Blue Button 2.0* initiative to improve beneficiaries’ access to their Medicare information through apps has made progress by adding more app developers to the program, but widespread use by beneficiaries has yet to take off.¹²⁶ (See TMC 2 for more information on the challenge of using technology to improve health outcomes for patients.)

In other areas, the Department sustained progress. Through the National Institutes of Health (NIH) initiative *All of Us*, HHS is leading an effort to collect 1 million or more volunteers’ medical history, lifestyle information, and genetic information to support advances in medical research. These data will be shared

with research partners to advance breakthroughs in precision medicine.¹²⁷ To realize the full potential of these data, NIH utilized modern approaches to collect and then disseminate data to its research partners.¹²⁸ At CMS, OIG found that almost all the Open Payments program data reported by CMS met requirements. These data help to promote transparency by making available to the public the financial relationships that providers (physicians and teaching hospitals) have with certain other entities (applicable drug manufacturers and group purchasing organizations).¹²⁹ Additionally, OIG created a data toolkit that stakeholders, like State Medicaid programs, can use to identify their beneficiaries at high risk of opioid misuse and facilitate intervention to prevent harm.¹³⁰ These successes must be replicated across HHS to remove barriers to other HHS program data and allow HHS partners to more effectively use that data.

Making data sharing between health care providers, patients, and payers commonplace

Several OpDivs have authority or influence to shape how data are shared within the industries they regulate, among HHS partners, and with individuals and patients. Most notable is HHS's potential to improve the availability and interoperability of electronic health information. Yet, the health care system and patients have not realized the benefits of modern approaches to improve the appropriate flow of electronic health information. Promoting interoperability is part of the four Secretarial priorities and HHS will need to continue utilizing its significant leverage to expedite progress.¹³¹

Routine and robust health information exchange between providers remains a challenge. Less than half of physicians using an electronic health record (EHR) to electronically send or receive patient health information.¹³² Only 14 percent of physicians electronically send patient health information to behavioral health and long-term-care providers.¹³³ The factors limiting increased interoperability and exchange are numerous and complicated. Several Departmental initiatives depend on improving the interoperability of electronic health information, including the transition to value-based care and payment. (See TMC 2.) Making real progress so that the health care system and patients can benefit from the improved flow of data will take sustained engagement within HHS, with HHS partners, and with external stakeholders such as organizations that set data standards.

Recently, HHS has taken significant steps using regulatory authorities and its influence to improve and potentially standardize the way in which health information can be accessed, used, and exchanged. In 2019, the Office of the National Coordinator for Health Information Technology (ONC) proposed rules directly related to improving interoperability and helping cement data standards and data exchange mechanisms. For example, ONC is incorporating Fast Health Interoperability Resource (FHIR) standards into its health IT certification program. ONC also proposed standardized use of APIs for certified health IT. In a coordinated effort, CMS proposed rules to improve the interoperability of health information at many entities it regulates through the use standard, open APIs.¹³⁴ This was a significant step to improving data exchange. CMS is also piloting novel approaches to provide Medicare claims data to providers through the *Data at the Point of Care* initiative.¹³⁵

Challenges with the flow of electronic health information can also impede patient access to their own data. In 2018, only 51 percent of patients were offered access to their data through online patient portals; of those patients who were offered access, only 30 percent viewed their medical record.¹³⁶ These challenges related to improving the flow of electronic health information to providers and patients may also affect other Departmental coordinated care initiatives. (See TMC 2.) Protecting data from misuse or unlawful disclosure Managing, using, and sharing data must be complemented by appropriately securing data. External threats to the confidentiality, integrity, and availability of HHS-held data are persistent and growing. Similar to data governance and sharing challenges, several aspects of cybersecurity within the Department are siloed within its OpDivs and programs. As a result, deployment of effective cybersecurity can be highly variable across the Department's OpDivs. Further increasing the challenge is the vital nature of many of the Department's programs, operations, and data. Interruption of these programs caused by a cyberattack may have significant negative effects on the health and welfare of the Nation. Outside of the Department's systems, many of the HHS's partners, grantees, and the health care system at large are subject to an increasing amount of cyber threats. Any doubts the public may have about HHS's ability to protect sensitive, personal health data may hinder the full potential of Federal initiatives that seek to leverage technology to create medical treatments of the future.

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Improving HHS's cybersecurity posture

The Department has made progress in improving its overall cybersecurity posture, but certain weaknesses persist and pose challenges. Recent OIG work found that the Department's enterprise-wide information security program was not effective but had improved in some areas.¹³⁷ Other OIG work that examined eight Departmental OpDivs identified vulnerabilities in configuration management, access control, data input control, and software patching.¹³⁸ This work highlights the challenge the Department faces to simultaneously improve the security across OpDivs while also helping provide resources and support so that OpDivs can take action to improve their own cybersecurity. (See TMC 4 for more information about FDA's role regarding cybersecurity of medical devices.)

HHS also faces other data security challenges outside of cyberthreats. For example, HHS has recognized the threat of foreign government action aimed at unduly influencing and capitalizing on medical research programs funded and overseen by the Department. HHS's challenge in responding to these threats is the need to protect these programs while also supporting an open, collaborative research approach that is critical to scientific advances.¹³⁹ The Department has made progress recognizing the threats, studying the potential impact on its programs, and exploring recommendations to improve its security posture.¹⁴⁰

Promoting the security and privacy of the health care system

HHS's responsibilities for ensuring cybersecurity also extend to the health care system. The statistics on the impact and persistence of cyberattacks demonstrate the magnitude of the problem facing HHS and the health care industry. HHS reported that in 2016, \$6.2 billion was lost in the U.S. health care system due to data breaches and that 4 in 5 U.S.-based physicians have experienced some form of cyberattack.¹⁴¹ Despite continued calls for action and additional awareness related to improving the health care system's cybersecurity, health care entities remain prime targets for cyberattacks and health care data are reported to be among the most valuable data for cybercriminals. In addition to data and identity theft, cyberthreats can also pose safety risks by causing system outages needed for patient care or exploiting vulnerabilities in the growing number of connected medical devices and other medical equipment involved in direct patient care. OIG found cybersecurity weakness at Medicaid managed care organizations and several State agencies.¹⁴² Additionally, OIG made recommendations on how FDA could integrate cybersecurity issues into its premarket review process for medical devices.¹⁴³

The Department made some progress to bolster cybersecurity in the health care industry. HHS launched the Health Sector Cybersecurity Coordination Center to increase the amount and frequency of cybersecurity information sharing between the Federal Government and the Healthcare and Public Health (HPH) sector.¹⁴⁴ HHS also worked with industry partners to publish a cybersecurity principles and practices document to educate health care entities on cybersecurity threats and practical steps they could take to mitigate risks.¹⁴⁵ ONC and OCR developed a security risk assessment tool designed to help providers identify where health information might be a risk within their organization.¹⁴⁶ FDA entered into an agreement with DHS to encourage greater coordination between the agencies to identify, address, and mitigate cybersecurity vulnerabilities in medical devices.¹⁴⁷ The Department also proposed rules to protect donations of cybersecurity technology within the health care industry to promote increased adoption of cybersecurity. These developments demonstrate HHS's commitment to working across the health care sector to better prepare for and remediate continuously evolving cyber threats.

The Department also plays a significant role in ensuring the privacy of sensitive individual data, such as personal health information, genetic information, and more. Most notably, OCR established and enforces the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) Privacy Rule's requirements. However, the bulk of the Privacy Rule's requirements were established nearly 20 years ago and may not adequately address modern issues related to individual privacy concerns with health information. For example, an individual's electronic health information that is on the patient's personal electronic device and not in the possession of a HIPAA-covered entity or business associate is not subject to the privacy protections of the HIPAA Privacy Rule. At the same time, individual demand to have easy access to their health information where and when they want it is increasing. This demand creates a challenge for HHS to create and promote better access for patients while reconciling the limits of existing privacy protections. Patient health information that falls outside of the typical framework covered by the Privacy Rule may be at risk of being misused. The Department's challenge is to keep up with changes in the health care industry and with non-traditional health care entities that may impact patient privacy. The Department has made progress by issuing guidance and frequently asked questions related to mobile apps, use of APIs, and working with the Federal Trade Commission to build a web-based tool for developers of health-related mobile apps.

6: Working Across Government To Provide Better Service to HHS Beneficiaries

Big problems require big solutions. HHS faces some of the largest and most complex problems that challenge our Government and the American public. These problems commonly transcend a single HHS program. Often, HHS's mission is only one piece of a larger puzzle, and HHS shares responsibility with multiple entities, including other Federal departments, States, and industry partners. Nearly all HHS programs require strong partnership from multiple entities, within and outside of HHS. This coordination can add complexity to HHS's work but also provides greater gains, marshalling all available resources to improve the Nation's health and well-being.

The potential benefits of effective collaboration are great, both in ensuring program efficiency and providing better service to HHS beneficiaries and the public. HHS and the Administration recognize that complex issues require coordinated solutions and see the Department as a leader in forging these partnerships. The Administration pre-designated HHS as the Quality Service Management Office for grants management across Federal Government in response to its Cross-Agency Priority Goal 5 (Sharing Quality Services).¹⁴⁸ Pending final approval by OMB, HHS will be called upon to provide leadership and best practices to other Federal agencies in the area of grants management. Likewise, HHS responded to the Administration's 2017 directive to reorganize Government¹⁴⁹ to make it more efficient, effective and accountable through its *ReImagine HHS* effort. *ReImagine HHS* outlined several core objectives for the Department, including Optimizing Coordination across HHS. The *ReImagine HHS* initiative also laid out specific shifts in strategy across the Department, several of which highlight the need for greater coordination and information sharing across HHS and with partner agencies and Departments.¹⁵⁰ To achieve these goals and optimize its operations, HHS must prioritize coordination and work to identify opportunities, overcome barriers, and seek accountability and improved outcomes. The need for coordinated responses will only grow in the years to come as health care and other human services become more complex and intertwined with other Federal, State, and private-sector programs. For example, CMS estimates that national health expenditures will grow rapidly during 2020–2027, reaching nearly \$6 trillion by 2027.¹⁵¹ Given that much of this growth is expected to be in the Medicare and Medicaid programs, HHS will continue to lead in managing policy that affects publicly and privately funded health care. Coordination is so

RELEVANT OPDIVS

All HHS

KEY ELEMENTS

- Building and sustaining effective partnerships
- Managing greater integration and efficiency among HHS partners
- Ensuring that HHS and its partners are accountable for ongoing coordination

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integral to success at HHS that it crosses many of the programs discussed in each TMC. Several TMCs highlight the broad and complex nature of HHS's work and the need to consider related issues outside of a single program or mission of a single agency. For example, the quality of care for HHS beneficiaries, described in TMC 3, is affected by not only the availability and quality of health services but also human services such as child care and health care education. Likewise, delivery of quality care through Medicaid depends on accurate and complete data from States, as referenced in TMC 5.

Building on HHS coordination efforts

Recent OIG work reveals the importance of effective and collaborative management within HHS and with HHS partners. In some areas, HHS has focused on collaboration and brought substantial gains, such as its extensive work within the Department and with law enforcement to combat opioid misuse and fraud. In other areas, HHS must work urgently to improve its coordination efforts, such as its management of ORR's UAC Program and programs to promote patient safety.

Confronting the opioid crisis

Fighting the Nation's opioid epidemic is an example of a collaborative and coordinated activity across many Federal, State, and local agencies. HHS has multiple programs and offices involved in fighting the opioid epidemic: CDC sets opioid equivalent dosage guidelines; CMS gives guidance to providers on prescribing opioids; SAMHSA issues grants for OUD treatment; and OIG investigates and excludes providers who illegally prescribe and distribute opioids. (See TMCs 3 and 4 on HHS's efforts to combat the opioid epidemic.) HHS's external partners in the fight include the Department of Justice's (DOJ's) Criminal Division, the Federal Bureau of Investigation (FBI), the Drug Enforcement Administration (DEA), as well as State and local law enforcement agencies.

This is a collaborative effort for which HHS and its partners have enjoyed some success. For the first time in 30 years, the number of opioid-related deaths is decreasing.¹⁵² In 2018, there was a significant decrease in the number of Part D beneficiaries who were prescribed opioids.¹⁵³ These improvements are due in part to better and more available anti-overdose drugs,¹⁵⁴ as well as aggressive law enforcement action to stop bad actors from providing opioids to people addicted to opioids.

A 2019 OIG study found that 36 percent of Medicare Part D beneficiaries in 5 Appalachian-region States received a prescription opioid in 2017; almost 49,000 beneficiaries received high amounts of opioids; and nearly 6,000 beneficiaries were at serious risk of opioid misuse (received extreme amounts of opioids or appeared to be doctor shopping).¹⁵⁵ OIG has worked with HHS, DOJ, and other law enforcement partners to prosecute people who illegally prescribe, dispense, or divert opioids. In October 2018, DOJ, in partnership with OIG, FBI, and DEA, launched the Appalachian Regional Prescription Opioid (ARPO) Strike Force.¹⁵⁶ As part of this Strike Force effort, OIG worked in cooperation with DEA, U.S. Attorneys, the FBI, and State Medicaid Fraud Control Units to investigate prescribing practices of physicians in the Appalachian Region.¹⁵⁷ These investigations have resulted in numerous indictments and arrests of doctors and nurse practitioners who were illegally prescribing opioids. In 2019, enforcement actions targeting the Appalachian Region yielded charges against 60 people, including 53 medical professionals, for allegedly illegally prescribing and distributing more than 32 million opioid pills to over 24,000 people.¹⁵⁸ In addition to taking bad providers off the street, the Strike Force team worked with CDC, DOJ,

and State public health officials to ensure that patients received access to needed medical care and did not experience interruption of care due to the law enforcement operation.

The UAC Program

One of the most visible examples of HHS program activities requiring coordination and information sharing among multiple agencies is ORR's UAC Program. (See TMC 3 for more information.) HHS is not the only Department with responsibility for children served by the UAC Program. These children usually are referred to ORR by the DHS, Customs and Border Patrol, and transported to ORR-funded facilities by Immigration and Customs Enforcement. Much attention is focused on the lack of coordination between HHS and these DHS programs regarding the identification, transfer, case management, and placement of unaccompanied children, particularly unaccompanied children who were separated from their parents at the border.¹⁵⁹ Without strong and collaborative planning, coordination, and execution, HHS faces challenges in effectively providing care and identifying sponsors for these unaccompanied children. HHS must continue to improve its information gathering and communication practices to ensure that separated children are reunited with their families in a timely manner. Enhanced communication and cooperation with DHS, DOJ, and other Government partners are critical

Emergency preparedness and response

Although assistance in responding to natural disasters and other public health emergencies is widely recognized as the responsibility of the Federal Emergency Management Agency (FEMA) within DHS and the Department of Housing and Urban Development (HUD), HHS provides important emergency preparedness and response services. (See TMC 4 for more on HHS's emergency preparedness challenges.) It is the lead Federal department responsible for providing medical support and coordination during public health emergencies, such as disease outbreaks.¹⁶⁰ Three OpDivs share this responsibility: Office of the Assistant Secretary for Preparedness and Response (ASPR), CDC, and CMS. ASPR coordinates HHS's response to public health emergencies with other Federal agencies, such as FEMA.¹⁶¹ ASPR also coordinates and oversees Healthcare Coalitions, which are groups of providers and public health entities that work together to prepare for, respond to, and recover from emergencies and maintains the Strategic National Stockpile for vaccines, medicines, and supplies.¹⁶² CDC conducts research about emergencies, provides critical guidance to providers, Government, and the public.¹⁶³ CMS oversees health care facilities participating in Medicare and Medicaid by requiring a set of minimum health and safety standards, including recently updated standards for emergency preparedness.^{164, 165}

OIG studies have repeatedly identified the need for improved coordination in emergency preparedness and response, both within and outside the Department. A 2019 OIG report determined whether HHS's response efforts to the 2014 Ebola outbreak were effective and efficient and found that HHS (1) had no strategic framework in place to coordinate global health security at the international or departmental levels before the Ebola outbreak, (2) was not prepared to deploy the resources needed for such a large-scale international response, and (3) did not have in place internal or external communication channels for responding to an international public health emergency.¹⁶⁶ Similarly, a 2018 OIG report assessed hospital preparedness for infectious diseases in the years since the 2014 Ebola outbreak, and found that coordination between ASPR, CDC, and CMS was sometimes lacking.¹⁶⁷ Hospital administrators reported that their staff had difficulty interpreting guidance from multiple government entities and understanding their role in serving the public during a crisis.

Patient safety

As described in TMC 3, OIG has conducted extensive work regarding protecting the safety of patients undergoing medical care, including a 2008–2018 series of reports that found alarming rates of patient harm as the result of medical care.¹⁶⁸ HHS’s responsibility for making health care safe and avoiding adverse events lies with CMS in overseeing facility compliance with health care standards and with the Agency for Healthcare Research and Quality (AHRQ) in conducting patient safety research and issuing guidance to providers. In these reports, OIG recommended that AHRQ and CMS work more closely together, and work with providers, to identify patient harm and develop technical assistance for the facilities and clinicians providing care. In response, AHRQ and CMS took action together, and with other HHS operating divisions, to develop new quality and safety measures and revise guidance to providers.

Federal Marketplace

Another example of a lack of coordination within HHS and with multiple stakeholders occurred during the roll-out of the Federal Marketplace under the *Patient Protection and Affordable Care Act of 2010*.¹⁶⁹ In a case study released in 2016, OIG found poor coordination and communication between the HHS Office of the Secretary (OS) and CMS contributed to the failed launch of the Federal Marketplace website HealthCare.gov.¹⁷⁰ The website project was transferred early in its development from a division within OS to CMS, and the transfer occurred without proper planning and coordination or a clear handoff of leadership. As the project progressed, CMS officials failed to adequately convey to OS that they were encountering deep and widespread problems with the policy, technology, and contracts associated with the website build.

As a result, the Department did not intervene and continued to plan for a website release date and functionality that CMS could not effectively meet. The website could not accommodate the volume of traffic it received and was plagued by performance problems in the first months of its operation. The OIG report identified lessons learned from this project and core management principles to apply to all Government programs, technological or otherwise: clear leadership; effective communication; willingness to adjust; and accountability for performance and meeting objectives. Attention to these areas helped CMS recover from the failed launch, develop a functioning system, and salvage the first open enrollment period. Better collaboration allowed CMS to leverage Departmental expertise and other resources, identify and address problems more quickly, make informed decisions, and provide clearer direction to the public. Going forward, CMS will continue to need close coordination with other Federal agencies and with States to ensure that marketplaces operate in accordance with requirements and meet emerging challenges.

Indian Health Service

OIG found similar themes in a 2019 case study of the IHS closure and reopening of the Rosebud Hospital Emergency Department (ED), an IHS-run facility in South Dakota.¹⁷¹ IHS has many partners in providing health care to AI/AN communities, including CMS (requiring that hospitals maintain basic standards), the AI/AN tribes, and the surrounding (often rural) communities. (See TMC 3 for more information on quality standards.) CMS found Rosebud Hospital was not in compliance with its ED standards, and CMS planned to terminate the hospital’s certification to receive Medicare and Medicaid reimbursements. The hospital was unable to bring its ED operations back into compliance, so IHS closed the ED temporarily. The closure proved highly problematic for other hospitals in the area, in that IHS did not adequately notify them of

the closure, and the hospitals were ill-prepared to receive Rosebud Hospital's emergency patients. After failed attempts to resolve the issues, IHS entered into a Systems Improvement Agreement with CMS and sought additional resources and support from the Department, including the Health Resources and Services Administration (HRSA). The Rosebud ED reopened following these collaborative efforts but has continued to struggle in maintaining compliance with CMS standards. The success of rural IHS services will depend on ongoing collaboration within and outside HHS, including Federal departments and agencies responsible for AI/AN programs, such as the Bureau of Indian Affairs in the Department of the Interior. A 2017 report by the Council of the Inspectors General on Integrity and Efficiency outlined management deficiencies that Inspectors General from HHS, Interior, and other Departments found in AI/AN programs, some of which were similar to Rosebud's problems with staffing and infrastructure.¹⁷² (See TMC 3 for more on concerns regarding quality of care at IHS facilities.)

Improving coordination in ongoing and future multi-agency efforts

HHS cannot accomplish its mission to enhance and protect the health and well-being of all Americans without strong partnerships and improved coordination. As HHS continues to find solutions to the Department's many challenges, it should draw on its prior accomplishments and failures in coordinating complex, multi-agency projects and develop a roadmap for success. In developing this roadmap, HHS should focus on three key areas: (1) sustaining effective partnerships, (2) managing and planning for greater integration and efficiency among its partners, and (3) ensuring that all partners are accountable for ongoing coordination and information sharing.

To fully assess these areas, HHS must address some difficult questions: What information does HHS need from its partners? How do all entities develop a common plan and communicate effectively? What barriers to collaboration exist, including competing interests and practical issues such as IT compatibility? Which agency is responsible for which part, and how do agencies hold themselves and each other accountable?

After developing this path, HHS should aspire to leverage effective coordination to address problems and reach for new, ambitious goals, such as raising standards for health and well-being, improving holistic outcomes for beneficiaries served by multiple programs, and developing more effective preventive care and other health management programs. HHS recognizes the need for coordination and higher shared goals. Such goals are achievable and would allow HHS to best serve its mission and the American public.

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Nonemergency Medical Transportation:

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