

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



2021
TOP MANAGEMENT AND PERFORMANCE
**CHALLENGES
FACING
HHS**

CHALLENGES FACING HHS

Introduction

The *2021 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) that the Department faces 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. These top challenges reflect overarching issues that affect multiple HHS programs and responsibilities. These are not the only challenges that confront HHS. OIG reports are a key resource that highlight specific opportunities to improve HHS programs and operations.

HHS is responsible for \$2.8 trillion in budgetary resources and its programs impact the lives of virtually all Americans. To identify the six TMCs, we integrated OIG's oversight, enforcement, data analytics, and risk analysis work. For each TMC, we describe the dimensions of the challenge, highlight the progress the Department has made in addressing the challenge, and identify what remains to be done.

Throughout this document, we highlight the unprecedented challenges the Department faces because of coronavirus disease 2019 (COVID-19). As the lead Federal agency for medical support and coordination during public health emergencies, HHS has numerous and significant responsibilities in providing assistance as the United States confronts the COVID-19 pandemic. HHS's responsibilities include working with Federal, State, Tribal, local, and international governments to respond effectively to the pandemic; supporting the development and distribution of vaccines, treatments, and research on COVID-19; assisting the health care system by providing flexibility, resources, and funding; ensuring the safety of the health care workforce; and protecting the health and well-being of the public. Challenges related to the Department's COVID-19 response are primarily addressed in TMC 1 on public health. However, the COVID-19 response affects nearly every aspect of Department operations, and challenges related to it are also addressed in other TMCs.

Management and performance challenges are inherently crosscutting. The TMCs reflect how multiple HHS staff divisions (StaffDivs) and operating divisions (OpDivs) are addressing these pressing issues. For example, the challenge of financial integrity highlighted in TMC 2 has natural intersections with the challenge of delivering value, quality, and improved outcomes in Medicare and Medicaid, which is the subject of TMC 3. Given that challenges cross internal HHS boundaries and externally with Federal and State agencies, coordination among HHS agencies and across the government sector is integral to addressing these challenges.

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

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

CHALLENGES FACING HHS

1 Safeguarding Public Health

4 Protecting the Health and Safety of HHS Beneficiaries

2 Ensuring the Financial Integrity of HHS Programs

5 Harnessing and Protecting Data to Improve the Health and Well-Being of Individuals

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

6 Improving Collaboration to Better Serve Our Nation

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Acronyms

ACF	Administration for Children and Families	HHS	US Department of Health and Human Services
ACO	Accountable Care Organization	IHS	Indian Health Service
ADHD	Attention Deficit Hyperactivity Disorder	IT	Information Technology
AHRQ	Agency for Healthcare Research and Quality	LCA	Least Costly Alternative
AMP	Average Manufacturer Price	MA	Medicare Advantage
API	Application Programming Interface	MAO	Medicare Advantage Organization
APTC	Advance Premium Tax Credit	MCO	Medicaid Managed Care Organization
ASPR	Office of the Assistant Secretary for Preparedness and Response	NIH	National Institutes of Health
CARES	Coronavirus Aid, Relief, and Economic Security Act	OCR	Office for Civil Rights
CCDF	Child Care and Development Fund	OGA	Office of Global Affairs
CDC	Centers for Disease Control and Prevention	OIG	Office of Inspector General
CHIP	Children’s Health Insurance Program	OMB	Office of Management and Budget
CIO	Chief Information Officer	ONC	Office of the National Coordinator for Health Information Technology
CMS	Centers for Medicare & Medicaid Services	ORR	Office of Refugee Resettlement
DHS	Department of Homeland Security	OTP	Opioid Treatment Program
DME	Durable Medical Equipment	ODD	Opioid Use Disorder
DMI	Data Modernization Initiative	PCS	Personal Care Services
DOJ	Department of Justice	PDMP	Prescription Drug Monitoring Program
EHR	Electronic Health Record	PERM	Payment Error Rate Measurement
EID	Emerging Infectious Diseases	PPE	Personal Protective Equipment
EUA	Emergency Use Authorization	PRF	Provider Relief Fund
FDA	Food and Drug Administration	REMS	Risk Evaluation and Mitigation Strategies
FFS	Fee-For-Service	SAMHSA	Substance Abuse and Mental Health Services Administration
FPS	Fraud Prevention System	SNF	Skilled Nursing Facility
FSIS	Food Safety Inspection Service	TANF	Temporary Assistance for Needy Families
FY	Fiscal Year	T-MSIS	Transformed Medicaid Statistical Information System
GAO	Government Accountability Office	UC	Unaccompanied Children
HC3	Health Sector Cybersecurity Coordination Center		
HHS	Department of Health and Human Services		
HIPAA	<i>Health Insurance Portability and Accountability Act of 1996</i>		
HRSA	Health Resources and Services Administration		

1: Safeguarding Public Health

HHS's core mission is to enhance the health and well-being of all Americans. Pandemic response and recovery efforts have exacerbated the Department's challenge to safeguard public health. With more than 730,000 deaths attributable to COVID-19 and more than 45 million cases of the disease in the United States as of October 28, 2021,¹ HHS must act vigilantly to mitigate the loss of life and negative short- and long-term health consequences associated with COVID-19 while effectively operating a range of programs and services that are essential to protecting individuals and communities. This work includes effectively preparing for future emergencies while advancing response capabilities, ensuring that products regulated by the Food and Drug Administration (FDA) are safe and effective, and combating the opioid epidemic while helping ensure access to treatment. To operate effective public health programs, the Department must ensure that its OpDivs and StaffDivs coordinate efforts internally as well as with partners at all levels of government and other stakeholders. (See TMC 6 for more information on the Department's challenge of coordinating with internal and external partners.)

KEY TAKEAWAYS

- I. Relevant Agencies: All HHS
- II. Elements of the Challenge:
 - Strengthening emergency preparedness and response capabilities
 - Providing adequate oversight of FDA-regulated products
 - Tackling the opioid epidemic while ensuring access to treatment

Strengthening emergency preparedness and response capabilities

Public health emergencies can severely strain public health and medical infrastructure and lead to serious illness and loss of life, often with greater impacts on the most vulnerable populations, such as nursing home residents. In 2020, two in five Medicare beneficiaries in nursing homes were diagnosed either with COVID-19 or likely COVID-19 and almost 1,000 more beneficiaries died per day in April 2020 than in April 2019.² The negative health impacts of emergencies can also exacerbate racial and ethnic health disparities. Black, Hispanic, and Asian Medicare beneficiaries in nursing homes were more likely to have had COVID-19 or likely COVID-19 compared to White beneficiaries,³ and HHS has identified pronounced racial and ethnic disparities in COVID-19 infections, hospitalizations, death rates, and vaccination rates that extend to the broader population.⁴ Provisional estimates from the Centers for Disease Control and Prevention (CDC) show a decline in U.S. life expectancy in 2020, with COVID-19 having had the greatest effect on the decline. CDC data also show an increase in racial and ethnic disparities pertaining to life expectancy in 2020.⁵ HHS programs must address racial, socioeconomic, geographic, and other types of disparities, and the effects that such disparities have on public health.

HHS has a leading role in preparing for, responding to, and recovering from the adverse health effects of public health emergencies including infectious disease outbreaks, natural disasters, and chemical, biological, radiological, and nuclear events. HHS is uniquely positioned to provide guidance, funding, and support to assist States and communities throughout the United States so that they can effectively and equitably plan for and respond to emergencies, as well as support sustained recovery efforts. The experience of the past year underscores that HHS must be prepared to address multiple public health emergencies occurring simultaneously with different response

needs and challenges, such as hurricanes and wildfires that have occurred during the COVID-19 public health emergency. A key challenge is to have adequate planning and mechanisms in place prior to a public health emergency to efficiently and rapidly deploy assets and provide relief to those in need of HHS resources and assistance during the emergency. This includes planning agency controls and strategies to mitigate disaster preparedness and response risk.⁶ In addition, an effective emergency response requires a prepared public health workforce. The *American Rescue Plan Act of 2021* provided HHS with additional funds, including \$7.6 billion to establish, expand, and sustain the public health workforce.⁷ HHS must ensure that the public health workforce is ready to address current and future emergencies.

For infectious disease emergencies, HHS plays a critical role in identifying, acquiring, developing, distributing, and administering medical countermeasures (e.g., vaccines, therapeutics, and diagnostics). Among HHS's operating divisions, the CDC is responsible for responding to health threats and providing critical scientific information to protect Americans. The Biomedical Advanced Research and Development Authority within the Office of the Assistant Secretary for Preparedness and Response (ASPR) promotes the development and acquisition of medical countermeasures, including supporting the transition of medical countermeasures from research through advanced development toward consideration for approval by FDA and inclusion in the Strategic National Stockpile. The National Institutes of Health (NIH) is responsible for research related to the development of medical countermeasures including vaccines. FDA is responsible for regulating the safety and effectiveness of such medical countermeasures and ensuring the safety and availability of the U.S. blood supply and tissue donations. FDA may use its Emergency Use Authorization (EUA) authority to facilitate the availability of medical countermeasures in public health emergencies, as it did for COVID-19 diagnostics, vaccines, and therapeutics. The Office of Global Affairs (OGA) is responsible for leading international engagements to support both preparedness for and responses to public health emergencies.

Existing OIG work on prior outbreaks of communicable disease illustrates the importance of ongoing HHS readiness to detect, assess, and respond to new disease outbreaks and other emergencies. For instance, a 2019 OIG report about HHS's response to the 2014 Ebola outbreak recommended that HHS develop department-wide objectives and a strategic framework for responding to international public health emergencies.⁸ HHS concurred with the recommendations in the report and indicated that it is continuing to coordinate these efforts and will provide additional updates.

In addition to coordinating emergency planning and response efforts effectively with its program offices, HHS works with States and localities to facilitate planning and preparedness to address a wide range of health and human service needs including the management and distribution of medical supplies, establishment of alternative care sites, and distribution of vaccines and antiviral drugs. (See TMC 6.) In an OIG survey of hospitals conducted in March 2021, hospitals reported that operating in "survival mode" for an extended period had created challenges with health care delivery, staffing, vaccinations, supplies, and finances. Hospitals found that the emergency exacerbated longstanding challenges in health care delivery, access, and health outcomes.⁹ Prior OIG work identified opportunities for health care facilities to improve emergency preparedness and response planning during infectious disease outbreaks and disasters.¹⁰ HHS should continue to support the development and maturation of health care coalitions and other entities in their efforts to plan for and coordinate emergency response among diverse entities such as hospitals, public health agencies,¹¹ emergency medical services, and emergency management.¹²

As the COVID-19 emergency continues to evolve and new data provide a deeper understanding of topics such as transmission, testing, therapeutics, vaccines, vaccination programs, public health communication, and short- and long-term health effects, HHS faces the challenge of ensuring that it is a continuously learning organization. HHS

must rely on up-to-date information to sustain and strengthen its emergency response and provide effective public health guidance to the American public.

Ensuring FDA-regulated products are safe and effective

FDA is charged with ensuring the safety, effectiveness, and security of human and animal drugs, biological products, and medical devices; ensuring the safety of the nation's food supply, cosmetics, and products that emit radiation; and regulating tobacco products. These functions are critical to ensuring that Americans can trust the expansive array of products in FDA's purview.¹³ FDA has the added challenge of facilitating emergency response efforts related to the current COVID-19 emergency, including reviewing scientific evidence and issuing emergency use authorizations, and approvals, for COVID-19 vaccines and other medical products, providing surveillance of medical product safety and effectiveness, and updating guidance based on emerging science.¹⁴ The American public relies on FDA to expeditiously assess new medical products or new uses of legally marketed medical products (such as drugs or vaccines) that treat or offer protection from negative health effects associated with COVID-19 without sacrificing assurances of safety and efficacy.

Drug, biologic, and medical device safety

FDA's responsibility to help ensure the safety and effectiveness of medical products begins before approval and continues after the product is marketed. This includes inspections of manufacturing facilities; reviewing drugs, devices, and biologics for safety, effectiveness and quality; authorizing the use of investigational medical products; and conducting post-market surveillance. The public relies on FDA to be expeditious in evaluating products and thoughtful in its decisions and processes regarding approval for marketing in the United States. OIG is currently assessing how FDA implements its accelerated approval pathway.¹⁵

FDA's task of assessing products has become more difficult as manufacturing processes and products have evolved. The drug, biologic, and medical device supply chain is becoming increasingly complex, and many of the products used in the United States are manufactured overseas or are dependent on raw materials that are produced overseas. For all FDA-regulated drugs, 74 percent of the manufacturing facilities producing active pharmaceutical ingredients and 54 percent of the manufacturing facilities producing finished dosage forms of human drugs were located outside of the United States in 2020¹⁶ In response to challenges with its foreign drug inspection process, FDA in May 2017 began implementing major programmatic changes to enhance its ability to protect public health. An OIG audit will assess whether programmatic changes improved FDA's foreign drug inspection process.¹⁷

Accurate drug tracing information is critical to identifying an illegitimate drug and removing it from the supply chain. If potentially harmful drugs enter the drug supply chain, investigators from FDA, State(s), and elsewhere need complete information about the trading partners that bought and sold the drug and about the drug's physical movement through the supply chain. An OIG evaluation found that tracing information could not be used to identify the physical movement through the supply chain for about half of selected drugs. FDA agreed with OIG's recommendations to take action to help protect patients from the effects of dangerous, ineffective, and illegitimate drugs by, for example, ensuring that trading partners in the drug supply chain are aware of Federal requirements and guidance and by seeking legislative authority to require information about a drug's complete physical path through the supply chain.¹⁸

The rapid evolution of science and technology presents new concerns for FDA to address via its oversight role. Managing cybersecurity risks associated with networked devices is increasingly difficult as more

medical devices use internet connectivity. Networked medical devices approved by FDA can be susceptible to cybersecurity threats such as ransomware and unauthorized remote access if the devices lack adequate security controls.¹⁹ These networked devices include infusion pumps, diagnostic imaging, and pacemakers that are commonly used in hospital settings and at home.

In 2021, OIG released a report highlighting the lack of oversight of medical devices by State surveyors and accrediting organizations in Medicare-participating hospitals, creating vulnerabilities to cyberattacks for patients requiring medical devices.²⁰ Additionally, in 2018 OIG released two reports assessing FDA's oversight of premarket and post-market cybersecurity risks to medical devices.²¹ An underlying issue identified in both reports was the opportunity for FDA to take further action in addressing cybersecurity threats to reduce risks to patients and the health care industry. FDA has made administrative changes to improve its premarket and post-market processes, but FDA should continue to take steps to enhance its ability to receive relevant information as well as securely share it with key stakeholders. (See TMC 5 on data for additional actions FDA has taken related to cybersecurity.)

Food safety

Foodborne illnesses are a largely preventable threat to public health. An estimated 1 in 6 Americans gets sick, 128,000 are hospitalized, and 3,000 die from contaminated foods each year.²² FDA has the complex responsibility of overseeing facilities that are responsible for producing foods that are safe. The American public relies on FDA, which works in collaboration with other Federal agencies and State, local, and territorial partners to help ensure the safety of both human and animal food.²³

FDA's current approach to food safety includes goals to "enhance traceability, improve predictive analytics, respond more rapidly to outbreaks, address new business models, reduce the contamination of food, and foster the development of stronger food safety cultures."²⁴ FDA must continue to modernize the food safety system and respond effectively and efficiently when issues are identified. FDA should conduct risk-based inspections of domestic and foreign food facilities within the timeframes required by the *Food Safety Modernization Act*, 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.²⁵ FDA has made organizational changes with the goal of improving incident response through, for example, its Coordinated Outbreak Response and Evaluation Network and should continue to improve the timeliness and effectiveness of its processes, such as food recalls, to optimize its ability to protect the public from outbreaks of foodborne illnesses.

Tobacco

Tobacco use is the leading cause of preventable death and disease in the United States.²⁶ FDA regulates the manufacturing, marketing, and distribution of tobacco products to protect public health and has made a commitment to reduce harm from tobacco products, particularly among youth. Although FDA and the CDC's 2020 National Youth Tobacco Survey showed fewer middle and high school-aged tobacco product users in 2020 compared to the previous year, roughly 16 percent of students used a tobacco product, including almost 24 percent of high school and 7 percent of middle school students. In 2020, e-cigarettes were the most used tobacco product among both middle and high school students.²⁷ FDA must continue efforts to reduce harm amid increasing concerns surrounding the use and detrimental health effects of electronic nicotine delivery systems such as e-cigarettes and vape pens.

Working with the CDC, FDA faces the challenge of better understanding the science of tobacco products and the most effective use of its authorities to regulate their manufacturing, marketing, and sale, including premarket reviews and health warnings on packaging and advertisements. OIG is assessing FDA's Tobacco Retailer Compliance Check Inspection program under which FDA contractors (generally States) carry out undercover-buy inspections of tobacco retailers to ensure they are complying with restrictions on sales to minors.²⁸

Combating the opioid epidemic and helping to ensure access to treatment

From 2018 to 2019, the number of drug overdose deaths increased by nearly 5 percent, and since 1999 the number has quadrupled. In 2019, opioids were involved in more than 70 percent of the more than 70,500 drug overdose deaths.²⁹ The pandemic and related stressors are thought to put people at risk for substance use disorder,³⁰ and substance use disorder puts adults at high risk for severe illness from COVID-19.³¹ Provisional data from the CDC show an approximately 30 percent increase in overdose deaths from February 2020 to February 2021, with more than 95,000 overdose deaths reported in that period.³² In early FY 2022, HHS released an overdose prevention strategy.³³

Current Federal priorities for drug policy include expanding access to evidence-based treatment, advancing racial equity in the approach to drug policy, and reducing the supply of illicit substances.³⁴ The Department should continue to use the tools available across its operating divisions to address the ongoing opioid epidemic while being mindful of patients' needs to access appropriate pain management, which may include the use of opioid analgesics.

FDA has key roles in ensuring the safe use of opioids. The agency approves new drugs before they are marketed in the United States, assesses the benefits and risks of each new drug,³⁵ and monitors the safety of marketed drugs as new information becomes available. FDA supports the treatment of opioid use disorders (OUDs) with FDA-approved drugs—i.e., buprenorphine, methadone, and naltrexone—as well as the development of additional therapies to treat OUDs, and employs tools to mitigate risks associated with approved drugs, including updating product labeling and developing Risk Evaluation and Mitigation Strategies (REMS) as needed.³⁶ An OIG evaluation found that data quality issues made it challenging for FDA to determine whether two REMS for opioid analgesics had been effective and that REMS may not be well-suited to quickly address the opioid crisis.³⁷ FDA must work to ensure that strategies it uses to mitigate the misuse and abuse of opioids achieve their intended impact.

The opioid crisis is partially fueled by opioids prescribed by licensed medical professionals, dispensed by licensed pharmacies, and paid for by Federal funds. Prescription opioids were involved in more than a quarter of all opioid overdose deaths in 2019.³⁸ The COVID-19 pandemic has heightened concern about opioid use and access to treatment. The pandemic has put people with OUD at particular risk, as they are at higher risk of developing COVID-19 and are more likely to experience hospitalizations or death from the illness.³⁹ More than 43,000 Medicare Part D beneficiaries had an opioid overdose—from prescription opioids, illicit opioids, or both—during 2020. Overall, nearly 1 in 4 Medicare Part D beneficiaries received opioids during 2020.⁴⁰ The number of beneficiaries who received drugs through Part D to treat OUD increased, but at a slower rate in 2020 than in prior years. Unlike in other recent years, there was no growth in the number of beneficiaries receiving prescriptions through Part D for the opioid overdose-reversal drug naloxone. These slower growth rates add to ongoing concerns about access to medications to treat OUD and naloxone. Ensuring this access is particularly important as we do not yet know the full extent to which the stressors of the COVID-19 pandemic may have increased the need for these drugs.

The Indian Health Service (IHS) also has an important role to play in preventing and detecting opioid misuse and abuse. Data from an OIG evaluation show that some patients received high amounts of opioids from IHS-run

pharmacies, and IHS has taken steps to ensure appropriate opioid use among its patients.⁴¹ At the same time, the agency could improve the efficiency of its opioid monitoring systems by further automating its system for electronic health records (EHRs). Additionally, IHS officials reported challenges in tracking patient care received outside IHS and in using State-run prescription drug monitoring programs (PDMPs), which are electronic databases that collect and disseminate controlled substance prescription information. Both factors can limit the abilities of IHS staff to monitor opioid use. IHS should assess the costs and benefits of updating the IHS EHR system with tools to support more automated monitoring, and request support from States and Federal partners to address challenges with State-run PDMPs.⁴²

Ensuring access to effective OUD treatment, especially in regions with greater risk for opioid misuse and overdose, remains crucial to combating the opioid epidemic.⁴³ People suffering from an OUD are at risk for withdrawal and relapse, and without effective treatment may seek out illicit opioids such as heroin. However, fewer than 20 percent of the 2.1 million people with OUDs received treatment in 2018.⁴⁴ Measures to address COVID-19 have further challenged access to treatment. In a survey of 143 opioid treatment programs (OTPs), OIG identified various challenges OTPs encountered during the COVID-19 pandemic including maintaining pre-pandemic service levels, managing impacts on facility operations, and maintaining patient participation in opioid treatment program activities, among others.⁴⁵

The *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act* requires Medicare to cover certain treatment services provided by opioid treatment programs including methadone. As part of the effort to ensure access to effective treatment, HHS needs data to monitor access and unmet needs. An OIG evaluation identified opportunities to enhance information about access and the need for medication to treat OUD through the Buprenorphine Waiver Program, one of the Substance Abuse and Mental Health Services Administration's (SAMHSA's) key initiatives for combating the opioid crisis by expanding treatment services.⁴⁶ In spring 2021, HHS released new buprenorphine practice guidelines designed to expand access to evidence-based treatment for OUD.⁴⁷

In addition, HHS must ensure that funding to address the opioid epidemic is efficiently and effectively spent for its intended purpose. An OIG audit found that 67 of 100 Health Resources and Services Administration (HRSA) health centers did not use grant funds that were intended to expand access to mental health and SUD services focusing on the treatment, prevention, and awareness of OUD consistent with Federal requirements and grant terms.⁴⁸ HHS's OpDivs must work with awardees and sub-awardees to ensure behavioral health grant dollars are used in accordance with Federal requirements and consistent with the funding opportunity.

2: Ensuring the Financial Integrity of HHS Programs

HHS is the largest civilian agency in the Federal government, with \$2.8 trillion in budgetary resources.⁴⁹ HHS's Medicare program is the Nation's largest health insurer by expenditures and handles more than 1 billion claims per year. Medicaid is the largest health insurer in terms of lives covered, with 81 million Medicaid beneficiaries and Children's Health Insurance Program (CHIP) enrolled individuals.⁵⁰ Medicare and Medicaid are the Department's largest programs; funding for these programs (including State funding) represents 41 cents of every dollar spent on health care annually in the United States.⁵¹ CMS's Office of the Actuary estimates that Medicare expenditures totaled \$915.4 billion and Medicaid expenditures totaled \$682.7 billion in 2020.^{52,53} Almost 140 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.⁵⁴ CMS bears the responsibility at HHS for administering these programs. As many providers faced fiscal uncertainty due to COVID-19, CMS took steps to provide increased flexibility and advance payments to mitigate the financial effects of the pandemic.

KEY TAKEAWAYS

- I. Relevant Agency: All HHS
- II. Elements of the Challenge:
 - Controlling costs by ensuring prudent payments for goods and services
 - Reducing improper payments
 - Combating fraud, waste, and abuse
 - Monitoring and reporting on the integrity of HHS programs

HHS is also the largest grantmaking and second largest contracting agency in the Federal government. In fiscal year (FY) 2020, HHS awarded \$244.7 billion in grants (excluding CMS grants) and \$160.7 billion in contracts.^{55,56} 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 full 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. This is a growing challenge due to looming financial shortfalls in the Medicare program,^{57, 58} the expansion of eligibility for Medicaid services, and the COVID-19 funds that HHS is responsible for distributing and overseeing via grants and other mechanisms. HHS must manage the efficient and effective use of funds internally and oversee the use of Federal funds by thousands of external funding recipients.

Controlling costs by ensuring prudent payments for goods and services

Whether HHS is paying for medical services, prescription drugs, or human service programs, managing what the Department pays and recognizing and remedying problematic payment policies are critical to controlling costs.

Medicare

Medicare should consider whether payment policies, which are generally set by statute by Congress, are continuing to deliver the intended value. For example, some current policies result in Medicare and beneficiaries paying more for care provided in certain settings than for the same care provided in other settings. An OIG report found that 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).⁵⁹ Likewise, in some situations Medicare pays hospitals different amounts for the same care depending on whether the hospital admits beneficiaries as inpatients or treats them as outpatients.

Additionally, Medicare must take steps to mitigate program integrity risks related to payment and coverage policies. For example, OIG found that hospitals increasingly billed for inpatient stays under Medicare severity diagnosis related groups at the highest severity level—the most expensive level—from FY 2014 through FY 2019. These are indications that hospitals may be engaging in inappropriate billing practices such as upcoding.⁶⁰

Prescription drug programs

In July 2021, President Biden issued an Executive Order aimed at combatting high prescription drug prices.⁶¹ Increased drug costs may limit patients' ability to afford needed prescription drugs, in some cases causing patients to skip or split medication doses or forgo purchasing medications altogether. HHS programs accounted for 38 percent (\$140 billion) of total U.S. prescription drug expenditures in 2019.⁶² The Medicare Prescription Drug program had net costs of \$83.8 billion for FY 2020.⁶³ Vulnerabilities exist in HHS's payment strategies for prescription drugs (including biologics).

The way that Medicare and Medicaid pay and reimburse for drugs can impact prescription drug prices and costs for programs and their beneficiaries. 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.⁶⁴ OIG found that CMS included prices for higher cost versions of drugs that are not covered under Medicare Part B when setting Part B payment amounts. Section 405 of the *Coronavirus Aid, Relief, and Economic Security Act (CARES)* required CMS to make the changes to Part B payment policy recommended by OIG. This lowered payment amounts for some Part B drugs as of July 1, 2021. OIG also found increases in costs for certain prostate cancer drugs reimbursed under Part B that had been subject to the least costly alternative (LCA) policy after that policy was rescinded. LCA bases the payment amount for a group of clinically comparable products on that of the least costly product. OIG found that Medicare expenditures for certain prostate cancer drugs would have been reduced by \$33.3 million over 1 year (from \$264.6 million to \$231.3 million) under the LCA policy.⁶⁵ Furthermore, 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 reimbursements for these drugs, leading to greater overall Part D spending and higher beneficiary out-of-pocket costs.⁶⁶

OIG also found that Medicaid could save hundreds of millions of dollars by excluding authorized generic drug transactions to secondary manufacturers from brand-name drugs' average manufacturer price (AMP) calculations. Estimated to save \$3.2 billion over 10 years, Section 1603 of the *Continuing Appropriations Act, 2020*, and *Health Extenders Act of 2019* amended section 1927(k)(1)(C) of the Act to exclude generic drug transactions to secondary manufacturers in the brand-name drug's AMP calculations.⁶⁷ Additionally, manufacturers' use of reasonable assumptions when calculating AMPs and best prices—a practice OIG's work has established as common—represents a vulnerability in drug pricing for thousands of drugs used in the Medicaid program.⁶⁸ 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.

Preventing and reducing improper payments

An improper payment is any payment that does not meet statutory, contractual, administrative, or other legally applicable requirements, and that may be an overpayment or an underpayment.⁶⁹ Reducing improper payments—such as payments to ineligible recipients or duplicate payments—is critical to safeguarding Federal funds. 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 65 percent, or \$134.2 billion, of all governmentwide estimated improper payments reported in FY 2020.⁷⁰ Furthermore, insufficient HHS oversight of grant programs and contracts poses risks of significant improper payments.

Medicare

Original Medicare fee-for-service (FFS), Medicare Part C (also known as Medicare Advantage (MA)), and Medicare Part D (also known as Medicare Prescription Drug) accounted for \$42.9 billion, or 32 percent, of the estimated improper payments that HHS reported in FY 2020.⁷¹ Notably, the Medicare FFS improper payment rate estimate during the past 3 years has decreased from 8.1 percent (\$31.6 billion) in FY 2018 to 7.3 percent (\$28.9 billion) in FY 2019, and to 6.3 percent (\$25.7 billion) in FY 2020.⁷² This represents positive momentum upon which the Department and CMS can build. However, some types of providers and suppliers pose heightened risks to the financial security of Medicare. For instance, OIG and CMS have identified especially high rates of improper payments for home health, hospice, and SNF care; durable medical equipment, Prosthetics, Orthotics, & Supplies (DMEPOS); chiropractic services; and certain hospital services.⁷³ CMS has taken corrective actions for Medicare FFS by focusing on specific service areas with high improper payment rates. The reduction in the improper payment rate was driven primarily by reductions in improper payments for home health, Part B, and DME claims. However, 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. Furthermore, CMS should ensure that it is prepared to detect and prevent improper payments in burgeoning areas, such as telemedicine and genetic testing.

Moreover, improper payments to Medicare Advantage Organizations (MAOs) pose a significant vulnerability for CMS and cost taxpayers billions of dollars. In FY 2020, the improper payment rate for the MA program (Part C) was 6.8 percent, for a total of \$16.3 billion in improper payments.⁷⁴ Unlike in FFS, through which CMS pays providers directly for each covered service received by a beneficiary, CMS under managed care makes a capitated payment to a MAO for each person enrolled in the organization. In turn, the MAO pays providers for services a beneficiary may require that are included in the organization's contract with CMS. CMS adjusts payments to pay MAOs different amounts for beneficiaries with different expected health care costs. This helps improve access to care for beneficiaries with greater health care needs and reduces incentives for selecting particular beneficiaries. However, OIG has found improper payments in MA that were driven by diagnoses not supported in the medical records.^{75, 76}

Medicaid

Medicaid is a Federal-State financing partnership with the 50 States, 5 territories, and the District of Columbia each offering its own program variation 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, and produces a national improper payment rate for each program. The estimated Medicaid improper payment rate increased significantly, from 14.9 percent in FY 2019 to

21.4 percent in FY 2020, while CHIP increased from 15.8 percent to 27.0 percent. These increases were largely due to the continued re-introduction of beneficiary eligibility errors which had previously been paused while CMS updated the PERM eligibility component.⁷⁷ Medicaid accounted for approximately \$86.5 billion in estimated improper payments in FY 2020. CMS attributes these increases to high levels of observed eligibility errors, such as those occurring when States maintain insufficient documentation to substantiate that income and other information were appropriately verified, failures in conducting timely and appropriate annual redeterminations, as well as errors when beneficiaries are claimed under incorrect eligibility categories that provide a Federal matching rate that was higher than appropriate.⁷⁸

OIG work has found that States are not always correctly determining the eligibility of individuals for receiving Medicaid benefits, resulting in potential improper payments. OIG audits have also identified substantial improper payments to providers across a variety of Medicaid services including school-based, nonemergency medical transportation, targeted case management, and personal care services (PCS).⁷⁹ In addition to other corrective actions, CMS has engaged with State Medicaid and CHIP agencies to develop corrective action plans that address State-specific reasons for improper payments identified through the PERM program and as part of other Medicaid fiscal oversight efforts. Given that CMS will apply the updated Medicaid eligibility measurements to the last set of States for the first time in FY 2021, the improper payment rate is likely to see similar, significant increases in this fiscal year. As such, it will be imperative that CMS focus its efforts to examine the reasons for and implement strategies to reduce Medicaid and CHIP improper payment rates.

Grants and contracts

Administering grant programs and contracts requires that HHS implement internal controls to ensure that 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's (ORR's) Unaccompanied Children (UC) Program grantees reporting unallowable costs and lacking effective systems for administering program funds.⁸⁰ OIG also found that ORR did not award or effectively manage a sole source contract in accordance with Federal regulations and HHS policies and procedures.⁸¹ Additionally, OIG found that HHS has taken minimal action to improve policies and procedures for ensuring Small Business Innovation Research Program awardee eligibility and has taken no action to improve policies and procedures for preventing duplicative funding.⁸²

To ensure that grant funds are used appropriately, HHS must track and report improper payment rates for its risk-susceptible grant programs and thus adhere to the *Payment Integrity Information Act of 2019*.⁸³ 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.⁸⁴ States receive block grants (\$16.2 billion in FY 2020) to design and operate TANF programs.⁸⁵ HHS has stated that it does not believe that 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 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. Although CMS has taken steps to improve its contract management and closeout processes, the Department needs to take additional actions to ensure that it is meeting other Federal requirements. For example, OIG found that CMS did not identify and report potential *Antideficiency Act* violations for 12 contracts used to establish the Federal Health Insurance Marketplace under the *Affordable Care Act*.⁸⁶ Additionally, OIG found that CMS did not administer and manage strategic communications services contracts in accordance with Federal requirements and made recommendations to both HHS and CMS to address the significant deficiencies we identified.⁸⁷ HHS is developing a permanent Procurement Management Oversight Review structure to provide further oversight of the HHS acquisition portfolio.

COVID-19 funding

Congress appropriated \$484 billion to HHS for the COVID-19 response.⁸⁸ This includes \$178 billion for the Provider Relief Fund (PRF) to support health care providers affected by the COVID-19 pandemic. PRF dollars are provided to hospitals and other health care providers on the front lines of the COVID-19 response and allocated to providers as part of general distributions and through targeted allocations to high impact areas, safety net hospitals, children's hospitals, rural providers, Tribal facilities, clinics and urban health centers, SNFs, and nursing homes.⁸⁹ In addition to PRF funds, Congress also appropriated additional funds for providers who serve rural Medicaid, CHIP, or Medicare patients. Furthermore, funds were dedicated to reimburse eligible providers and facilities for COVID-19 testing, treatment, and vaccine administration for individuals who do not have health coverage, as well as to patients whose health insurance does not cover vaccine administration fees or does cover but typically has patient cost-sharing.^{90,91} HHS has developed financial assistance policy guidance and tracking mechanisms to support the COVID-19 supplemental funding appropriations.⁹² Efficient and effective management and administration will be essential to ensuring that COVID-19 response programs achieve their intended purposes and provide relief to intended individuals and entities. OIG is conducting a series of audits of PRF distributions.⁹³

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 to detect and prevent fraud. The Department should also apply a robust variety of program integrity strategies to protect HHS programs. These strategies must include systems and processes to detect and prevent fraud, as well as plans for addressing fraud when it occurs.

COVID-19 funds

As noted above, HHS received \$484 billion in COVID-19 funding.⁹⁴ Moreover, as of May 2021, CMS had made advanced and accelerated payments to Medicare providers totaling more than \$107.3 billion and paid providers for certain services at enhanced rates applicable during the public health emergency.⁹⁵ In addition, as of September 2020, CMS reported more than \$104.3 billion in Other Assets, which are mainly

composed of these advanced and accelerated payments.⁹⁶ CMS also suspended or reduced the scope of many program integrity safeguards, such as provider enrollment screening. While these steps may be appropriate to ensure access to care, they also raise the risk that fraud will be committed by those seeking to exploit the emergency. Regardless of the source of funds, HHS must effectively and efficiently manage the use of funds internally, award and manage contracts related to COVID-19 funding in accordance with contracting requirements, and appropriately oversee the external use and accounting of Federal funds by thousands of recipients. HHS should ensure that funds are paid only to eligible recipients—in correct amounts—and used in accordance with program requirements.

Furthermore, HHS must apply effective internal controls and efficiently manage the collection, maintenance, and analysis of relevant data that are key to ensuring that COVID-19 funds are used for their intended purposes. OIG has identified serious concerns related to fraud schemes that would divert funds intended for COVID-19 response and recovery. For example, OIG settled a case for civil monetary penalties, involving a provider that received PRF funds despite having its Medicare billing privileges revoked and attesting in the PRF portal that it was not revoked.⁹⁷ OIG is currently investigating several other entities that allegedly received PRF funds despite being ineligible and providers that falsely attested that they were eligible to receive PRF funds. In May 2021, the Department of Justice (DOJ) and OIG announced criminal charges for the misuse of COVID-19 funds.⁹⁸ Among other charges, funds were allegedly misappropriated from PRF based on false applications.

HHS must also take action to protect individuals from being defrauded under the guise of the public health emergency. In August 2021, OIG alerted the public about COVID-19-related fraud schemes and potential harm to beneficiaries.⁹⁹ OIG noted that fraudsters were offering unapproved and illegitimate COVID-19 tests, HHS grants, and Medicare prescription cards in exchange for personal details, including Medicare information. Any personal information collected can be used to fraudulently bill Federal health care programs and commit medical identity theft.

Furthermore, as with all HHS grant programs, it will be critical that the Department provide up-to-date policies to COVID-19-related grant recipients and help 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 lack adequate monitoring.

Medicare and Medicaid

CMS must be vigilant in identifying and addressing fraud in its programs. 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 providers to organized criminal enterprises with no legitimate role in health care. OIG has encountered scams in which fraudsters use technology to impersonate official government personnel from HHS or OIG. Scammers target individuals through various methods including phone, email, or social media to obtain money or personal, medical, or financial information. OIG routinely alerts the public about emerging fraud scams. In recent years, OIG has issued fraud alerts involving durable medical equipment, genetic testing, and telephone fraud.¹⁰⁰ To combat fraud, CMS should continue its important coordination with, and support for, law enforcement, including taking parallel administrative actions as

appropriate.

Managed care

HHS faces a significant challenge in conducting oversight of managed care programs and protecting against fraud, waste, and abuse. Managed care is the primary delivery system for Medicaid, covering at least some services for more than 80 percent of all enrollees.¹⁰¹ In Medicare, more than one-third of beneficiaries are currently enrolled in MAOs. OIG has found weaknesses in MAOs' and Medicaid Managed Care Organizations' (MCOs') efforts to identify and address fraud and abuse by their providers.¹⁰² For example, OIG has found Medicaid MCO capitation payments were made in one State on behalf of beneficiaries who were concurrently eligible and residing in another State.¹⁰³ To ensure program integrity requirements are met, CMS requires MAOs and Medicaid MCOs, prepaid inpatient health plans, and prepaid ambulatory health plans (referred to as managed care plans) to implement compliance programs that are designed to prevent, detect, and correct instances of fraud, waste, and abuse. However, these programs vary widely among the MAOs and Medicaid MCOs, 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 managed care plans. This makes effective program integrity oversight by CMS more complex and challenging.

Furthermore, the MA program is vulnerable to fraud, waste, and abuse perpetrated by MAOs to inappropriately inflate the payments that they receive from Medicare or to inappropriately deny care that they are obligated to provide. In multiple audits of MAOs, OIG sought to determine whether the MAOs submitted diagnosis codes to CMS for use in the risk adjustment program in accordance with Federal requirements. OIG found that risk-adjustment data that MAOs submit to CMS for use in the risk-adjustment program was not always supported by medical records. OIG has recommended that certain MAOs refund overpayments and enhance their policies and procedures to prevent, detect, and correct noncompliance with Federal requirements.¹⁰⁴ OIG also found that billions of dollars in estimated MA risk-adjusted payments supported solely through chart reviews or diagnoses reported only on health risk assessments raise concerns about the completeness of payment data submitted to CMS, the validity of diagnoses on chart reviews and health risk assessments, and the quality of care provided to beneficiaries.^{105, 106} OIG has made recommendations to CMS to improve its oversight of MAOs so that MAOs will ensure practices drive better care—not just higher profits—as well as enact policies and procedures to improve the integrity and usefulness of payment data.

Additionally, significant concerns have been raised that the capitated payment model used in MA may provide a potential incentive for MAOs to inappropriately deny access to services and payments to increase their profits. An MAO that inappropriately denies authorization of services for beneficiaries or payments to health care providers may contribute to physically or financially harming beneficiaries and misuse Medicare program dollars that CMS paid for beneficiaries' health care. OIG found that high numbers of overturned denials upon appeal and persistent performance problems identified by CMS audits raise concerns that some beneficiaries and providers may not be getting services and payment that MAOs are required to provide.¹⁰⁷

To strengthen CMS's oversight of the MA program, OIG has recommended that CMS make improvements to MA encounter data.¹⁰⁸ CMS has taken action to address potential errors in the data and ensure that billing provider identifiers are active and valid on all records. However, CMS must also provide targeted oversight of MAOs that have submitted a higher percentage of records with potential errors, track how

MAOs respond to edits that reject data, and establish and monitor performance thresholds related to MAOs' submissions of records with complete and valid data.¹⁰⁹ Additionally, CMS continues to validate the completeness and accuracy of Medicare and Medicaid managed care plan encounter data and periodically updates guidance for MAOs in order to improve encounter data submission. OIG has found that identifiers for ordering providers are an essential tool for safeguarding program integrity but are largely missing from the encounter data, despite evidence that many MAOs can and do already collect this information.¹¹⁰

CMS should take further actions to ensure the completeness, validity, and timeliness of Medicaid encounter data. OIG found that most States did not provide complete and/or accurate data on Medicaid managed care payments to providers in the national data system—the Transformed Medicaid Statistical Information System (T-MSIS). CMS and States need complete and accurate payment data to effectively monitor and administer Medicaid managed care, the primary delivery system of the Medicaid program. The need for complete and accurate payment data is more important than ever, given the unprecedented stress that the COVID-19 pandemic has placed on the Medicaid program.¹¹¹

Furthermore, CMS should work with its contractors and with States to improve efforts to identify and address fraud and abuse.¹¹² Additionally, the agency should work to ensure that appropriate information and referrals are sent to law enforcement. To improve Medicaid managed care plans' identification and referrals of cases of suspected fraud or abuse, CMS is working with States to provide technical assistance and education on best practices. (See TMC 5 for more information on expanding HHS's capacity to use and share data to support evidence-based policymaking, program management, and program involvement.)

Marketplace insurance

The Department must be attuned to ensuring that payments for advance premium tax credits (APTCs) for enrollees in marketplace insurance are accurate. There was an estimated 20 percent increase in people eligible for subsidized marketplace coverage after passage of the *American Rescue Plan Act of 2021* and an estimated \$35.5 billion increase in premium tax credits.¹¹³ OIG work has found weaknesses in State and Federal marketplace systems for ensuring correct eligibility determinations and accurate APTC payments. For example, a recent OIG audit determined that APTCs payments were paid on behalf of enrollees who did not make required premium payments and recommended improvements to processes and data collection and sharing with the Internal Revenue Service.¹¹⁴

Grants

Without adequate oversight and internal controls, HHS grants and contracts are vulnerable to fraud schemes including embezzlement.¹¹⁵ HHS has worked to strengthen some of its program integrity efforts that are focused on grant programs. For instance, it issued guidance and developed tools to help HHS's awarding OpDivs examine prospective grantee risk prior to awarding grants.¹¹⁶ This information enhances awarding OpDivs' assessment of prospective grant recipients' integrity and potential performance.

Prescription drugs

OIG has found that 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 of inappropriate use and causing significant harm such as overdose. Also, potentiator drugs (drugs that exaggerate euphoria and escalate the potential for misuse when combined with opioids) and drugs indicated to treat OUDs (particularly buprenorphine) are at high risk for diversion. 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 being diverted for resale or recreational use. OIG has also recommended that 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.¹¹⁷ In addition, the Department must guard against fraud in OUD treatment programs, including the submission of fraudulent insurance claims for purported OUD treatment and testing services.¹¹⁸

Furthermore, opioid treatment services were not being claimed by selected providers in accordance with applicable Federal and State regulations. Treatment deficiencies included individual counseling sessions not supported with adequate documentation, take-home medications not provided in accordance with Federal or State regulations, methadone dosing services administered without proper authorization, and individual counseling and methadone services provided without a treatment plan in effect.¹¹⁹

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 also require pharmacies that bill Medicare Part D to enroll in the Medicare program. Currently, CMS's three key tools for safeguarding against fraud—enrollment, revocation, and preclusion—apply to pharmacies only when they bill Medicare Parts B or C, not when they bill Medicare Part D.¹²⁰ Furthermore, 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.)

Systems and processes for detecting and preventing fraud

For 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, FPS has continuously run predictive algorithms and provided other sophisticated analytics nationwide on Medicare FFS claims prior to payments to identify, prevent, and stop fraudulent claims. However, OIG found that FPS is not as effective in preventing fraud, waste, and abuse in Medicare as it could be and recommended that CMS make better use of the performance results within its FPS to refine and enhance its predictive analytic models.¹²¹

An effective provider enrollment screening process is an important tool for preventing Medicaid and Medicare fraud. It plays a vital role in identifying unscrupulous providers and preventing them from enrolling in Medicaid and Medicare. OIG work has found that Medicaid is vulnerable to being defrauded by high-risk providers that were not properly screened. Specifically, OIG found 13 States had not implemented fingerprint-based criminal background checks for their high-risk Medicaid providers as of January 2019. We also found that unscrupulous providers could exploit loopholes in the provider enrollment process to enroll in Medicaid without undergoing these checks.¹²² In addition, OIG found 23 States had not enrolled all providers serving Medicaid beneficiaries in their respective Medicaid programs, exposing them to potentially harmful providers that had not been screened for fraud, waste, and abuse.¹²³ Furthermore, OIG work found that nearly 1,000 terminated providers—or 11 percent of all terminated providers—were inappropriately enrolled in State Medicaid programs.¹²⁴ Despite legislative requirements

in the *21st Century Cures Act* designed to strengthen Medicaid program integrity, terminated providers continue to serve Medicaid beneficiaries. CMS should: (1) ensure that all States fully implement fingerprint-based criminal background checks for high-risk Medicaid providers; (2) work with States to ensure that they have the controls required to prevent unenrolled providers from participating in Medicaid; and (3) follow up with States to remove terminated providers that OIG identified as inappropriately enrolled in Medicaid.

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 to protect resources. Although HHS continues to maintain a clean opinion on its basic financial statements, addressing weaknesses in financial management systems and resolving issues related to reporting requirements of the *Digital Accountability and Transparency Act of 2014* remain challenges for HHS.¹²⁵ For FY 2020, OIG recommended that HHS continue to focus efforts on resolving issues related to its information technology (IT) system controls and completing data cleanup activities.

In addition, financial management systems help OpDivs and StaffDivs ensure operational effectiveness and efficiency, financial reporting reliability, and compliance with applicable laws and regulations. OIG continues to find deficiencies in internal controls over segregation of duties, configuration management for approved changes to HHS financial systems, and access to HHS financial systems.¹²⁶ These deficiencies collectively constitute a significant deficiency in internal controls. 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 duties¹²⁷

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

HHS continues to reform Medicare and Medicaid to promote quality, efficiency, and value of care. Reforms underway touch virtually every type of health care service and offer opportunities for better care and health outcomes, improved access and health equity, lower costs, more transparency and choices for consumers, and reduced administrative burden.¹²⁸ Reforms also come with an array of operational and program integrity challenges.

Medicare and Medicaid are the two largest and most complex health care programs at HHS. They use multiple delivery models (FFS, managed care, and new models such as accountable care organizations (ACOs)); cover a broad array of health conditions, providers, services, and settings; and operate pursuant to intricate statutory directives and regulatory schemes. People of all ages and backgrounds—from seniors to children, and from the healthy to the seriously ill—depend on these programs. In fall 2021, the CMS Innovation Center set a strategic goal for its next 10 years “to transform the health system into one that achieves equitable outcomes through high quality, affordable, person-centered care.” CMS further committed to designing models that include a variety of providers who care for underserved populations.^{129 130}

Medicare and Medicaid beneficiaries are increasingly choosing managed care options, and more providers are participating in value-based models. Continued growth in value-based care and payment is expected in public and private health care programs. CMS’s Innovation Center continues to test new models across the health care spectrum. In a recent report to Congress, CMS estimated that more than 27.8 million Medicare and Medicaid beneficiaries and individuals with private insurance in multi-payer model tests had been included in Innovation Center models and initiatives as of September 30, 2020.¹³¹ Estimated payments for model tests and initiatives (excluding reimbursement for covered services) totaled about \$13 billion for FYs 2010-20. Among its permanent value-based programs, CMS administers the Quality Payment Program for physician reimbursement and the Medicare Shared Savings Program for ACOs. CMS recently announced plans to expand value-based care in home health. CMS paused timelines and modified some model and program requirements because of the COVID-19 public health emergency.

Both Medicare (FFS, Part C, and Part D) and Medicaid have proven susceptible to fraud, waste, and abuse. FY 2020 estimates of improper payments ranged from 6.3 percent (for Medicare FFS) to 21.4 percent (for Medicaid) of total expenditures. Improper payments for Medicare, Medicaid, and CHIP totaled approximately \$134.2 billion.¹³² These programs are on the Government Accountability Office’s (GAO’s) list of high-risk government programs. OIG’s enforcement work shows that wrongdoers defraud Medicare and Medicaid through schemes ranging from false

KEY TAKEAWAYS

- I. Relevant Agency: CMS
- II. Elements of the Challenge:
 - Aligning program incentives with quality, equity, and health outcomes
 - Strengthening program integrity
 - Delivering on the promise of innovative technology to improve health outcomes

billings to kickbacks. OIG's oversight work demonstrates a range of vulnerabilities including:

- flawed program design and administration (e.g., improper payments) (see TMC 2);
- misaligned program incentives and confusing or insufficient program guidance;
- deficient delivery of care to beneficiaries such as poor quality and unsafe care (see TMC 4) or inappropriate utilization;
- gaps in provider enrollment systems and available data needed for proper oversight (see TMCs 2 and 5); and
- challenges with adequate access for beneficiaries to covered services in both FFS and managed care.

To reduce disease spread and expedite the delivery of medically needed care during the COVID-19 public health emergency, CMS implemented flexibilities addressing coverage and payment for items and services, and OIG implemented targeted flexibilities with respect to application of fraud and abuse authorities to specified types of business arrangements.¹³³ These flexibilities introduce additional regulatory risks and compliance challenges for stakeholders implementing them and the Department overseeing their effectiveness. Moreover, the pandemic amplified the effects of longstanding, systemic health care disparities among communities of color and in underserved areas.

To ensure the effectiveness of Medicare and Medicaid in delivering value, the Department should focus on three facets of the challenge: (1) aligning program incentives with quality, equity, and health outcomes; (2) strengthening program integrity; and (3) delivering on the promise of innovative technology.

Aligning program incentives with quality, equity, and health outcomes

Developing effective incentives and policies to drive better health outcomes is difficult given the complexities of medicine, the evolving science of quality measurement, and the varying needs of the populations served by these programs. The Department is undertaking initiatives to streamline, improve, and target quality measures more precisely and to move from process measures to outcome measures. In March 2021, CMS launched Meaningful Measures 2.0: Moving from Reduction to Modernization to "reduce the number of measures in its programs" and "further shape the entire ecosystem of quality measures that drive value-based care."¹³⁴ CMS reported that since the inception of the original initiative in 2017 it has reduced the number of Medicare quality measures by 18 percent, saving more than 3 million hours and a projected \$128 million.¹³⁵ With the new iteration, CMS aims to better address health care priorities and gaps, emphasize digital quality measurement, and promote patient perspectives.

Moving forward, HHS should ensure that its programs use effective, evidence-based measures to improve quality of care and beneficiary outcomes. CMS must clearly define actionable and meaningful quality and outcomes measures for its programs and ensure their reliability, accuracy, and utility. CMS should continue, where appropriate, to align its efforts with other OpDivs using quality measurements to enhance efficiency and strengthen quality measurement. Accuracy and completeness of reported quality and performance information is critical for payment purposes. A recent OIG report found that CMS's monitoring was generally effective at ensuring that Medicare Shared Savings Program ACOs report complete and accurate data through claims, administrative data, and the CMS web portal. The report identified weaknesses in contractor oversight that could result in incomplete or inaccurate data reported through a patient survey.¹³⁶

Value-based models typically pay, in full or in part, based on health outcomes achieved for patients and reductions in health care costs. Providers are reimbursed for a set or bundle of services, often provided across a continuum of care settings, with accountability for outcomes and costs over an established period. To meet care and cost goals, providers are furnishing a range of services not typically reimbursed under volume-based, traditional fee-for-service. These might include social services, care coordination, or health information technology. Especially when nontraditional services affect the amount of payment, HHS should be attentive to ensuring that such services contribute to achieving quality, equity, and efficiency outcomes. Because these interventions are not reflected in normal claims data, CMS should ensure it has the available data necessary to understand the services provided and evaluate their effectiveness. This may require that CMS partner with other OpDivs and Federal agencies that support social services. Operation and oversight of models that integrate traditional health and other services may be hampered by data silos both within HHS and across the Federal Government. (See TMC 5 on data sharing.) There is a heightened program integrity risk if add-on, nontraditional services are offered to patients for marketing purposes, rather than to foster improvements in patient health outcomes, efficiencies, or equity.

In November 2020, CMS and OIG issued regulations intended to promote value and quality through better coordinated care for patients and broader sharing of patient information for patient care.¹³⁷ HHS should monitor results to ensure that the regulations operate as intended to promote beneficial arrangements and practices, and are not subject to abuse.

Access to care and health equity are longstanding challenges that have been exacerbated by the COVID-19 pandemic. OIG work has long identified access issues in Medicare and Medicaid. For example, a report examining provider shortages and limited availability of behavioral health services in New Mexico's Medicaid managed care provides insights into challenges likely shared by other States. Identified challenges included an uneven distribution of licensed providers across the state, staff retention, poor care coordination, and a lack of transportation and broadband services. Promising initiatives to increase availability of behavioral health services included open-access scheduling, a "treat first" clinical model, care integration, and telehealth.¹³⁸ Ensuring that programs have accurate demographic and other data is a requisite step in identifying, understanding causes of, and addressing health disparities. A recent OIG analysis of Medicare claims data showed that in nursing homes in 2020 about half of the Black, Hispanic, and Asian beneficiaries—and 41 percent of the White beneficiaries—had or likely had COVID-19.¹³⁹

New payment structures, care delivery methods, business arrangements among providers, and incentives all give rise to risk-management challenges in Medicare and Medicaid. Notwithstanding identified successes, CMS must maintain a steady focus on quality of care and health outcomes. This is particularly true during the COVID-19 public health emergency when normal guardrails and conditions have been adjusted to address exigent public health circumstances and when providers may temporarily be unable to meet optimal care guidelines. (See TMC 4 for further discussion of quality-of-care challenges.)

Strengthening program integrity

HHS must be attentive across FFS and managed care programs to assess, identify, and mitigate program integrity risks. The nature of fraud and abuse risk differs depending on how Medicare and Medicaid pay for services. Traditional FFS risks, arising from volume-sensitive payments, include inappropriate increased utilization, increased program costs, and improper patient steering. In managed care, a capitated payment system leads to risks such as: stinting on care to reduce costs, discriminating against expensive patients, or manipulating or falsifying data used to measure performance, outcomes, acuity, or diagnoses for risk adjustment. In nontraditional health care models that

marry FFS payments with value-based payments, such as shared savings or partial capitation payments, elements of both FFS and managed care risks may be present. In evaluating and managing risks for a specific model, CMS must consider the range of incentives in the model. Managed care is not immune from risks created by mixed incentives. OIG's oversight and enforcement work has revealed opportunities for "downstream" fraud and abuse in managed care by providers paid by plans on an FFS basis. (See TMC 2 for further discussion of program integrity in managed care.)

In testing and implementing value-based models, CMS must continue to focus on program integrity risks, incorporating safeguards to reduce them and strategies to correct them. Focusing on program integrity risk is especially important for models that introduce new payment incentives, which could lead to new fraud schemes, and for models for which customary payment, coverage, or fraud and abuse laws do not apply due to waivers, exceptions, or safe harbors. Additional risks may arise from novel flexibilities granted because of the COVID-19 public health emergency. HHS should incorporate guardrails to mitigate risks when designing flexibilities, monitor implementation of flexibilities for any abuse, and take prompt action to correct problems and hold wrongdoers accountable.

Many value-based models promote care in home and community settings through in-person home visits, remote monitoring, and other technologies. These services can be less costly and are often preferred by patients. OIG work in areas such as hospice care, home health, and PCS consistently demonstrates that patients and the programs may be vulnerable to fraud and abuse in home- and community-based settings. Moreover, home-based services may not meet quality of care requirements. For example, OIG work showed that hospices lacked oversight of their registered nurses, resulting in nurses failing to meet requirements for visiting beneficiaries' homes to assess the quality of care provided by hospice aides.¹⁴⁰

Additional risks to program integrity across Medicare and Medicaid 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 are covered in more detail in TMCs 2, 4, 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, OIG's work examining how ACOs use health IT showed that, although ACOs have used health IT to aid in care coordination, the full potential of health IT has not been realized.¹⁴¹

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. HHS should also be attentive to the challenges beneficiaries face in choosing reliable apps and technologies and assuring themselves that providers with whom they engage via an app or technology are trustworthy. (See TMC 5 for further discussion.) HHS will need to ensure that rural beneficiaries and underserved populations can participate fully in a technology-enriched, value-driven health system.

The Department also faces challenges in ensuring that evolving technologies are effective, enhance patient access to quality care, and support providers' ability to furnish such care. Law enforcement actions have illustrated how telephone-based remote physician consultations can turn a familiar fraud scheme—charging Medicare for DME or

other services patients do not need—into a larger scale scheme with less effort. HHS must provide appropriate oversight of rapidly evolving technologies such as telehealth, networked medical devices, robotics, genomic testing, and remote monitoring.¹⁴² New technologies and apps are being developed by entities and individuals (e.g., engineers or scientists) who may be unfamiliar with 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 system will need education, guidance, and appropriate oversight.

During the COVID-19 public health emergency, HHS determined that virtual services could be safer for patients and issued broad flexibilities for providers to furnish telehealth and other virtual care in settings and under conditions not typically allowed. HHS should monitor and assess services furnished and billed under these flexibilities for compliance with requirements, payment accuracy, and quality of care to ensure the flexibilities work as intended. As policymakers consider how and whether to incorporate such services into regular programs after the public health emergency abates, it will be important to consider program integrity risks. These risks could include unknown or unqualified providers furnishing virtual services, providers offering and billing for services not suitable for virtual care, substandard services, unsecured technology or data transmission, and improper incentives to beneficiaries, who receive virtual care or provide Medicare billing numbers to those purporting to furnish virtual services.

HHS faces a growing challenge in understanding and, as appropriate, overseeing providers' use of AI 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. AI and machine learning are introducing new paradigms that require fresh thinking about quality of care, compliance, and fraud prevention. Relatedly, HHS will need to assess how it can use AI, machine learning, and other technologies to foster program integrity, value, and quality of care in Medicare, Medicaid, and other HHS programs. (See TMC 1 for further information about FDA's role in emerging technology.)

In summary: 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, and 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 and social determinants of health as well as new uses of digital technology. This is vitally important given the current and anticipated growth in the costs of 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 program costs in the coming decades and improving the lives and health outcomes of the beneficiaries they serve.

4: Protecting the Health and Safety of HHS Beneficiaries

HHS programs provide critical services to diverse populations across a broad range of settings including hospitals, clinics, child care facilities, shelters, and beneficiaries' own homes. Some services are directly provided by HHS personnel, some delivered via HHS grant programs, some delivered by contractors working for HHS, and others rendered by professionals of a beneficiary's choosing who then claim reimbursements from Federal programs. Services include health care, education, child care, and, in limited circumstances, taking legal custody for select populations. Ensuring that intended beneficiaries receive appropriate services that meet standards for quality, are free from abuse or neglect, and are not exposed to infectious agents represents a major challenge for the Department. As the Department supports the Nation's efforts to respond to and recover from the COVID-19 pandemic, there will be challenges to ensuring safety and quality for beneficiaries receiving all varieties of care and services.

KEY TAKEAWAYS

- I. Relevant Agencies: ACF, CMS, IHS, HRSA, SAMHSA
- II. Elements of the Challenge:
 - Ensuring safety and quality of care for beneficiaries of Federal health care programs
 - Protecting the health and safety of children served by HHS programs
 - Preventing abuse and neglect

Ensuring safety and quality of care for beneficiaries of Federal health care programs

HHS operates the Medicare program to serve about 63.3 million elderly or disabled Americans. In partnership with the States, the Medicaid program serves almost 76.5 million beneficiaries, and the CHIP program serves 7.4 million beneficiaries.¹⁴³ IHS provides direct services for about 2.6 million members of 574 Federally recognized Tribes.¹⁴⁴ These programs cover specific health care services that may include hospital care, physician services, prescription drugs, immunizations, hospice care, home and community-based care, DME, and skilled nursing care.

Delivering covered services

Ensuring access to and use of 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 more than 500,000 children with attention-deficit/hyperactivity disorder (ADHD) who were Medicaid-enrolled did not receive timely followup care, and that more than 50,000 such children did not receive behavioral therapy as recommended by professional guidelines.¹⁴⁵ At the other end of the life cycle, OIG found that more than 80 percent of hospice providers—a growing health care sector serving beneficiaries and their families at extremely vulnerable times near end-of-life—had quality-of-care deficiencies.¹⁴⁶ Additionally, fixed daily payment structures may incentivize hospices to enroll beneficiaries for longer time periods but scrimp on care. At times, the greatest barrier to care derives from the beneficiary's own behaviors and beliefs. The Department is currently working to overcome substantial vaccine hesitancy that has hampered COVID-19 vaccination efforts, despite ample supplies of and an adequate ability to distribute and administer three highly safe and effective vaccines.¹⁴⁷

Improving quality of care

Although the Department has made progress, more work remains to improve access to and quality of all types of care. Oversight work 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, 29 percent in rehabilitation hospitals, 33 percent in SNFs, and 46 percent in long-term care hospitals.¹⁴⁸ OIG also 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.¹⁴⁹ OIG is currently conducting a study to update the harm rate for Medicare beneficiaries in hospitals. The review will assess progress made in reducing harm in the decade since the prior study was released in 2010.¹⁵⁰ Additionally, OIG identified a 13 percent rate of adverse events for patients at IHS hospitals with higher rates for older patients, labor and delivery patients, and patients treated in smaller hospitals.¹⁵¹ OIG also found that care in labor and delivery services at IHS Hospitals frequently deviated from national clinical guidelines or best practices, including for crucial services such as inducing labor and treating postpartum hemorrhage.¹⁵² (See TMC 6 for more information on cross-government efforts to keep patients safe.)

Nursing Homes. The Department continues efforts to improve the quality of covered services as well the 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 is intended to facilitate informed comparisons of nursing homes. As the COVID-19 pandemic continues, beneficiaries and their families are struggling to find accurate and timely information about infection rates in nursing homes or the vaccination status of staff. Nursing home residents were prioritized for COVID-19 vaccinations, but this vulnerable population sustained an outsized toll from the disease, especially early in the pandemic. In 2020, 42 percent of Medicare beneficiaries in nursing homes were diagnosed with or likely had COVID-19, with rates of disease even higher in Black, Latino, and Asian populations.¹⁵³ Especially given limited visitation and other access to nursing homes during the COVID-19 pandemic, accurate information about nursing home quality is critically important to inform patients' and families' choices. Given the important role friends and families usually play in identifying and reporting quality issues—an information source that may be diminished during the pandemic—OIG conducted an education and outreach campaign to promote nursing homes' attention to quality and inform patients, staff, and others on how to report quality-of-care concerns. The Quality Improvement Organizations (QIOs) have also conducted education and outreach to nursing homes, including assistance with COVID infection control and promoting vaccination for residents and staff.

As the COVID-19 pandemic has taken a heavy toll on beneficiaries in nursing homes, longstanding staffing and quality-of-care concerns remain pressing. Additionally, nursing homes were charged with implementing new infection control imperatives needed to maintain operations during natural disasters, utility service disruptions, and other occurrences that complicate continual delivery of care. OIG continues its series of audits to assess nursing homes' compliance with health and safety regulations. Such oversight is especially important as the pandemic brought a decrease in onsite nursing home surveys conducted on behalf of CMS.¹⁵⁴ OIG has recommended that CMS safeguard the health and safety of nursing home residents by ensuring facility correction of deficiencies.¹⁵⁵ Government enforcement actions have stopped some poorly performing nursing homes from rendering deficient 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.¹⁵⁶

Hospice care. OIG has identified as a top priority for HHS improving hospice care, including strengthening the survey process and better educating beneficiaries and their families and caregivers.¹⁵⁷ Furthermore, beneficiaries and families need better information about hospice providers.¹⁵⁸ CMS has announced plans to revamp its Hospice Quality Star Rating System to enable better informed decision making for beneficiaries seeking hospice care.

Indian Health Service. After a series of OIG reports about quality-of-care problems in IHS-operated hospitals,¹⁵⁹ IHS created a Quality Framework and Office of Quality to provide better guidance and oversight to its facilities and clinical staff.¹⁶⁰ IHS is also working to establish a nationwide compliance program to address several OIG recommendations and improve care for beneficiaries. However, some longstanding challenges, such as recruiting and retaining qualified staff, persist. As discussed below, there is also a pressing need to protect patients—especially children—from predators within the ranks of health care and service providers. To continue improvements at IHS, OIG has recommended that IHS prioritize developing and implementing a staffing program to ensure sufficient qualified staff at 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.¹⁶¹

Protecting the health and safety of children served by HHS programs

HHS operates or funds many programs that provide child care, education, and residential care in addition to health care for children, including some especially vulnerable children such as children living in foster care and children in the UC Program. The Head Start program promotes school readiness for nearly 900,000 children from low-income families,¹⁶² and the Child Care and Development Fund (CCDF) provides child care assistance for about 1.4 million children from low-income families.¹⁶³ The importance of properly vetting program staff to ensure children's safety is discussed below.

Operating the UC Program

Through the UC 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. An unaccompanied child may have arrived in the United States alone or may have been separated from parents or legal guardians at the border. The UC Program merits specific discussion as it uniquely tasks the Department with assuming custody for children and the ensuing responsibility for their welfare. Through the UC Program, ORR places unaccompanied children in State-licensed 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 UC Program in 2002, it has served more than 400,000 children. As of August 31, 2021, more than 16,000 UCs were in HHS custody with a length of stay averaging 28 days.¹⁶⁴ The number of children entering the United States fluctuates and the Department must be prepared to serve additional children at

times of increased need. In response to the increasing number of referrals of unaccompanied children in 2021, ORR opened Influx Care Facilities and Emergency Intake Sites to provide additional space when the capacity of permanent shelters was exceeded.

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 parents or guardians at or after arrival. HHS reported to a court as part of a lawsuit that 2,737 children who had been separated by the Department of Homeland Security (DHS) had remained in ORR care as of June 2018. Following OIG's January 2019 report finding that significantly more children had been separated from their parents than previously reported, the government identified an additional 1,556 children who had been separated. Neither ORR nor DHS had kept adequate records about separated families, impeding efforts to identify and reunite them. As of June 30, 2021, a court-appointed steering committee reported that it had been unable to locate the parents of 368 children; efforts to locate them were continuing. OIG also reported, and subsequent court filings confirmed, that children for various reasons continued to be separated by DHS from their parents, perhaps because of a parent's criminal history. However, ORR did not always receive adequate information about the parents of separated children.¹⁶⁵ The lack of complete and accurate data about separated children complicates HHS's ability to ensure appropriate placement. 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. OIG also found failures in conducting required staff background checks and insufficient clinical staff to serve children's mental health needs,¹⁶⁶ lack of oversight over facilities' use of inspection checklists to ensure security measures,¹⁶⁷ and shortcomings in incident reporting systems to protect children's safety.¹⁶⁸

The Department must work to ensure that UC Program-funded facilities meet all safety requirements, including new infection control priorities related to COVID-19, 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. Thousands of HHS-funded providers hold positions of trust that bring them into close contact with beneficiaries, often behind closed doors and at especially vulnerable times in the beneficiaries' lives. 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 serving a prison sentence for sexually assaulting boys he treated as patients. This disturbing case commanded extensive attention, and the Department committed to collaborating with a Presidential Task Force on Protecting Native American Children in the IHS system established in March 2019.¹⁶⁹ The task force released a report in July 2020 detailing its investigation of institutional and systemic breakdowns that failed to protect children from abuse.¹⁷⁰ (See TMC 6 regarding protecting IHS patients.) 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 UC facility staff whose jobs entail access to children.¹⁷¹ OIG is currently reviewing whether the UC Program's Influx Care Facilities and Emergency Intake Sites, which are

not State-licensed, conduct required background checks before employees are hired and implement mitigation strategies to ensure the safety and well-being of children if ORR permitted employees to have direct access to children before background checks were completed.¹⁷² Failure to conduct adequate background checks has been a problem in other HHS-funded child care programs as well. In several audits, OIG found that some States have not fully implemented CCDF requirements to conduct comprehensive criminal background checks on current and prospective staff.¹⁷³ Additionally, some IHS-funded, Tribe-run health centers failed to conduct required background checks on employees working with American Indian children.¹⁷⁴ Implementation of background checks for long-term care providers remains a challenge as well.¹⁷⁵ 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 UC Program, Head Start, and CCDF-funded programs. 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 all care settings are at risk of abuse and neglect. 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 such as family members who were paid by Federal health care programs to care for the beneficiary at home. Group homes provide care to many especially vulnerable people, including adults with developmental disabilities. OIG's work found extensive failures in the proper handling of critical incidents, including the suspected abuse and neglect of group home residents.¹⁷⁶ About 1.8 million Medicare beneficiaries receive care in SNFs each year.¹⁷⁷ OIG has identified substantial failures to report incidents of potential abuse or neglect of Medicare beneficiaries living in SNFs who require treatment in hospital emergency departments.¹⁷⁸ In addition, OIG work identified cases of potential abuse of Medicare beneficiaries in hospice care and that hospices failed to act in some instances.¹⁷⁹ These cases reveal vulnerabilities in beneficiary protections that CMS must address to better ensure that beneficiary harm is identified, reported, addressed, and ultimately prevented. All States have enacted mandatory reporting laws that require certain individuals such as school teachers or nursing home staff to report suspected abuse or neglect targeting vulnerable individuals. However, many instances of abuse and neglect go unreported, making it harder to help victims and hold wrongdoers accountable.¹⁸⁰ During the ongoing COVID-19 pandemic, as many students did not attend school in person and many patients were unable to receive visitors, ensuring well-functioning processes that identify and report abuse is particularly important. Continued oversight and contact with family and friends can be particularly important to ensure quality care in nursing homes. OIG is reviewing continuity of on-site oversight by CMS and State Survey Agencies during the pandemic. Also, CMS has issued guidance to help nursing homes resume in-person visitation while minimizing the risk of COVID-19 transmission.

The Department has created several resources to better address the abuse and neglect of residents in 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.¹⁸¹ OIG is committed to promoting the continued adoption of model practices to improve critical incident reporting systems.

It is important to prevent harm by identifying providers and facilities that are 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.¹⁸² OIG has also explored Medicaid claims data as an additional way to identify potential child abuse and neglect.¹⁸³ 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 sufficiently 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.

5: Harnessing and Protecting Data to Improve the Health and Well-Being of Individuals

The Department continues to improve how it collects, manages, shares, and secures its data. Yet, HHS faces significant challenges to both protect data from persistent cybersecurity threats and improve how the Department and related entities share an increasingly large amount of critical data, including public health data. The demands of these dual challenges have been made readily apparent during the pandemic. Responding to COVID-19 has required HHS to collect and report a wide range of data on an unprecedented scale. At the same time, large-scale cybersecurity attacks such as the SolarWinds hack demonstrated the need to improve cybersecurity governmentwide. HHS will need to apply lessons learned during its pandemic response in order to sustain and accelerate its efforts to get the right information to the right people at the right time.

HHS's capabilities to operationalize and change how it uses, shares, and protects data for the COVID-19 response was in part aligned with the focus HHS had placed on modernizing its data practices across the Department.¹⁸⁴ The pandemic accelerated that need, and the Department built new systems intended to improve and centralize some data functions to support the COVID-19 response including HHS Protect—a platform for the authentication, amalgamation, and sharing of health care information.¹⁸⁵ Standing up and collecting data via HHS Protect presented initial difficulties related to the scalability, veracity, and security of the data critical for COVID-19 response and recovery. According to hospitals, changing reporting requirements and systems added to the frustration and burden of health care providers in the midst of the pandemic.¹⁸⁶ Continued modernization of HHS data practices is needed for HHS and its OpDivs to fulfill their missions, especially to prepare for future public health threats. All of this must happen as the Department continues to respond to COVID-19 and while the quantity, frequency, and sophistication of cybersecurity risks to HHS increases rapidly.

HHS's authorities shape how an individual's data are used and protected by other private and public entities. These authorities are increasingly important in a technology-enriched health and human services delivery system. HHS made progress, but COVID-19 has presented a new challenge by amplifying demand for easier access to data. While many health care providers, State and local governments, and others switched to remote and virtual interactions to slow the spread of COVID-19, the need to continue to improve data interoperability and security was evident. At the same time, the health care industry and related private sector entities have faced persistent and systemic cybersecurity challenges, particularly ransomware attacks.

The response to COVID-19 also highlighted HHS's need to focus on racial and geographical disparities within programs. These disparities warrant further scrutiny of how data is collected and used in health care settings under

KEY TAKEAWAYS

- I. Relevant Agency: All HHS
- II. Elements of the Challenge:
 - Expanding HHS's capacity to use and share data to support evidence-based policymaking, program management and program improvement
 - Providing data to HHS partners and promoting public data access and sharing
 - Protecting data from misuse or unlawful disclosure

HHS's jurisdiction to ensure equitable access and care for beneficiaries. Improved and appropriate data collection and access can provide key support for efforts addressing systemic disparities. HHS will need to sustain efforts to ensure that early progress turns into lasting structural improvement across the health and human service systems. (See TMC 6 for more information on reducing health disparities.)

Expanding HHS's capacity to use and share data to support evidence-based policy making, management, and program improvement

Data are central role to every HHS program.¹⁸⁷ HHS operations depend on the effective collection, use, and exchange of a large amount of sensitive and important data about individuals, health care providers, key public health assets, regulated industry, and other entities and actors. The Department and its programs are increasingly able to collect, store, and analyze data from disparate sources and provide new pathways within HHS to improve access to data. 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 data across its programs. Although most OpDivs primarily collect data to administer their own programs, the use of data across programs and OpDivs remains a challenge. Data are often housed within a single OpDiv's "data silo" and not easily shared with other parts of HHS, even though OpDiv missions often overlap.¹⁸⁸ Data silos also impede data sharing within OpDivs.

The effect of these data silos was seen during the response to the pandemic, limiting how HHS and its partners gained insight about COVID-19.¹⁸⁹ In January 2021, President Biden issued an Executive Order on Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats.¹⁹⁰ The Executive Order highlighted the need to advance innovation in public health data and analytics, enhance data collection and collaboration capabilities for high-consequence, public health threats, and build a better public health infrastructure. Achieving a mature public health reporting system that can respond to future public health threats requires extensive collaboration among Federal, State, local, and Tribal entities. It requires interoperability and security across a range of systems to allow for the exchange of data in a timely fashion and data collection that is accurate, timely, and efficient in order to track and thwart emerging health threats. Similarly, through OGA the Department must continue to engage with international stakeholders to ensure that the public health reporting system can support international response and coordination.

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. These technologies often depend on large, standardized data sets and will require collaboration across the Department. Eliminating or reducing data silos within the Department and increasing appropriate access across programs will be an essential step for improving program management and evidence-based decisionmaking, as well as laying the groundwork for HHS to benefit from emerging technologies. For example, the CDC Data Modernization Initiative (DMI) includes plans to deploy next-generation tools to improve public health surveillance.¹⁹¹ To effectively develop, deploy, and use those tools, HHS will have to rely on representative data from across its programs, which will require complex technical coordination among diverse types of data, some of which have technical limitations.

Improving data governance to enhance program management

One critical step for improving HHS's capacity to utilize its data is the adoption of a better data governance approach. Effective data governance can improve communication and transparency by making data more available and useable. However, data governance practices are not consistent across HHS. The need to improve data governance is not unique to the Department and is a priority and a requirement for all Federal

agencies.¹⁹² Although progress has been promising, 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 that are received and managed by the Department. This challenge will play a significant role as CDC moves forward with its DMI and especially its newly launched initiative—the Pandemic Ready Interoperability Modernization Effort.¹⁹³ This new, multiyear collaboration with the U.S. Digital Service is designed to automate data, improve public health reporting, and develop a flexible, cloud-based infrastructure that will improve public health data quality and IT systems. As this and other efforts move forward, HHS should learn from previous projects that encountered complex data collection and reporting issues in other HHS programs.

For example, OIG has raised concerns about the completeness and quality of data submissions by States for the national Medicaid data set, T-MSIS.¹⁹⁴ CMS's recent progress related to T-MSIS may be helpful in providing lessons learned. Nearly all State Medicaid programs now report data directly to T-MSIS, and CMS has worked with States to improve the quality of data submissions and release T-MSIS data to researchers. Based on this progress, CMS is able to use T-MSIS to provide programmatic insights, including insight about COVID-19 treatment and testing and how the public health emergency affected Medicaid service utilization.¹⁹⁵ CMS also publishes data quality information related to several data categories in T-MSIS through its DQ Atlas web application.¹⁹⁶ The DQ Atlas and other reviews indicate that there are still issues with the completeness and reliability of some T-MSIS data. CMS has issued guidance to States to improve T-MSIS reporting of certain variables including the collection of race, ethnicity, and social determinants of health data. But additional guidance and testing is needed.¹⁹⁷ (See also TMC 3 regarding data for new care models.) And OIG's recent analysis of Medicaid managed care payments illustrates that most States did not provide complete or accurate data in T-MSIS about managed care plan payments to providers.¹⁹⁸ It will be important for HHS to proactively address similar data quality and governance challenges as HHS modernizes how it collects and uses external data from grantees or other organizations.¹⁹⁹

Although much of HHS's data are publicly available, some may not be easy to use. Or there may be other barriers such as a lack of standardization that limit stakeholders' and the public's access or use of the data.²⁰⁰ Those barriers present a challenge to providing increased access to HHS data that are vital for public health and welfare and that could lead to innovation and improvement in health and human service systems. Many HHS external stakeholders rely on effective dissemination of data collected by departmental programs. Much of HHS's data are publicly available but may not be well understood or in easily accessed formats. For example, currently, most public access to HHS data does not use contemporary approaches, such as the use of application programming interfaces (APIs). OpDivs are planning and have made some progress to expand access to these important assets. In May 2020, NIH made beta access available to its *All of Us* Researcher Workbench.²⁰¹ In its first year of allowing beta access to its workbench for more than 800 researchers and more than 570 research projects, NIH has added new types of data including wearables and results from the COVID-19 Participant Experience Survey. NIH has also brought together 16 types of EHRs from more than 50 data providers and has continued to improve the research tools that can be used by researchers in the *All of Us* workbench.²⁰² In September 2019, FDA released a Technology Modernization Action Plan.²⁰³ Among other goals, FDA aims to improve how it uses data and technology to carry out its mission and improve communication and collaboration with other government and external stakeholders.

FDA has also made progress related to its New Era for Smarter Food Safety by, for example, prioritizing technology-enabled traceability.²⁰⁴ These approaches and plans 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 in general have not fully realized and benefited from modern approaches to improve the appropriate flow of electronic health information. As part of HHS's Information Technology Strategic Plan, two key goals are aimed at improving health information exchange: enhance data and interoperability, and improve IT management and governance.²⁰⁵ Although work continues to improve upon the capabilities that enable this effort and there are signs of recent progress, routine and robust health information exchange between providers remains a challenge.²⁰⁶ In 2019, 55 percent of acute-care hospitals electronically performed all four interoperability functions, which are to find patient health information and send, receive, and integrate patient summary-of-care records from sources outside health systems.²⁰⁷ This is up from 23 percent of hospitals in 2014. Among the interoperability functions, the largest increase was in hospitals that can integrate data, rising from 40 percent to 71 percent over the same timeframe.²⁰⁸

Interoperability of EHRs also plays a crucial role in providing data for the response to COVID-19 and could be key to public health modernization efforts. HHS and other entities are exploring how best to use electronic case reporting (eCR), which is the automated generation and transmission of case reports from health care providers' EHRs to public health agencies. CDC is leading the project called eCR Now, which is designed to rapidly deploy eCR operations through the use of Fast Healthcare Interoperability Resources APIs to meet the demands of public health reporting. As of July 2021, more than 9,200 facilities were actively sending COVID-19 case reports at multiple jurisdictions at the same time.²⁰⁹

Improvement in the way patients and providers can access, use, and exchange electronic health information continues largely in response to HHS regulatory action taken in 2020. Office of the National Coordinator for Health Information Technology (ONC) and CMS regulations related to interoperability, data standards, and data exchange mechanisms continue to shape industry progress as health care providers, health IT developers, and others operationalize the requirements, such as use of standard, open APIs.²¹⁰ Still, the health care industry faces some fundamental issues that hinder widespread interoperability. For example, ONC continues its efforts to improve the ability to match patient data across health IT, and in late 2020 began a new initiative to standardize how patient addresses are included in their electronic health records.²¹¹ The challenge for HHS will be translating these authorities and other initiatives into more widespread improvements across the health care industry. This will require further engagement to ensure progress is not limited to those health care entities with resources to implement modern technologies and data practices.

Combating persistent, emerging cyberthreats and protecting data

The risk of cybersecurity attacks that threaten the confidentiality, integrity, and availability of government-held data are persistent and growing. For example, the recent rise in ransomware attacks is a major challenge. Overall ransomware is up more than 150 percent in North America as a result of a confluence of factors including an increase

in the use of hard-to-trace cryptocurrencies, ransomware-as-a-service, and successful ransomware operations through which cybercriminals are paid.²¹² Although ransomware risks are not unique to HHS, overall the Department and the Federal Government have been targeted by increasingly complex cybersecurity attacks that seek to exploit a range of vulnerabilities that exist across Government agencies.

In response to growing cybersecurity threats to Government operations, the Administration has made improving the cybersecurity of the Federal Government a top priority. In the May 2021 Executive Order “Improving the Nation’s Cybersecurity,” the President directed Federal agencies to fundamentally and systemically change the approach to cybersecurity that crosses Departments and industries and that will require significant investments of resources and cultural and organizational change.²¹³ The Executive Order will likely require HHS to reorient how its OpDivs and StaffDivs carry out the increasingly complex task of managing and implementing cybersecurity safeguards across a range of entities. In response, the Department will likely need to undertake a multiyear effort in coordination with other Federal agencies to assess and change its approach to cybersecurity, such as continuing efforts to reduce the several aspects of cybersecurity that remain siloed within OpDivs and StaffDivs. This effort will need to begin even as cyberthreats to HHS remain elevated, as adversaries attempt to take advantage of the public health emergency to infiltrate HHS systems or impede their performance.

Many HHS partners and grantees—and the health care system at large—are similarly subject to increases in cyberattacks. Consistent with cybersecurity advisory warnings, the potential for an increased and imminent threat of cybercrime in the form of ransomware to hospitals and other health care providers was realized as an increasing number of hospitals and other providers were victims of ransomware, with nearly 34 percent of health care organizations reported being hit by ransomware.²¹⁴ Public confidence in the health care sectors’ and HHS’s ability to protect crucial public health data or sensitive, personal health data is important for the success of Federal initiatives that seek to leverage technology to create future medical treatments. OIG is continuing to conduct work addressing cybersecurity in HHS programs.

Cybersecurity challenges in a federated environment

Although the Department continues to improve its overall cybersecurity posture, OIG and GAO audits have identified challenges and systemic weaknesses.²¹⁵ One persistent challenge that underpins a number of cybersecurity issues is the federated nature of IT and cybersecurity environments across HHS. For example, 24 of NIH’s 28 entities receive individual funding from Congress and administer their own budgets. Each NIH entity designates its own chief information officer (CIO) who coordinates with the NIH CIO. This type of environment poses challenges in managing and responding to cybersecurity threats across distinct entities. Most OpDivs are stewards of sensitive personal information and are required to protect such information from improper disclosure, including by external entities. Given the size, complexity, and constant use of this data, OpDivs face challenges in ensuring that third parties access this information for legitimate purposes. For example, OIG investigations of health care fraud often involve criminals that use valid credentials to access systems with program beneficiary information for illicit purposes, such as identify theft.

To ensure cybersecurity governance is effective across HHS, the Department has instituted policies and procedures; however, it has limited capabilities to assess compliance with, implementation of, and effectiveness of its policies and procedures within OpDivs and StaffDivs. Progress is being made to improve HHS-wide insights into cybersecurity. For example, the HHS Computer Security Incident Response Center and the Health Sector Cybersecurity Coordination Center (HC3) serve as central points of contact for incident reporting, information sharing, and cyber-data repositories.²¹⁶ As HHS implements

the cybersecurity Executive Order and enhances the governance, capabilities, and awareness of both of these entities, HHS's overall cyber hygiene should continue to improve.

In addition to cybersecurity, other threats to HHS programs and grantees put the integrity of information and data at risk. HHS is responsible for scientific development, integrity, and security at NIH. Foreign entities seek to gain medical research and intellectual property developed by the Federal government to further their economic and research goals or disrupt the normal functioning of the Department. Taxpayer-funded medical research is being targeted by foreign adversaries. While these risks are complex and affect many aspects of U.S. national interests, HHS- and NIH-funded research and grantees continue to be targeted. OIG work has identified several issues that NIH can address to improve its safeguards, and NIH is making progress by, for example, working with the HHS Office of National Security.²¹⁷ However, NIH must continue to strengthen its safeguards against foreign influence by updating its policies and procedures while advancing its technological capabilities to assess, identify, and respond to foreign threats.

Promoting the security and privacy of the health care system

HHS's responsibilities for ensuring cybersecurity also extend to the health care system. The strength of the health care system's cybersecurity defenses continues to be tested as cyberthreats increase during the COVID-19 pandemic. Additionally, many health care providers rapidly shifted care to telehealth and other remote technology and thus provided additional openings for possible attacks. Sustained utilization of telehealth may pose new cybersecurity challenges because health care entities remain primary targets, and health care data are reportedly among the most valuable data for cybercriminals. In addition to data and identity theft, cyberthreats can also pose safety risks by causing outages of systems needed for patient care or exploiting vulnerabilities in the growing number of connected medical devices and other medical equipment involved in direct patient care. To ensure these areas of focus are not vulnerable and remain effective, HHS will need to work with the health care industry to improve cybersecurity by, for example, ensuring contingency plans are updated and tested to cover telehealth.

The Department has made some progress to bolster cybersecurity in the health care industry. Since 2019, HC3 has issued many products aimed at educating the health care industry on specific threats, mitigation efforts, and other educational materials. The products describe trends and new cybersecurity threats designed to take advantage of the COVID-19 pandemic.²¹⁸ 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 privacy concerns about the use and disclosure of protected health information. Some of the limitations associated with HIPAA were highlighted as the health care industry responded to COVID-19. In response, OCR took several actions including exercising its enforcement discretion to support greater flexibilities for the types of technology used for telehealth and issuing guidance about sharing patient health information on COVID-19 to emergency first responders.²¹⁹ OCR's response to COVID-19 foreshadows the need for potential future actions to address privacy issues as the health care industry continues to modernize. As health care providers and patients shift to using more telehealth, remote-based care, and emerging technologies, new challenges related to the privacy and security of patient health information will arise. The Department's challenge is to keep up with changes in the health care industry and with nontraditional health care entities that may impact patient privacy.

6: Improving Collaboration to Better Serve Our Nation

HHS faces some of the largest and most complex issues confronting our Government and the Nation. These problems commonly transcend a single HHS program. Often HHS's mission is only one piece in a larger puzzle of overlapping and coordinating responsibilities. To achieve its mission, HHS needs to collaborate effectively across HHS programs and with other Federal agencies as well as outside the Federal government including with Tribal, State and local governments, international entities, industry, and other stakeholders.

Improving HHS's collaboration can help Americans receive more efficient, higher-quality health and human services and benefit from greater advances in the sciences underlying them. Cross-agency efforts led by the Department such as the Secretary's Intradepartmental Council on Native American Affairs and the Behavioral Health Coordinating Council, along with those related to Department management and data, provide opportunities for HHS programs to work more efficiently and in greater alignment. Effective partnerships with other Federal agencies help ensure that critical initiatives and resources, such as those for emergency preparedness and response and law enforcement investigations, are working in concert. Established networks of information exchange, such as through the Secretary's Tribal Advisory Committee, can better allow HHS programs to reflect community needs. Effective collaboration with HHS's vast array of nongovernmental stakeholders—from health care practitioners to food and drug manufacturers, health systems, nursing homes, hospices, professional associations, scientists, consumers, and community nonprofits, just to name a few—is essential to delivering the best services and care to the American people and supporting HHS programs in achieving their intended outcomes.

The need for collaboration crosses many of the programs and challenges discussed in other TMCs, highlighting the broad and complex nature of HHS's work. To run effective and efficient programs, HHS must consider issues and impacts outside a single program or mission for any one of its agencies. For example, the importance of data access and sharing across stakeholders is discussed in TMC 5.

Barriers to HHS collaboration include navigating a wide breadth of stakeholders with different goals and authorities, the scope and complexity of the problems for which HHS needs partnerships to resolve, and the ever-changing landscape of the health and human services sectors. Overcoming these barriers requires HHS to engage in intentional and sustained efforts toward building effective partnerships both domestically and internationally, communicating effectively, managing collaborative work, and maintaining accountability. Recent OIG work reveals the importance of effective and collaborative management within HHS and with HHS's partners, and areas for improvement.

KEY TAKEAWAYS

- I. Relevant Agency: All HHS
- II. Elements of the Challenge:
 - Combating COVID-19
 - Reducing health disparities
 - Turning the tide on the opioid crisis
 - Protecting children
 - Keeping patients safe

Combating COVID-19

The unprecedented nature of the COVID-19 pandemic underscores the critical importance of effective coordination in emergency preparedness and response. From the onset of the pandemic, various stakeholders were quickly called upon to collaborate on a myriad of efforts including those related to temporary emergency expansions, distributing Federal funds, managing health care programs, nursing home safety, vaccine development and distribution, testing, personal protective equipment (PPE) and respirator availability from the national stockpile, and public health guidance.

An OIG survey of hospitals responding to COVID-19 that was conducted in late March 2020 found that changing and sometimes inconsistent guidance from Federal, State, and local authorities on issues such as testing, use of PPE, and obtaining supplies from the national stockpile posed challenges for hospitals and the public.²²⁰ In a follow-up survey conducted in March 2021, hospitals reported receiving varying information from different levels of government about who was eligible to receive the COVID-19 vaccine and when they were eligible.²²¹ Federal, State, and local governments had prioritized different population groups to receive vaccines and hospitals reported that these differences in priorities complicated eligibility determinations, which meant the process could be time-consuming and resource-intensive. Reports from OIG related to coordination in past emergencies found Federal agencies can reduce burdens on States and other stakeholders by consolidating outgoing communication and requests for data or information, and that clearly defined roles can ensure that staff are not working at cross-purposes.^{222,223}

The Department has taken steps to address challenges to emergency coordination efforts. Related to cross-agency coordination, ASPR, CDC, and CMS implemented a joint OIG recommendation in 2020 to continue to help hospitals sustain preparedness for emerging infectious diseases (EID) by coordinating guidance and providing practical advice for all hospitals.²²⁴ These agencies have taken actions to update EID preparedness guidance to ensure that it is clear and concise, develop strategies for updating information about EID threats, and provide practical advice that hospitals can easily employ. These efforts continued during the COVID-19 response.

Reducing health disparities

The disparate impacts of the COVID-19 pandemic on various racial and ethnic groups have brought health equity concerns to the forefront. Health disparities are differences in health that adversely affect certain groups. People of color have been found to experience disparities in areas such as access to care and quality of care.²²⁵ Such disparities have profound implications for the health and well-being of these individuals.

The COVID-19 Health Equity Task Force was established by Executive Order 13995, *Ensuring an Equitable Pandemic Response and Recovery*, which was issued on January 21, 2021.²²⁶ The task force is part of a government-wide effort to identify and eliminate health and social disparities that result in disproportionately higher rates of exposure, illness, hospitalization and death related to COVID-19. In addition to HHS, five additional Federal agencies are represented on the task force including the Departments of Agriculture, Education, Housing and Urban Development, Justice, and Labor. The task force's mission is to provide specific recommendations to the President for mitigating inequities caused or exacerbated by the COVID-19 pandemic and for preventing such inequities in the future.

One of the COVID-19 Health Equity Task Force's interim recommendations is to create data transparency related to the demographics of those receiving therapeutics and providing public health intervention funding to address barriers to care. OIG has work assessing HHS efforts to collect and analyze data on disparities to address the COVID-19 pandemic as well as, more broadly, to identify and mitigate health disparities. In an evaluation of Medicare claims

data that analyzed differences by beneficiary characteristics including race and ethnicity, OIG found that Black, Hispanic, and Asian Medicare residents of nursing facilities had higher rates of COVID-19 diagnoses than White Medicare residents.²²⁷ Ensuring that Medicare is able to assess disparities is key to improving overall health, advancing health equity, and reducing overall health care costs. The ability to assess disparities hinges on the quality of the underlying race and ethnicity data. (See TMC 5 for more information on improving data related to health disparities.)

Addressing the opioid crisis

The COVID-19 pandemic has further challenged HHS efforts to achieve its goal of reducing opioid morbidity and mortality. The pandemic may be exacerbating the Nation's opioid epidemic and individuals with an OUD may be at greater risk for COVID-19.²²⁸ (See TMC 1). A number of OpDivs within HHS and other Federal agencies play a role in addressing opioid abuse and misuse, and coordination among them and other partners is vital to turn the tide on this crisis. State sharing of PDMP data, for example, may help to improve safe prescribing practices and prevent prescription drug abuse and misuse.²²⁹ Better collaboration is a key step in helping reduce geographic disparities in access to medication to treat OUD. Improved stakeholder communication may also help make medication to treat OUD more available through better data collection and expand the use of data to measure performance.²³⁰

Protecting children

HHS faces substantial continued challenges in coordinating with respect to the Unaccompanied Children Program. (See TMC 4 for program background.) In a review of challenges that HHS faced in responding to the zero-tolerance policy and reunifying separated children with their parents,²³¹ OIG identified shortfalls in internal HHS communication, collaboration across Federal agencies, and outreach to critical stakeholders. These challenges impeded HHS in protecting children in its custody. In the Department, key senior HHS officials did not act on the OpDiv staff's repeated warnings that family separations were occurring and might increase, which impeded the Department's ability to provide prompt and appropriate care for separated children when the zero-tolerance policy was implemented. For example, HHS could not always place separated children in HHS-funded care provider facilities in a timely manner due to the lack of sufficient bed capacity.

Problems with interagency coordination also limited the Department's ability to plan for the care of children in its custody. For instance, information was not effectively shared in advance of the zero-tolerance policy, despite existing channels to facilitate high-level interagency coordination and engagement on important immigration issues.²³² Furthermore, HHS and DHS did not collaborate on systems for tracking separated families across agencies for later reunification, leaving HHS to struggle to identify separated children and reunite them with their parents. Additionally, poorly communicated guidance from HHS complicated care provider facilities' ability to care for children separated from their parents.

HHS oversees numerous other programs that provide direct services to children. Program funding may pass from the Federal government to States and then to local implementing entities that provide services such as foster care and child care. OIG audits of State compliance with employee background checks and other health and safety requirements in HHS programs found lapses that can put children at risk,^{233, 234} supporting the need for better coordination between HHS and States to keep children safe. (See TMC 4 for more information on keeping children safe.)

Keeping patients safe

Health care and mental health care providers, as well as providers furnishing OUD treatment, hospice, and nursing home services are among those on the frontline of ensuring safety for beneficiaries receiving care through HHS programs and at HHS facilities. OIG reports have identified issues with HHS oversight of, coordination with, and outreach to external partners that may leave patients at risk of harm. These include a series of reports finding deficiencies in State agency oversight of nursing homes' compliance with life safety and emergency preparedness requirements.²³⁵ (See TMC 4 regarding patient safety.)

Recent cases of patient abuse by IHS employees have raised concerns about protecting the American Indian/Alaska Native population. The convictions of a former IHS pediatrician in September 2018 and 2019 brought attention to the issue and shed light on areas requiring improvement within IHS.^{236, 237} An OIG memorandum to IHS on past and ongoing OIG audits reported that Tribal health programs that received *Indian Self-Determination and Education Assistance Act* funds from the IHS were not conducting required Federal Bureau of Investigation fingerprint background checks for all employees, contractors, and volunteers who have regular contact with Indian children.²³⁸ This increases the risk that an individual in one State with a disqualifying criminal history in a different State could be hired into a position that involves regular contact with Indian children.

In response to OIG's memorandum, IHS issued a letter to Tribal leaders identifying the need for immediate action and steps toward a collaborative response to address this vulnerability, which may compromise the safety and well-being of Indian children who receive treatment at IHS-funded Tribal health programs.²³⁹ It is imperative that HHS ensure that both IHS and Tribe-operated health facilities meet Federal requirements for background verifications of employees, contractors, and volunteers in contact with children served by the facilities, and that health care providers treating these children are appropriately licensed.

By building and sustaining effective partnerships, HHS can better safeguard and improve the programs so crucial to the health and well-being of the Nation.

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