

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



2020
TOP MANAGEMENT AND PERFORMANCE
**CHALLENGES
FACING
HHS**

INTRODUCTION

The 2020 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) 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 six challenges reflect overarching issues that affect multiple HHS programs and responsibilities. These are not the only challenges that confront HHS, and OIG reports are a key resource that highlight specific opportunities to improve HHS programs and operations.

HHS is responsible for a \$2.4 trillion portfolio, 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 the emergence of novel coronavirus disease 2019 (COVID-19). As the lead Federal agency for medical support and coordination during public health emergencies, HHS has numerous significant responsibilities to assist communities throughout the United States (U.S.) to prepare for, respond to, and recover from the fast-moving COVID-19 pandemic. HHS’s responsibilities include working with Federal, State, Tribal, and local and international governments to effectively respond; supporting the development of vaccines, treatments, and other 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 for 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.

COVID-19 Challenges

Throughout the TMCs, we highlight the unprecedented challenges the Department faces in its response to the COVID-19 pandemic.

- TMC 1: Mitigating the loss of life and negative health consequences associated with COVID-19, while promoting the operation of essential programs and services.
- TMC 2: Ensuring responsible stewardship, transparency, and accountability of COVID-19 funds.
- TMC 3: Ensuring telehealth and other flexibilities implemented during the public health emergency work as intended.
- TMC 4: Protecting the health and safety of people especially vulnerable to COVID-19 and ensuring access to, safety, and efficacy of COVID-19 immunizations and treatments.
- TMC 5: Ensuring that public and private stakeholders have access to timely, accurate, and secure data related to the COVID-19 response and recovery.
- TMC 6: Fostering effective coordination among Federal, State, Tribal, and private sector stakeholders to combat COVID-19.

Management and performance challenges are inherently cross-cutting. 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, the subject of TMC 3. Given that challenges cross both internal HHS boundaries and externally with Federal and State agencies, coordination among HHS agencies and across government is integral to addressing these challenges.

In addition to this annual publication, OIG maintains a list of significant unimplemented OIG recommendations, including legislative recommendations, to address vulnerabilities. These recommendations are drawn from OIG's audits and evaluations. OIG identifies the top unimplemented recommendations that 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, is on our website at <https://oig.hhs.gov>.

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Safeguarding Public Health

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Safety of HHS Beneficiaries

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Ensuring the Financial
Integrity of HHS Programs

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Harnessing Data To Improve
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Acronyms

ACF	Administration for Children and Families	HRSA	Health Resources and Services Administration
ACO	Accountable Care Organization	HHS	U.S. Department of Health and Human Services
ADHD	Attention Deficit Hyperactivity Disorder	IHS	Indian Health Service
AHRQ	Agency for Healthcare Research and Quality	IT	Information Technology
AI	Artificial Intelligence	MA	Medicare Advantage
AI/AN	American Indian/Alaska Native	MAO	Medicare Advantage Organization
API	Application Programming Interface	MAT	Medication Assisted Treatment
ASPR	Office of the Assistant Secretary for Preparedness and Response	MCO	Medicaid Managed Care Organization
CCDF	Child Care and Development Fund	NIH	National Institutes of Health
CDC	Centers for Disease Control and Prevention	OCR	Office for Civil Rights
CHIP	Children's Health Insurance Program	OGA	Office of Global Affairs
CMS	Centers for Medicare & Medicaid Services	OIG	Office of Inspector General
CTO	Office of Chief Technology Officer	OMB	Office of Management and Budget
DHS	Department of Homeland Security	ONC	Office of National Coordinator for Health Information Technology
DME	Durable Medical Equipment	ORR	Office of Refugee Resettlement
DOJ	U.S. Department of Justice	ODD	Opioid Use Disorder
EHR	Electronic Health Record	PCS	Personal Care Services
EID	Emerging Infectious Diseases	PERM	Payment Error Rate Measurement
FBI	Federal Bureau of Investigation	PPE	Personal Protective Equipment
FDA	Food and Drug Administration	PSO	Patient Safety Organizations
FFS	Fee-For-Service	SAMHSA	Substance Abuse and Mental Health Services Administration
FPS	Fraud Prevention System	SNF	Skilled Nursing Facility
FY	Fiscal Year	TANF	Temporary Assistance for Needy Families
GAO	U.S. Government Accountability Office	TEFCA	Trusted Exchange Framework and Common Agreement
HC3	Health Sector Cybersecurity Coordination Center	T-MSIS	Transformed Medicaid Statistical Information System
HEAL	Helping to End Addiction Long-term Initiative	UAC	Unaccompanied Alien Children
HIPAA	<i>Health Insurance Portability and Accountability Act of 1996</i>		

1: Safeguarding Public Health

HHS's core mission is to enhance the health and well-being of all Americans. The emergence and spread of COVID-19 has greatly exacerbated the Department's challenge to ensure public health and safety. HHS must act vigilantly to mitigate the loss of life and negative health consequences associated with COVID-19, while continuing to operate a range of programs and services that are essential to protecting individuals and communities. This includes facilitating the safe delivery of necessary medical care unrelated to COVID-19 (e.g., routine screenings, vaccinations, and mental health and substance use disorder services), ensuring that medical products regulated by the Food and Drug Administration (FDA) are safe and effective, and working to identify and combat health disparities. To operate effective public health programs, the Department must ensure that its agencies coordinate with each other, as well as with partners at all levels of government. (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 and 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. HHS has a lead 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, and radiological nuclear events. HHS is uniquely positioned to provide guidance, funding, and support to assist communities throughout the U.S. so that they can respond to and deliver health services in response to emergencies, as well as to support sustained recovery efforts.

A key challenge is having adequate planning prior to a public health emergency and mechanisms in place to efficiently and rapidly deploy assets and provide relief to those in need of HHS resources and assistance during a public health emergency. HHS plays a critical role in identifying, acquiring, developing, distributing, and administering medical countermeasures (e.g., vaccines, therapeutics, and diagnostics) to effectively prevent and treat infectious diseases. Among HHS's offices, the Centers for Disease Control and Prevention (CDC) is responsible for responding to health threats and providing critical scientific information to protect Americans, the Biomedical Advanced Research and Development Authority (BARDA) 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 towards consideration for approval by the FDA and inclusion into the Strategic National Stockpile. The National Institutes of Health (NIH) is responsible for research related to the development of medical countermeasures. 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. And, the Office of Global Affairs (OGA) is responsible for leading international engagements to support both preparedness and response for public health emergencies.

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 management and distribution of medical supplies, establishment of alternative care sites, and distribution of vaccines and antiviral drugs. (See TMC 6) HHS should support 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, emergency medical services, and emergency management).¹ Community planning is essential to managing and distributing medical equipment and supplies. Past OIG work highlighted the importance of identifying sufficient storage space, maintaining and replacing equipment, and determining the logistics of transporting the equipment when needed.²

OIG is conducting work examining HHS's response to the current COVID-19 pandemic. Existing OIG work on prior outbreaks of communicable diseases 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 departmentwide objectives and a strategic framework for responding to international public health emergencies.³ HHS concurred with the recommendations in the report and indicated that it continues to coordinate on these efforts and will provide additional updates.

In addition, health care facilities must have emergency plans in place to keep individuals and staff safe from harm. Prior OIG work has identified opportunities for health care facilities to improve emergency preparedness and response planning during infectious disease outbreaks and disasters.⁴ For example, during Hurricane Sandy, OIG identified gaps in nursing home emergency preparedness and response.⁵ Similarly, during the Ebola outbreak in 2014, many hospitals reported that they were unprepared to receive cases and experienced challenges, such as difficulty using Federal guidance, to sustain preparedness.⁶ More recently, OIG's March 2020 survey of hospitals caring for patients known or suspected to have COVID-19 identified challenges with testing and caring for patients, keeping staff safe, and maintaining or expanding their facilities' capacity to treat patients with COVID-19.⁷ ASPR, CDC, and the Centers for Medicare & Medicaid Services (CMS) recently took steps to provide practical advice to hospitals and coordinate guidance, and these efforts should continue.

As the COVID-19 emergency continues to evolve and scientific studies provide a deeper understanding of transmission risk, long-term health effects, and other impacts, HHS faces the challenge of ensuring it is a continuous learning organization that uses up-to-date information to sustain and strengthen its emergency response. This includes addressing the availability of timely testing, providing guidance to reduce the risk of transmission, and identifying, developing, and deploying medical countermeasures (such as safe and effective therapeutics or vaccines). HHS has the significant challenge of adapting as the pandemic evolves to minimize negative health impacts on all Americans. As part of addressing this challenge, HHS must account for racial, socioeconomic, geographic, and other disparities and the effects that such disparities have on public health. Additionally, HHS must continue to plan for other emergencies, such as hurricanes, wildfires, and other natural disasters, which have and may continue to occur simultaneously with the COVID-19 pandemic.

Providing adequate oversight of FDA-regulated products

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.⁸ FDA has the added challenge of facilitating emergency response efforts related to the current COVID-19 emergency. 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. This challenge also encompasses approving and facilitating the widespread availability of COVID-19 tests.

Drug, biologic, and medical device safety

FDA's responsibility to ensure the safety and effectiveness of medical products begins before approval and continues after the product is marketed. This includes overseeing manufacturing facilities; reviewing drugs, devices, and biologics for safety and effectiveness; authorizing the use of investigational medical products; and conducting postmarket surveillance. The public relies on FDA to be expeditious in evaluating products and thoughtful in its decisions regarding approval for marketing in the U.S.

FDA's task of assessing products becomes more difficult as manufacturing processes and products become more intricate. The drug, biologic, and medical device supply chain is becoming increasingly complex, and many drugs used in the U.S. are manufactured overseas. In 2019, FDA reported that approximately 53 percent of the finished dosage from manufacturing facilities and 72 percent of active pharmaceutical ingredient manufacturing facilities of human drugs for the U.S. market were located outside of the U.S.⁹ OIG has identified vulnerabilities with FDA's oversight of manufacturing and distributing drugs, including high-risk drugs such as compounded drugs.¹⁰ This presents FDA with many challenges as medical products move through the supply chain and are at risk of diversion, theft, counterfeiting, and adulteration. When problematic products are identified, it is imperative for FDA to be able to trace the path drugs follow from manufacturer to patient.

The rapid speed at which science and technology are evolving presents new concerns for FDA to address via its oversight role. Further, managing the 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.¹¹ These networked devices include hospital-room infusion pumps, diagnostic imaging, and pacemakers.

In 2018, OIG released two reports assessing FDA's oversight of premarket and postmarket cybersecurity risks to medical devices.¹² An underlying issue identified in both reports was the opportunity for FDA to take further action in addressing cybersecurity threats to reduce risk to patients and the health care industry. FDA has made administrative changes to improve its premarket and postmarket 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

FDA has the complex responsibility of keeping the foods that it regulates safe. An estimated 1 in 6 Americans get sick from contaminated foods each year, and 3,000 die.¹³ Foodborne illnesses are largely preventable, and the American public relies on FDA, working with partners including CDC, to ensure the safety of both human and animal food.¹⁴ The Department must ensure that FDA continues to modernize the food safety system and responds effectively 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.¹⁵ FDA has made organizational changes with the goal of improving incident response through, for example, instituting its Coordinated Outbreak Response and Evaluation Network, and should continue to 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

FDA is also in charge of regulating tobacco products and has made a commitment to reduce harm from tobacco products, particularly among youth. FDA must undertake this effort amid increasing concerns surrounding the growing use and detrimental health effects of electronic nicotine delivery systems, such as vape pens and e-cigarettes. Working with 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. It remains a priority for FDA to address the public health crisis of youth e-cigarette use by, among other things, focusing product review and enforcement on youth-appealing products and investing in campaigns to educate youth about the dangers of e-cigarette use.

Tackling the opioid epidemic and ensuring access to treatment

In 2017, the President declared the opioid crisis a public health emergency. While the Nation has made progress with addressing the opioid crisis, significant challenges remain. In 2018, approximately 2 million people had an opioid use disorder (OUD),¹⁶ and an estimated 69.5 percent of all drug overdose deaths involved an opioid.¹⁷ Although the overall rate of drug overdose deaths involving opioids decreased from 2017 to 2018, it increased in five states. Additionally, in 2018 the overall rate of overdose deaths from synthetic opioids increased by 10 percent and two-thirds of opioid overdose deaths involved synthetic opioids (excluding methadone).¹⁸ There are also new and highly dangerous patterns of use, including polysubstance use of both methamphetamines and illicit fentanyl or fentanyl analogs.¹⁹

HHS developed a five-point strategy in 2017 to combat the opioid crisis and must continue working toward addressing the problem and adjusting its approach as appropriate. HHS's OpDivs have an essential role to play in preventing substance use disorders and facilitating the delivery of safe and effective treatment, including continuity of care during the coronavirus outbreak. The Department should continue to use the tools available across its programs to address the opioid epidemic while being mindful of patients' needs to access appropriate pain management, which may include the use of opioid analgesics.

Moreover, the impacts of COVID-19 on people's daily lives present new, complicating obstacles to effectively providing care related to mental health and substance use disorders. The pandemic and related stressors are thought to put people at risk for developing substance use disorders or relapsing, and those with OUD may experience negative respiratory and pulmonary health effects that make them particularly vulnerable to COVID-19.²⁰ Of additional concern, chronic respiratory disease is known to increase the risk of fatal overdose among people taking opioids, and COVID-19 could similarly increase the risk of overdose for people who have OUD.²¹ Ensuring access to effective treatment remains crucial to combating the opioid epidemic, and the COVID-19 pandemic may create additional obstacles to effectively running opioid treatment programs and providing care.

The opioid crisis is partially fueled by opioids prescribed by licensed medical professionals, dispensed by licensed pharmacies, and paid for by Federal funds. OIG identified 71,260 Medicare Part D beneficiaries who, in 2017, were prescribed opioids in quantities, or from sources, suggesting that they were at serious risk of misuse or overdose. In 2018, most of this same beneficiary population received high quantities of opioids, 11 percent had an overdose or adverse effect, and only a small subset received naloxone or medication-assisted treatment (MAT) through Medicare.²² Ensuring access to appropriate pain management therapies and combating opioid abuse remains a high priority, and CMS should continue to expand its role in ensuring that beneficiaries receive treatment for opioid use disorder. In particular, CMS should educate beneficiaries and providers about access to MAT drugs and naloxone.

The Indian Health Service (IHS) also has an important role in preventing and detecting opioid misuse or abuse. A 2019 OIG report found that IHS hospitals did not fully use the States' prescription drug monitoring programs when prescribing or dispensing opioids at certain IHS hospitals.²³ In addition, the hospitals did not use available data to identify risks in their prescribing and dispensing practices, such as giving patients opioid doses as high as 500 daily morphine milligram equivalents; and giving opioids and benzodiazepines at the same time, which puts patients at greater risk of a potentially fatal overdose. IHS could improve the quality of care for prescribing and dispensing opioids to the American Indian/Alaska Native (AI/AN) population by fully utilizing States' prescription drug monitoring programs.

Additionally, FDA has an important role to ensure the safe use of opioids. FDA approves new drugs before they are marketed in the U.S., assessing the benefits and risks that a drug can be taken safely and effectively.²⁴ FDA also monitors the safety of marketed drugs as new information becomes available. Through this framework, FDA has a range of tools and authorities: encourage the development of abuse-deterrent formulations of opioids to reduce the risk that such products may be abused; employ tools to mitigate risks associated with approved drugs, including the Risk Evaluation and Mitigation Strategy program; pursue measures that include withdrawing drugs from the market when there are serious safety concerns; and support the treatment of OUDs with FDA-approved drugs—buprenorphine, methadone, or naltrexone—as well as the development of additional therapies to treat OUD.²⁵

Ensuring access to treatment

HHS must work diligently across all of its programs to ensure access to effective, specialized OUD treatment. HHS continues to manage and oversee investments to address OUDs. From 2016 to 2019, HHS awarded more than \$9 billion in grant funding to States, Tribes, and local communities to increase access to prevention, treatment, and recovery services. For example, in FY 2019, NIH awarded \$945 million for grants, contracts, and cooperative agreements across 41 States through the Helping to End Addiction Long-term Initiative (NIH HEAL Initiative), which aims to improve treatments for chronic pain, curb the rates of OUD and overdose, and achieve long-term recovery from opioid addiction.²⁶ To address OUD and mortality, it is vital for the public to be able to access specialized and effective, quality substance use disorder treatments, including MAT. 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, only a fraction of the 2.1 million people with OUDs received treatment in 2018 (19.7 percent).²⁷ MAT combines the use of medications with counseling and behavioral therapies, which can be an effective treatment for OUDs. A 2020 OIG review found access to buprenorphine services remains challenging in many localities and recommended Substance Abuse and Mental Health Services Administration (SAMHSA) geographically target its efforts to increase providers who can treat patients in need of buprenorphine services in high-need counties.²⁸

There is a great need for treatment, especially in areas disproportionately affected by the opioid epidemic, including the AI/AN population and rural communities. HHS must ensure that money to address the opioid epidemic is efficiently and effectively spent for its intended purpose. OIG found that States have been slow to spend their awards under the State Targeted Response to the Opioid Crisis; of the total \$1 billion in the grant program, \$304 million remains unspent after 2 years.²⁹ Additionally, OIG's audit of the Health Resources and Services Administration's (HRSA) Access Increases in Mental Health and Substance Abuse Services (AIMS) grant found that HRSA followed its policies and procedures for awarding AIMS grants but did not always follow its policies and procedures when monitoring health centers' compliance with supplemental funding requirements.³⁰ It is paramount that HHS's OpDivs, including SAMHSA and HRSA, work with grantees and subgrantees to ensure grant dollars are used effectively for their intended purposes. Additionally, HHS must continue to implement the *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act*, which, among other things, requires Medicare to cover certain treatment services provided by opioid treatment programs, including methadone.

2: Ensuring the Financial Integrity of HHS Programs

HHS is the largest civilian agency in the Federal government, with a \$2.4 trillion budget, representing one-third of the total Federal budget.³¹ HHS's Medicare program is the Nation's largest health insurer by expenditures, handling more than 1 billion claims per year. Medicaid is the largest health insurer in terms of lives covered, with 76.5 million beneficiaries in Medicaid and the Children's Health Insurance Program (CHIP) enrolled individuals.³² Medicare and Medicaid are the Department's largest programs; funding for these programs (including State funding) represents 37 cents of every dollar spent on health care.³³ 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.³⁴ CMS bears the responsibility at HHS for administering these programs. Medicare expenditures totaled \$796 billion in 2019.³⁵ The Federal Medicaid budget totaled \$411.3 billion in FY 2019 (with an additional \$17.5 billion for CHIP).³⁶ 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 pricing 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 grant-making and second-largest contracting agency in the Federal government. In FY 2020, HHS awarded \$244.7 billion in grants (excluding CMS)³⁷ and \$160.7 billion in contracts.³⁸ Responsible stewardship that ensures the transparency and accountability of HHS funds is paramount to making sure that HHS beneficiaries and the American public get the true benefit of this substantial financial investment.

The Department must protect the fiscal integrity of HHS funds and ensure that beneficiaries have access to the services they need, especially in light of looming financial shortfalls in the Medicare program,^{39, 40} the expansion of Medicaid services to a larger population, and the increased dollar amounts that HHS is responsible for distributing and overseeing via grants and other mechanisms. HHS must not only manage the efficient and effective use of funds internally, but also oversee the thousands of external funding recipients' use of Federal funds to fulfill the Department's mission. Further, responsible stewardship, transparency, and accountability of the significant amount of funds provided to HHS for the COVID-19 response are needed to ensure that HHS beneficiaries and the American taxpayers receive the biggest return on their financial investment.

Controlling costs by ensuring prudent payment 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 payment policies that inadvertently incentivize improper billing or inflate prices are critical to controlling costs.

Medicare

Medicare should act as a prudent payer on behalf of taxpayers and beneficiaries, including instituting

payment policies delivering greater value. (See TMC 3 for more information on value-based payment models.) In certain contexts, Medicare payment policies, which are generally set by statute by Congress, may result in Medicare and beneficiaries paying more for care provided in certain settings than for the same care provided in other settings. For example, Medicare could have potentially saved \$4.1 billion over a 6-year period if swing-bed services at critical access hospitals had been paid for at the same rates as at skilled nursing facilities (SNFs).⁴¹ Likewise, Medicare pays hospitals different amounts for the same care depending on whether the hospital admits beneficiaries as inpatients or treats them as outpatients.

Prescription drug programs

Vulnerabilities exist in HHS's payment strategies for prescription drugs and biologicals. HHS programs accounted for 43 percent (\$143 billion) of the total U.S. prescription drug expenditures in 2018.⁴² Increased costs may limit patients' ability to afford needed prescription drugs, in some cases causing patients to skip or split doses of medication or forgo purchasing medications altogether. The way that Medicare and Medicaid pay for drugs can result in additional costs for programs and their beneficiaries. In the Part D program, for example, OIG found that although there was a 17-percent decrease in Medicare Part D prescriptions for brand-name drugs from 2011 to 2015, there was a 77-percent increase in total reimbursement for these drugs, leading to greater overall Part D spending and higher beneficiary out-of-pocket costs.⁴³ 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.⁴⁴ In addition, CMS includes prices for higher-cost versions of drugs that are not covered under Medicare Part B when setting Part B payment amounts. OIG found that, because CMS included non-covered versions when setting payment for two Part B drugs, Medicare and beneficiaries paid an extra \$366 million from 2014 through 2016.⁴⁵ 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 should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements.⁴⁶ 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 and Medicaid accounted for 59 percent, or \$103.6 billion, of all governmentwide estimated improper payments reported in FY 2019.⁴⁷ 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 accounted for \$46.2 billion, or 43 percent, of the estimated improper payments that HHS reported in FY 2019.⁴⁸ Notably, the Medicare FFS improper payment rate estimate decreased from 8.1 percent (\$31.6 billion) in FY 2018 to 7.3 percent (\$28.9 billion) in FY 2019.⁴⁹ This represents positive momentum upon which the Department and CMS can build. However, some types of providers and suppliers pose heightened risk to the financial security of Medicare. For instance, OIG and CMS have identified especially high rates of improper payments for home health, hospice, and SNF care; durable

medical equipment (DME); chiropractic services; and certain hospital services.⁵⁰ HHS and CMS have taken corrective actions for the Medicare FFS program focusing on specific service areas with high improper payment rates. This year's reduction in the improper payment rate was driven by a reduction 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. Further, 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 MA plans pose a significant vulnerability for CMS and cost taxpayers billions of dollars. In FY 2019, the improper payment rate for MA was 7.9 percent, for a total of \$16.7 billion in improper payments. Unlike in FFS, where CMS pays providers directly for each covered service received by a beneficiary, under managed care, CMS makes a capitated payment to a managed care plan for each person enrolled in the plan. In turn, the plan pays providers for services a beneficiary may require that are included in the plan's contract with CMS. CMS risk-adjusts payments to pay MA Organizations (MAOs) different amounts for beneficiaries with different expected health care costs. This helps to ensure that beneficiaries with greater health care needs have continued access to MA plans. However, OIG has found that improper payments in MA are largely driven by improper risk adjustment payments (See below for more information about risk adjustment vulnerabilities.)^{51, 52}

Medicaid

Medicaid is a Federal-State financing partnership with the 50 States, 5 territories, and the District of Columbia, each offering its own program variations reflecting State and local needs and preferences. CMS's Payment Error Rate Measurement (PERM) program measures improper payments in Medicaid and CHIP in all 50 States and the District of Columbia and produces a national improper payment rate for each program. The estimated improper payment rate increased significantly, from 9.8 percent in FY 2018 to 14.9 percent in FY 2019 (CHIP increased from 8.6 percent to 15.8 percent), largely due to changes in how CMS measured and reported beneficiary eligibility errors.⁵³ Medicaid accounted for approximately \$57.4 billion in estimated improper payments in FY 2019. CMS attributes these increases to high levels of observed eligibility errors, including States maintaining insufficient documentation to substantiate that income and other information was appropriately verified, failures to conduct timely and appropriate annual redeterminations, and claiming beneficiaries under incorrect eligibility categories that provide a higher Federal matching rate than was appropriate.⁵⁴

OIG work has found that States are not always correctly determining eligibility of individuals to receive 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, non-emergency medical transportation, targeted case management, and personal care services (PCS).⁵⁵ 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 continues to use the updated Medicaid eligibility measurements for additional states in FY 2020, the improper payment rate is likely to see similar, significant increases for this fiscal year and in the near future. As such, it will be imperative that CMS focus its efforts to examine and reduce the Medicaid and CHIP improper payment rates.

Grants and contracts

Administering grant programs and contracts requires HHS to implement internal controls to ensure program goals are met and funds are used appropriately. For grant programs, this includes oversight and guidance to award recipients. HHS is responsible for providing up-to-date policies to grant recipients and helping States and other grantees address their own financial management and internal control issues. Without proper internal controls, funds may be misspent, duplication of services may occur, and sub-recipients may not be adequately monitored. OIG has identified grantee-level concerns in several HHS programs, including some Office of Refugee Resettlement (ORR) Unaccompanied Alien Children (UAC) Program grantees reporting unallowable costs and lacking effective systems for administering program funds.⁵⁶ 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.⁵⁷

As a critical element of ensuring that grant funds are used appropriately, HHS must track and report improper payment rates for its risk-susceptible grant programs, in keeping with the *Payment Integrity Information Act of 2019*.⁵⁸ 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.⁵⁹ States receive block grants (\$16.5 billion annually) to design and operate TANF programs.⁶⁰ HHS has stated that it does not believe it has the statutory authority to collect from States the data necessary for calculating an improper payment rate for the TANF program. The Office of Management and Budget (OMB) has identified TANF as a risk-susceptible program that must report estimated rates and amounts of improper payments. HHS must continue to pursue 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 Marketplace under the *Affordable Care Act*.⁶¹ 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.⁶²

COVID-19 funding

As of October 2020, the total HHS COVID-19 appropriation was \$251 billion, including \$175 billion in Provider Relief Funds. Provider Relief Fund monies are for hospitals and other health care providers on the front lines of the coronavirus response. This funding is intended to support health-care-related expenses or lost revenue attributable to COVID-19 and to ensure that uninsured Americans can receive testing and treatment for COVID-19. By October 2020, HHS had allocated approximately \$145 billion for Provider Relief Fund payments, including \$50 billion for Medicare providers; \$15 billion for Medicaid, CHIP, and dental providers; \$59.8 billion in targeted allocations to high impact areas, safety net hospitals, rural providers, Tribal facilities, clinics and urban health centers, skilled nursing facilities, and nursing homes; and \$20 billion

for general distribution, including providers previously ineligible for payment, such as those who began practicing in 2020.⁶³ HHS has developed financial assistance policy guidance and tracking mechanisms to support the COVID-19 supplemental funding appropriations.⁶⁴ 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.

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.

Fraud involving COVID-19 funds

As noted above, HHS has been appropriated \$251 billion in COVID-19 funding. Moreover, as of October 2020, CMS had made accelerated and advanced payments to Medicare providers totaling \$108 billion and is paying providers for certain services at enhanced rates applicable during the public health emergency. CMS also temporarily 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 risks of fraud 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 thousands of external funding recipients' use and accounting of Federal funds. HHS should ensure that funds are paid only to eligible recipients in correct amounts and used in accordance with program requirements. Additionally, the Department must identify and fight fraud that would divert funds intended for COVID-19 response and recovery. This includes taking action to protect individuals from being defrauded under the guise of the public health emergency. Effective internal controls and the collection, maintenance, and analysis of relevant data are key to ensuring that funds are used for their intended purposes.

Further, 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 physicians to organized criminal enterprises with no legitimate role in health care.

Managed Care

HHS faces a significant challenge in protecting managed care programs and other non-traditional models 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.⁶⁵ In Medicare, 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.⁶⁶ CMS requires MAOs and Medicaid MCOs, prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) (hereinafter referred to as managed care plans) to implement compliance plans that include measures to prevent, detect, and correct instances of fraud, waste, and abuse and non-compliance with CMS's program requirements. However, these plans vary widely among the MAOs, as does the detection of suspected fraud. In Medicaid managed care, program integrity responsibilities are even more dispersed, as they are shared among CMS, States, and managed care plans. This makes effective oversight by CMS more complex and challenging.

Further, the MA program is vulnerable to fraud, waste, or 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. OIG 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.^{67, 68} OIG has made recommendations to CMS to improve its oversight of MA plans so that plans will ensure practices drive better care and not just higher profits and 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 payment in an attempt to increase their profits. An MAO that inappropriately denies authorization of services for beneficiaries or payments to health care providers may contribute to physical or financial harm and also misuses 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.⁶⁹

To strengthen CMS's oversight of the MA program, OIG has recommended that CMS make improvements to MA encounter data.⁷⁰ 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' submission of records with complete and valid data.⁷¹ Additionally, CMS is working to validate the completeness and accuracy of Medicare and Medicaid managed care plan encounter data and release best practices guidance for MAOs to improve encounter data submission.

In addition, to improve Medicaid managed care plan identification and referral of cases of suspected fraud or abuse, CMS is working with States to provide technical assistance and education on best practices. CMS should take further actions to ensure the completeness, validity, and timeliness of Medicaid encounter

data. Further, the agency should work with its contractors and with States to improve efforts to identify and address fraud and abuse. Additionally, CMS should work to ensure that appropriate information and referrals are sent to law enforcement.

Grants and contracts

Without adequate oversight and internal controls, HHS grants and contracts are vulnerable to fraud schemes, including embezzlement.⁷² HHS has worked to strengthen some of its program integrity efforts focused on grant programs. For instance, it issued guidance and developed tools to help HHS awarding OpDivs examine prospective grantee risk prior to awarding grants.⁷³ This information enhances awarding OpDivs' assessment of prospective grant recipients' integrity and potential performance.

Fraud involving prescription opioids

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

OpDivs should improve efforts to identify and investigate potential fraud and abuse in prescription drug programs. For instance, CMS should collect comprehensive data from Medicare Part D plan sponsors. CMS should 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.⁷⁴ Further, CMS should ensure that national Medicaid data are adequate to detect suspected fraud or abuse. The lack of reliable national Medicaid data hampers enforcement efforts. (See TMC 5.) CMS and States should follow up on prescribers with questionable prescribing patterns to ensure that Medicare Part D and Medicaid are not paying for unnecessary drugs that are being diverted for resale or recreational use. OIG has also recommended that 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.⁷⁵ 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.⁷⁶

Systems and processes for detecting and preventing fraud

With respect to detecting and preventing fraud and improper payments, CMS's Fraud Prevention System (FPS) serves as an important tool that should be improved to increase its effectiveness. Since 2011, the FPS has continuously run predictive algorithms and other sophisticated analytics nation-wide against Medicare FFS claims prior to payment to identify, prevent, and stop fraudulent claims. However, OIG found that the FPS is not as effective in preventing fraud, waste, and abuse in Medicare as it could be and recommended that CMS should make better use of the performance results within its FPS to refine and enhance its predictive analytic models.⁷⁷

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.⁷⁸ 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.⁷⁹ Furthermore, OIG work found that nearly 1,000 terminated providers—or 11 percent of all terminated providers—were inappropriately enrolled in State Medicaid programs.⁸⁰ 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 for the protection of resources. Although HHS continues to maintain a clean opinion on their 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*⁸¹ remain challenges for HHS. OIG has recommended that HHS continue to focus its efforts on resolving issues related to its IT system controls and completing data cleanup activities.

In addition, financial management systems help OpDivs ensure operational effectiveness and efficiency, financial reporting reliability, and compliance with applicable laws and regulations. OIG continues to find significant deficiencies in internal controls over segregation of duties, configuration management for approved changes to HHS financial systems, and access to HHS financial systems.⁸² HHS must take additional actions to address and resolve these issues, including continuing to work to control user access, ensuring proper approval of and documentation supporting system changes, and ensuring appropriate segregation of duties so that no one employee can both enter and approve information entered into HHS financial management systems.⁸³

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. Changes affect virtually every type of health care service and come with an array of operational and program integrity challenges. The changes also offer opportunities for better health outcomes, better quality of care, lower costs, improved transparency and choices for consumers, and reduced administrative burden on providers.⁸⁴

Medicare and Medicaid are the two largest and most complex programs at HHS. Both programs offer benefits in multiple formats (FFS, managed care, and newer payment models); cover a broad array of health conditions, providers, services, and settings; and operate pursuant to intricate statutory directives and regulatory schemes. To reduce disease spread and expedite the delivery of medically needed care during the COVID-19 public health emergency, CMS and OIG have implemented targeted flexibilities addressing coverage and payment for items and services, as well as application of fraud and abuse authorities to specified types of business arrangements.⁸⁵ These flexibilities introduce additional regulatory risks and compliance challenges for stakeholders implementing them and the Department overseeing their effectiveness.

An increasing number of Medicare and Medicaid beneficiaries are enrolling in managed care options, and an increasing number of providers are participating in value-based health care models. The Health Care Payment Learning & Action Network, an HHS-sponsored public-private partnership, estimated that for calendar year 2018, 90 percent of providers in Medicare FFS were paid based, at least in part, on quality and value, with 41 percent being paid under an alternate payment model or a population-based payment. The comparable figures for Medicaid were 34 percent and 23 percent, respectively.⁸⁶ Continued growth in value-based care is expected. CMS's Innovation Center continues to test and introduce new models across the health care spectrum, from hospitals to hospices, from integrated delivery systems to small primary care practices, and from urban areas to sparsely populated rural areas. Examples of models designed to accelerate development and testing of new payment and delivery service models include the Accountable Health Communities Model focused on unmet social needs; an Artificial Intelligence (AI) Health Outcomes Challenge to demonstrate how AI tools can be used to predict unplanned hospital and SNF admissions and adverse events; and the Direct Provider Contracting Models to test direct contracting between payers and physician practices. Recently announced models focus on patients needing insulin and patients with OUD, among others. Some models involve partnerships with states; some are all-payer models designed to align with private sector initiatives. Among its permanent value-based programs, CMS administers the Quality Payment Program for physician reimbursement and the Medicare Shared Savings Program for accountable care organizations (ACOs). CMS paused timelines and modified some model and program requirements because of the COVID-19 public health emergency.

KEY TAKEAWAYS

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

Both Medicare (FFS, Part C, and Part D) and Medicaid have proven susceptible to fraud, waste, and abuse, with FY 2019 estimates of improper payments ranging from 7.3 percent (Medicare FFS) to 14.9 percent (Medicaid) of total expenditures. Improper payments for Medicare and Medicaid totaled approximately \$103.6 billion.^{87, 88} Both programs have been on the U.S. Government Accountability Office's (GAO's) list of high-risk government programs for years. OIG's enforcement work shows that wrongdoers defraud Medicare and Medicaid through schemes ranging from false 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 (e.g., 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 ensure effectiveness of Medicare and Medicaid in delivering value, the Department should focus on three facets of the challenge: (1) aligning program incentives with quality and health outcomes, (2) strengthening program integrity, and (3) delivering on the promise of innovative technology.

Aligning program incentives with quality and health outcomes

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

The Department is undertaking initiatives to streamline, improve, and target quality measures more precisely and to move from process measures to outcome measures. Through its *Meaningful Measures* initiative, CMS reports it rolled back 20 percent of measures because they were topped out, duplicative, or overly burdensome.⁸⁹ Pursuant to Executive Order 13877 on Health Care Price Transparency and Quality, in May 2020, HHS published a National Health Quality Roadmap, in consultation with the Secretaries of Defense and Veterans Affairs, to improve patient outcomes through enhanced effectiveness and efficiency in the health care quality system supported by Federal investments. The roadmap identifies specific strategies and planned actions to drive change through establishment of coordinated governance and oversight; modernized data collection, reporting, and sharing; and reforming how measures are used in Federal quality programs.⁹⁰

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 reduce unnecessary provider burden and strengthen quality measurement. Accuracy and completeness of reported quality and performance information is also critical for payment purposes.

CMS should take steps to support and develop high-performing ACOs. OIG work examining ACOs' strategies for transitioning to value-based care identified lessons learned from the Medicare Shared Savings Program. These lessons addressed engaging beneficiaries in improving their health outcomes, managing beneficiaries with costly or complex care needs, reducing avoidable hospitalizations, controlling costs and improving quality in skilled nursing and home health care, addressing behavioral health needs and social determinants of health, and using technology to increase information sharing among providers.⁹¹ Based on this work, OIG recommended—and CMS concurred—that CMS support and share successful ACO strategies. These strategies may be adaptable in other value-based models.

The Department has been engaged in the Regulatory Sprint to Coordinated Care led by the Deputy Secretary to reform regulations administered by CMS, OIG, SAMHSA, and the Office for Civil Rights (OCR) to promote value and quality through better coordinated care for patients and broader sharing of patient information for patient care. To date, CMS and OIG have issued proposed regulations, SAMHSA has issued final regulations, and OCR has issued a request for information.⁹² Once final rules are issued, HHS should monitor results to ensure that the regulations operate as intended to promote beneficial arrangements and practices, and are not subject to abuse.

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 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, or acuity, as well as to receive improper payments. 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 care 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 waivers of customary payment, coverage, or fraud and abuse laws have been issued. Additional risks may arise from novel flexibilities granted because of the COVID-19 public health emergency. HHS should mitigate risks when designing flexibilities, monitor implementation of flexibilities for any abuse, and take prompt action to correct problems and hold wrongdoers accountable.

Value-based care models increasingly 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, recent OIG work showed that hospices lacked oversight of their registered nurses, resulting in nurses failing to meet requirements to visit beneficiaries' homes to assess quality of care provided by hospice aides.⁹³

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 it considers how and whether to incorporate such services into the regular programs before or after the public health emergency abates, HHS should be attuned to program integrity risks such as 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 to receive virtual care or provide their Medicare billing number to those purporting to furnish virtual services.

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 information technology (IT) showed that, although ACOs have used health IT to aid in care coordination, the full potential of health IT has not been realized.⁹⁴

HHS faces challenges in achieving a connected health care system to support better coordinated and value-based care in which patients' data—including conventional health care data and newer types of data related to social determinants, demographics, and personal trackers—flow freely across provider settings, with appropriate privacy and security protections. As health-related apps and technologies proliferate with the delivery of care, beneficiaries will need access to new and integrated information. This information should enable beneficiaries to choose reliable apps and technologies and to assure themselves that providers they engage with via an app or technology are trustworthy. (See TMC 5.) HHS will need to ensure that rural beneficiaries and underserved populations are not left out of 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. The law enforcement action known as Operation Brace Yourself illustrated how telephone-based remote physician consultations can make a familiar fraud scheme—charging Medicare for DME that patients do not need—bigger with less effort. HHS must provide appropriate oversight of rapidly evolving technologies, such as telehealth, networked medical devices, robotics, genomic testing, and remote monitoring. In many cases, new technologies and apps are being developed by individuals and entities—often engineers or scientists—unschooled in the complex regulations governing health care and unaware of the

range of program integrity risks their inventions may face. These new participants in the health care system will need education, guidance, and appropriate oversight.

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 likely 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 sum: realizing the promise of value-based care and payment structures

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

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, child care facilities, and beneficiaries' own homes. Some services are directly provided by HHS personnel, some delivered via HHS grant programs, and others rendered by professionals of the beneficiary's choosing, who then claim reimbursement from Federal programs. Services include health care, education, child care, and even physical 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 current race to develop treatments for and immunizations to protect against COVID-19, there will be challenges to ensure equitable distribution of risks and benefits of participation in clinical trials, as well as access to and safety and efficacy of immunizations and treatments.

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 62 million elderly or disabled Americans. In partnership with the States, the Medicaid program serves almost 68 million beneficiaries, and the CHIP program serves 6.7 million beneficiaries. IHS provides direct services for about 2.6 million members of 574 Federally recognized Tribes. These programs cover specific health care services, which may include hospital care, physician services, prescription drugs, hospice care, home- and community-based care, DME, and skilled nursing care.

Delivering covered services

Ensuring access to care that meets quality and safety standards remains a challenge. Even when Federal health care programs cover care, many beneficiaries do not actually receive the care they need. For example, OIG found that over 500,000 children with attention deficit hyperactivity disorder (ADHD) who were Medicaid-enrolled did not receive timely follow-up care, and that over 50,000 such children did not receive behavioral therapy as recommended by professional guidelines.⁹⁵ At the other end of the life cycle, OIG found that more than 80 percent of hospice providers, a growing sector of health care serving beneficiaries and their families at an extremely vulnerable time near end-of-life, had quality-of-care deficiencies.⁹⁶ Additionally, fixed daily payment structures may incentivize hospices to enroll beneficiaries for longer time periods but scrimp on care.

Quality 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 SNF, and 46 percent in long-term-care hospitals.⁹⁷ 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.⁹⁸ 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 2010.⁹⁹ OIG also has work underway to measure the rate of adverse events for patients at IHS Hospitals and work looking at substandard care in labor and delivery services at IHS Hospitals. (See TMC 6 for more information on cross-government efforts to keep patients safe.)

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 facilitates informed comparison of nursing homes. Besides selecting appropriate nursing homes, beneficiaries and families need access to better information about other types of providers, such as hospices.¹⁰⁰ CMS has announced plans to revamp its Hospital Quality Star Rating System to enable better informed decision-making for beneficiaries seeking hospital care. Especially given some curtailment of visitation 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, as this information source may be diminished during the pandemic, OIG launched an education and outreach campaign to promote nursing homes' attention to quality and inform patients, staff, and others how to report quality of care concerns.

As the COVID-19 pandemic has taken a heavy toll on beneficiaries in nursing homes, longstanding staffing and quality of care concerns remain pressing, as well as new infection control imperatives. OIG continues its series of audits to assess nursing homes' compliance with health and safety regulations. CMS enforcement actions have stopped some poor-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.¹⁰¹ Further, after a series of OIG reports about quality of care problems in IHS-operated hospitals,¹⁰² IHS created a new Quality Framework and Office of Quality to provide better guidance and oversight to its facilities and clinical staff.¹⁰³ 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 other service providers.

Although the Department has made progress, more work remains to improve access to, and quality of, all types of care. Among the top priorities, as identified by OIG work, are improving hospice care, including strengthening the survey process and better educating beneficiaries and their families and caregivers,¹⁰⁴ and improving the health and safety of nursing home residents by ensuring facility correction of deficiencies.¹⁰⁵ To continue improvements at IHS, OIG has recommended that IHS prioritize developing and implementing a staffing program to ensure there is sufficient qualified staff, including those at remote facilities; enhance training for staff and hospital leaders; intervene quickly and effectively when quality problems are identified; and establish better procedures, including improved external communication.¹⁰⁶

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 UAC Program. The Head Start program promotes school readiness for nearly 1 million children from low-income families, and the Child Care and Development Fund (CCDF) provides child care for about 1.3 million children from low-income families. The importance of properly vetting program staff to ensure children's safety is discussed below.

Operating the UAC Program

Through the UAC Program, ORR assumes custody of children who enter the U.S. without immigration status and have no parent or guardian in the U.S. able to provide for their physical and mental well-being. The child may have arrived in the U.S. alone, or in certain circumstances, may have been separated from their parents or legal guardians at the border. The UAC Program merits specific discussion, as it uniquely tasks the Department with assuming physical and legal custody for children, and the comprehensive responsibility for their welfare thus entailed. Through the UAC Program, ORR places unaccompanied or separated children in 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 UAC Program in 2002, it has served more than 400,000 children.

In recent years, ORR has been called upon to care for more children, including children who did not come to the U.S. alone but were separated from their parent or guardian at or after arrival. HHS reported to a court as part of a lawsuit that 2,737 children had been separated by the Department of Homeland Security (DHS) and remained in ORR care as of June 2018. Following OIG's January 2019 report finding that significantly more children had been separated from their parents than had previously been 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 October 2020, a court-appointed steering committee reported that it was unable to locate parents of 545 children; efforts to do so are continuing. OIG also reported, and subsequent court filings confirmed, that children continued to be separated by DHS from their parents for reasons such as the parents' criminal history; however, ORR did not always receive adequate information about parents of separated children.¹⁰⁷ 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,¹⁰⁸ lack of oversight over facilities' use of inspection checklists to ensure security measures,¹⁰⁹ and shortcomings in incident reporting systems to protect children's safety.¹¹⁰

The Department must work to ensure that UAC Program-funded facilities meet all safety requirements, including new infection control priorities related to the current COVID-19 pandemic, and provide adequate

medical and mental health care. As discussed further below, HHS must also enhance efforts to ensure that all staff with access to children have passed required background checks.

Preventing abuse and neglect

HHS funds and oversees many types of services for a broad range of beneficiaries. Countless HHS-funded providers 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 has committed to collaborating with a Presidential Task Force on Protecting Native American Children in the IHS system established in March 2019.¹¹¹ The Task Force released a report in July 2020 detailing its investigation of institutional and systemic breakdowns that failed to protect children from abuse.¹¹² Better attention to protecting vulnerable beneficiaries of all ages in all HHS care settings is also needed.¹¹³

Vetting providers and staff

Although even the most thorough vetting cannot completely prevent all potential predators from abusing Federal programs to gain access to victims, background checks are a useful tool. OIG identified failure to conduct required background checks for UAC facility staff whose jobs entail access to children.¹¹⁴ Failure to conduct adequate background checks has been a problem in other HHS child care programs as well. OIG found that some States have not fully implemented CCDF requirements to conduct comprehensive criminal background checks on current and prospective staff.¹¹⁵ Additionally, some IHS-funded tribally run health centers failed to conduct required background checks on employees working with American Indian children.¹¹⁶ Implementation of background checks for long-term-care providers remains a challenge as well.¹¹⁷ Along with demonstrating job-specific competency and qualifications, ensuring that staff pass all required background checks is an important safety measure.

The Department should improve efforts to ensure staff pass required background checks before they have access to patients in various health care settings and to children in the UAC Program, Head Start, and CCDF 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. About 1.8 million Medicare beneficiaries receive care in SNFs each year.¹¹⁸ Home and community-based services allow many Medicaid beneficiaries the opportunity to avoid undesired facility care. However, some beneficiaries have been abused or neglected by individuals, including some family members that Federal health care programs paid to care for the beneficiary at home. Group homes provide care to many especially vulnerable people, including adults with developmental disabilities. OIG's work found extensive failures to properly handle critical incidents, including suspected abuse and neglect of group home residents.¹¹⁹ OIG has also identified substantial failures to report incidents of potential abuse or neglect of Medicare beneficiaries living in SNFs

who require treatment in hospital emergency departments.¹²⁰

All States have enacted mandatory reporting laws that require certain individuals, like school teachers or nursing home staff, to report suspected abuse or neglect of vulnerable individuals. However, many instances of abuse and neglect go unreported, making it harder to help victims and hold wrongdoers accountable.¹²¹ During the ongoing COVID-19 pandemic, with many students not going to school and many patients not able to receive visitors, ensuring well-functioning processes to identify and report abuse is particularly important. Continued oversight and contact with family and friends can be particularly important to ensure quality of care in nursing homes. OIG is reviewing continuity of on-site oversight by CMS and State Survey Agencies during the pandemic. Also, CMS 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 abuse and neglect of residents of group homes. These resources include model practices for: (1) State incident management and investigation, (2) State incident management audits, (3) State mortality reviews, and (4) State quality assurance.¹²² The model practices offer strategies designed to better protect group home residents and several States have adopted these model practices.

It is important to prevent ongoing harm by identifying providers and facilities subjecting beneficiaries to abuse or neglect. States and other partners should use claims data to better identify unreported abuse and neglect. OIG created a resource guide to help accomplish this goal.¹²³ OIG has also explored Medicaid claims data as an additional way to identify potential child abuse and neglect.¹²⁴ Additional efforts would help to improve reporting. For example, CMS should compile a list of diagnosis codes that indicate potential abuse or neglect, conduct periodic data extracts, and encourage States to better use data to facilitate compliance with mandatory reporting laws.

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

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

Improving how the Federal government manages, shares, and secures its data is a priority for both Congress and the Administration.¹²⁵ The COVID-19 pandemic has underscored the need for significant and sustained efforts to modernize data practices across the Department. The response to COVID-19 is directly dependent on data that HHS collects or generates. Ensuring that government officials, researchers, the public, and other stakeholders can access timely, accurate data is critical. Data that HHS generates or collects are used to support nearly all COVID-19 response efforts, including tracking spread within nursing facilities, allocating health care resources across the country, and distributing health care Provider Relief Funds.

HHS's capabilities to operationalize and change how it internally uses and shares data for the COVID-19 response was in part aligned with the focus HHS has placed on "Leveraging the Power of Data" as one of its six strategic shifts for its *ReImagine HHS* effort.¹²⁶ Under this initiative and other associated Federal government action actions, HHS recognized the need to transform "the way HHS internally shares, analyzes, and derives new insights by leveraging data across HHS agencies...."¹²⁷ The pandemic accelerated that need, and the Department built new systems to improve and centralize some data functions in support of the COVID-19 response, including "HHS Protect."¹²⁸ The implementation of "HHS Protect" faces significant challenges including standardized and consistent reporting to HHS Protect by hospitals,¹²⁹ potential data accuracy, and the public use of data,¹³⁰ all of which highlight many longstanding issues associated with collecting, managing, and sharing data across HHS OpDivs. Continued modernization of HHS data practices is needed for HHS and its OpDivs to fulfill their missions, especially in support of the COVID-19 response.

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 service delivery system. HHS made progress on this front, but COVID-19 has presented a new challenge by amplifying demand for easier access to data. As 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. Data access needs to follow where people are, not where data happens to be. HHS will need to sustain efforts to ensure early progress turns into lasting structural improvement across the health and human service systems.

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 the public data access and sharing
 - Protecting data from misuse or unlawful disclosure

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

Data play a central role in every HHS program or policy mission.¹³¹ The COVID-19 pandemic has highlighted how data are essential in the success of HHS programs and stakeholder engagement. HHS operations depend on the effective collection and use of a large amount of sensitive and important data about individuals, health care providers, key public health assets, and other entities and actors. These data are vital to improving the health and welfare of individuals in the Nation. The Department and its programs are increasingly able to collect, store, and analyze data from disparate sources and able to 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 that 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 ("data silo") and not easily shared with other parts of HHS, even though OpDiv missions often overlap.¹³² These restrictions potentially impair the Federal government's response to COVID-19 by limiting how HHS and its partners gain insight about COVID-19.¹³³ As part of the pandemic response, HHS, other Federal agencies, State, local, and Tribal officials must work together on a nearly constant basis. Through OGA, the Department also engages with international stakeholders during a public health emergency. These collaborations require timely access to data that can flow across data silos within HHS, to different levels of government, and key stakeholders. HHS has stated that it built HHS Protect to centralize and report out data on COVID-19 quickly and improve the sharing, parsing, housing, and accessing of relevant COVID-19 data.¹³⁴ The Department continues to work on HHS Protect to address implementation difficulties that led to confusion among hospitals and public health officials.¹³⁵ Although HHS Protect was established in exigent circumstances during a pandemic under short timelines, the challenges it faces are likely indicative of future challenges that HHS may encounter as it continues to modernize its data practices.

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

Improving data governance to enhance program management

One critical step to improving HHS's capacity to utilize its data is the adoption of a better data governance approach. 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 Federal agencies.¹³⁶ It is also part of HHS Strategic Plan and the Digital Strategy at HHS.¹³⁷ The Department is taking steps to improve its data governance and more effectively use its data. In 2019, the Office of Chief Technology Officer (CTO) released a report detailing a vision of how to improve internal sharing and data analysis.¹³⁸ Additionally, under the Reimagine Data Insights Initiative, HHS launched a proof of concept data-sharing platform called "Unifi." The platform is designed to address a number of internal data-sharing issues, including automating workflow for data access requests, making open source data analytic toolkits

available, and providing dashboards and other reports to allow for more transparency about HHS data. 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 received and managed by the Department. This challenge will play a significant role as CDC moves forward with the Public Health Data Modernization Initiative to update antiquated systems and support improvement of State and local health departments' data capacities.¹³⁹ As HHS, CMS, CDC, and other OpDivs moved quickly to implement additional COVID-19 reporting requirements for health care providers and other entities, some of these efforts encountered challenges that are consistent with 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 named the Transformed Medicaid Statistical Information System (T-MSIS).¹⁴⁰ 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 to release T-MSIS data to researchers. However, concerns still exist about the completeness and reliability of the T-MSIS data. CMS has issued guidance to States to improve T-MSIS reporting of certain variables, but additional guidance and testing is needed.¹⁴¹ Similar data quality and governance challenges will be important to proactively address as HHS modernizes how it collects and uses external data from grantees or other organizations.¹⁴²

Building advanced capacity to use data to improve programs

Improving how HHS, its programs, and its employees use data is a critical component of the 2018 HHS's Data Strategy and the 2019 CTO report on internal data sharing. Better use of data may improve evidence-based policy making, improve internal administrative functions, and support the deployment of emerging technologies, all of which are part of the larger Federal and Departmental strategies to promote efficient and appropriate data use.¹⁴³

HHS's ability to use new technologies that can make the Department more effective and efficient is dependent on how well data can be gathered and curated from multiple OpDivs. For example, the CDC Data Modernization Initiative includes plans to deploy next-generation tools to improve public health surveillance.¹⁴⁴ Technologies such as machine learning and AI must function on top of large data sets. To effectively deploy those tools, HHS will have to rely on data from across its programs, which will require complex technical coordination among diverse types of data, some of which have technical limitations.¹⁴⁵ The Department is making progress by exploring solutions through Unifi, pilots, initiatives, limited scope projects, and internal training focused on improving data science skills within HHS.¹⁴⁶

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

Increasing data access and sharing with HHS partners and the public

There is an increasing recognition that Federal agency stakeholders¹⁴⁷ and the public can also use Federal data assets for the public good.¹⁴⁸ That value continues to be demonstrated throughout the response to COVID-19 as data collected or generated by HHS provides necessary information to the public. Much of HHS's data are publicly available but may not be easy to use or may have other barriers, such as a lack of standardization, that limit stakeholders' and the public's access or use.¹⁴⁹ 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. HHS also has significant authority, incentives, and influence to change the way data are shared in the health care system, public health, emergency preparedness and response, medical research, and other sectors that are vital to the Nation. Despite that significant influence, many of these sectors do not easily or regularly share data, to the detriment of patients, individuals, and the public.

Expanding and improving access to HHS data

Many HHS external stakeholders rely on effective dissemination of data collected by Departmental programs. Most importantly for the COVID-19 response, many State and local public health departments utilize HHS data to track the spread of COVID-19. However, the complex public health surveillance system and the underlying data infrastructure overseen by HHS faces challenges in providing COVID-19 data to the public and other external stakeholders. For example, in July 2020, HHS changed COVID-19 reporting processes for hospitals from the CDC National Healthcare Safety Network to HHS Protect to streamline data for the COVID-19 response.¹⁵⁰ The change caused confusion on how the public and other stakeholders could obtain hospital COVID-19 data previously made public by CDC and there were delays in HHS Protect making updated data publicly available. HHS also had successes. CMS, through the Data.CMS.gov platform, made COVID-19 nursing home data available after it updated reporting requirements.¹⁵¹ Both examples demonstrate potential challenges and the value of HHS using modern approaches to make data publicly available.

Currently, most public access to HHS data does use contemporary approaches, such as the use of application programming interfaces (APIs). Although data might be available, they may not be well understood or in easily accessed formats. OpDivs are 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.¹⁵² NIH utilized a modern, iterative approach providing researchers access to the *All of Us* data earlier in the data collection process to facilitate continued development of the research platform based on feedback from researchers. In September 2019, FDA released a Technology Modernization Action Plan.¹⁵³ Among other goals, FDA aims to improve how it uses data to carry out its mission and improve communication and collaboration with other government and external stakeholders. 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 have not fully realized and benefited from modern approaches to improve the appropriate flow of electronic health information. Promoting interoperability is part of the four Secretarial priorities and HHS will need to continue utilizing its significant leverage to expedite progress.¹⁵⁴

Routine and robust health information exchange between providers remains a challenge, although there are signs of recent progress. In 2018, 46 percent of acute care hospitals electronically performed all four interoperability functions: find patient health information, send, receive, and integrate patient summary of care records from sources outside their health system.¹⁵⁵ 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 62 percent over the same timeframe.¹⁵⁶ Interoperability of electronic health records (EHR) also plays a crucial role in providing data for the response to COVID-19. Many agencies in HHS, including CDC, FDA, the Office of National Coordinator for Health Information Technology (ONC); external standards organizations; and individual developers moved quickly to develop and issue interoperability standards related to COVID-19 data.¹⁵⁷ The level of effort and engagement needed to issue these COVID-19 standards highlights that the factors limiting increased interoperability and exchange more broadly are numerous and complicated. Several Departmental initiatives depend on improving the interoperability of electronic health information, including the transition to value-based care and payment (See TMC 3). Making real progress so that the health care system and patients can benefit from the improved flow of data will take sustained engagement within HHS, with HHS partners, and with external stakeholders such as organizations that set data standards.

Recently, HHS has taken significant steps using regulatory authorities and its influence to improve and potentially standardize the way in which health information can be accessed, used, and exchanged. In 2020, ONC finalized rules directly related to improving interoperability and helping cement data standards and data exchange mechanisms.¹⁵⁸ In a coordinated effort, CMS finalized rules to improve the interoperability of health information at many entities it regulates through the use of standard, open APIs.¹⁵⁹ Additionally, the CMS pilot to provide Medicare claims data to providers via API in the *Data at the Point of Care* pilot involved provider organizations that included over 100,000 providers.¹⁶⁰ ONC also moved to the next stage of implementing the Trusted Exchange Framework and Common Agreement (TEFCA) by selecting a recognized coordinating entity to develop, update, implement, and maintain TEFCA.¹⁶¹ While TEFCA holds promise for improving how health information is exchanged, many hurdles remain. Overcoming them will require close coordination between government, the recognized coordinating entity, and industry. The challenge for HHS will be translating these new authorities 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.

Protecting data from misuse or unlawful disclosure

Managing, using, and sharing data must be complemented by appropriately securing data. External threats to the confidentiality, integrity, and availability of HHS-held data are persistent and growing. Similar to data governance and sharing challenges, several aspects of cybersecurity within the Department are siloed within its OpDivs and programs. As a result, deployment of effective cybersecurity can be highly variable across the Department's OpDivs. Further increasing the challenge is the vital nature of many of the Department's programs, operations, and data. Interruption of these programs caused by a cyberattack may have significant negative effects on the health and welfare of the Nation. This is especially true given HHS's central role in the COVID-19 response. Cyber threats to

HHS increased due to adversaries attempting to take advantage of the public health emergency to infiltrate HHS systems or impede their performance, which included a large distributed denial-of-service attack that persisted for weeks.¹⁶² Outside of the Department's systems, many of HHS's partners and grantees, and the health care system at large, are subject to an increasing amount of cyber threats. For example, in October 2020, HHS, CISA, and the Federal Bureau of Investigation (FBI) issued a cybersecurity advisory warning of the potential for increased and imminent cybercrime threat in the form of ransomware to hospitals and other health care providers.¹⁶³ Public confidence in 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 medical treatments of the future.

Improving HHS's cybersecurity posture

The Department has made progress in improving its overall cybersecurity posture, but certain weaknesses persist and pose challenges. Recent OIG work found that HHS continues to implement changes to strengthen the maturity of its enterprise-wide cybersecurity program but the program still has some weaknesses and deficiencies.¹⁶⁴ Other OIG work that examined eight Departmental OpDivs identified vulnerabilities in configuration management, access control, data input control, and software patching.¹⁶⁵ This work highlights the challenge the Department faces to simultaneously improve the security across OpDivs while also helping provide resources and support so that OpDivs can take action to improve their own cybersecurity. (See TMC 1 for more information about FDA's role regarding cybersecurity of medical devices.)

HHS also faces data security challenges outside of cyberthreats. For example, HHS has recognized the threat of foreign government action aimed at unduly influencing and capitalizing on medical research programs funded and overseen by the Department. HHS's challenge in responding to these threats is the need to protect these programs while also supporting an open, collaborative research approach that is critical to scientific advances.¹⁶⁶ The Department has made progress recognizing threats, working with law enforcement as appropriate, studying the potential impact on its programs, and working with grantees to mitigate risks.¹⁶⁷

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 continue to increase during the COVID-19 pandemic. Additionally, many health care providers rapidly shifted care to telehealth and other remote technology. If telehealth and remote care utilization remain at levels seen during the pandemic, health care cybersecurity may also depend on where and how patients access care. This may pose a significant challenge because health care entities remain prime targets for cyberattacks, and health care data are reported to be among the most valuable data for cybercriminals. In addition to data and identity theft, cyberthreats can also pose safety risks by causing system outages needed for patient care or exploiting vulnerabilities in the growing number of connected medical devices and other medical equipment involved in direct patient care.

The Department made some progress to bolster cybersecurity in the health care industry. Since 2019, the HHS Health Sector Cybersecurity Coordination Center (HC3) has issued a number of 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.¹⁶⁸ FDA has continued to issue safety communications on medical device cyber vulnerabilities working in partnership with the Cybersecurity

Infrastructure Security Agency of DHS (CISA).¹⁶⁹ The Department also proposed rules to protect donations of cybersecurity technology within the health care industry to promote increased adoption of cybersecurity.¹⁷⁰ These developments demonstrate HHS's commitment to working across the health care sector to better prepare for and remediate continuously evolving cyber threats.

The Department also plays a significant role in ensuring the privacy of sensitive individual data, such as personal health information, genetic information, and more. Most 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. Most recently, OIG found that pharmacies were accessing a CMS Medicare beneficiary eligibility system for inappropriate purposes, including to evaluate marketing leads or by allowing marketing companies to use the pharmacies' information to access to the CMS system. This put the privacy of beneficiaries' personal health information at risk. As HHS and OpDivs continue to collect more data, ensuring that external entities access and use this information for authorized purposes will be vital to protect the privacy and security of millions of individuals.

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 associated with 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.¹⁷¹ 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. The Department has made progress by issuing guidance and frequently asked questions related to mobile apps, use of APIs, and working with the Federal Trade Commission to build a web-based tool for developers of health-related mobile apps.¹⁷²

6: Improving Collaboration To Better Serve Our Nation

HHS faces some of the largest and most complex issues that challenge 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. For HHS to achieve its mission, it needs to collaborate effectively, including across HHS programs and 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 Rural Health Task Force and the Secretary's Intradepartmental Council on Native American Affairs, 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 critical initiatives and resources are working in concert, such as those for emergency preparedness and response and law enforcement investigations. Established networks of information exchange with other governments, such as through the Secretary's Tribal Advisory Committee, can better allow HHS programs to reflect community needs. Collaboration with HHS's vast array of non-governmental stakeholders—from health care providers, to food and drug manufacturers, health systems, nursing homes, hospices, professional associations, scientists, 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.

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

Barriers to HHS collaboration include navigating a breadth of stakeholders with different goals and authorities, the scope and complexity of the problems that HHS needs partnerships to solve, and the ever-changing landscape of the health and human services sectors. Overcoming these barriers requires the Department 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
 - Turning the tide on the opioid crisis
 - Protecting children
 - Keeping patients safe

Combating COVID-19

The COVID-19 pandemic underscores the critical importance of effective coordination in emergency preparedness and response. The unprecedented nature of the pandemic quickly increased the need for collaboration among stakeholders, including related to temporary emergency expansions, Federal funds distribution, managing health care programs, nursing home safety, vaccine development, 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, 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 and confused hospitals and the public.¹⁷³ Reports from OIG related to coordination in past emergencies have found that by consolidating outgoing communication and requests for data or information, Federal agencies can reduce burden on States and other stakeholders and that clearly defined roles can ensure that staff are not working at cross-purposes.

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 May 2020 to continue to help hospitals sustain preparedness for emerging infectious diseases (EID) by coordinating guidance and providing practical advice for all hospitals.¹⁷⁴ 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 have continued during the COVID-19 response.

Turning the Tide on the Opioid Crisis

The COVID-19 pandemic has further challenged HHS in achieving its goal of reducing opioid morbidity and mortality. The pandemic may be exacerbating the nation's opioid epidemic and individuals with an opioid use disorder may be at greater risk for COVID-19 (see TMC 1).¹⁷⁵ 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 prescription drug monitoring program data, for example, may help to improve safe prescribing practices and prevent prescription drug abuse and misuse.¹⁷⁶

Part of the framework of HHS's strategy to combat opioid abuse, misuse, and overdose is supporting stakeholder efforts to make MAT available to all individuals with OUD who meet the eligibility criteria. To do so, HHS has a goal to increase the number of MAT providers.¹⁷⁷ Aligned with this goal, OIG recommended that SAMHSA work with its State partners and grantees to determine the best strategies to expand access to buprenorphine services, particularly targeted to high-need counties with low-to-no patient capacity, and to partner with HRSA in ongoing efforts to address health professional shortage areas.¹⁷⁸ Better collaboration is a key step in helping to reduce geographic disparities in access to MAT. Improved stakeholder communication may also help make MAT more available. In another recent report, OIG recommended that CMS educate Medicare Part D beneficiaries and providers about access to drugs for MAT and naloxone and partner with SAMHSA when developing these educational strategies.¹⁷⁹

Protecting Children

In 2017 and 2018, the Department of Justice (DOJ) and DHS took steps to increase enforcement of immigration laws, culminating in the spring 2018 implementation of a "zero-tolerance" policy for certain immigration offenses. Under that policy, large numbers of families entering the United States without authorization were separated by DHS.

Typically, adults were held in Federal detention while their children were transferred to the care ORR within HHS. A June 20, 2018, Executive Order curtailed the policy but did not address reunification of families already separated. On June 26, 2018, a Federal district court issued a preliminary injunction prohibiting family separations (subject to some exceptions) and ordered the Federal government to quickly reunify separated families who met certain criteria.

In a review of challenges that HHS faced in responding to the zero-tolerance policy and with reunifying separated children with their parents,¹⁸⁰ 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 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 inter-agency coordination also limited the Department's ability to plan for the care of children in its custody. For instance, Federal agencies involved in immigration did not effectively share information in advance of the zero-tolerance policy, despite existing channels to facilitate high-level interagency coordination and engagement on important immigration issues. Furthermore, HHS and DHS did not collaborate on systems to track 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.

An audit of facilities serving children who arrive in the United States unaccompanied, as well as children who are separated from their parents or legal guardians by immigration authorities, found shortfalls in operations that could put children at risk, including related to required FBI fingerprint and out-of-State Child Protective Services background checks for employees.¹⁸¹ OIG recommendations emphasized the importance of the Administration for Children and Families' (ACF's) monitoring of, and communication with, these facilities to help ensure children's safety.

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 are providing such services as foster care and child care. OIG audits of State compliance with employee background check and other health and safety requirements in HHS programs found lapses that can put children at risk,^{182, 183} 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, OUD treatment, and hospice and nursing home services are among those on the front-line of ensuring safety for beneficiaries receiving care through HHS programs and at HHS facilities. Reports from OIG have identified issues with HHS coordination with, and outreach to, external partners that may leave patients at risk of harm, including a series of reports finding deficiencies in State Agency oversight of nursing homes' compliance with life safety and emergency preparedness requirements.¹⁸⁴

Recent cases of patient abuse by IHS employees have raised concerns about protecting the AI/AN 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.^{185, 186} An OIG report examining IHS's patient protection policies emphasized, among other recommendations, the need for the agency to reach out to Tribal communities to inform them of patient rights, solicit community concerns, and address barriers that may deter patients and their families from reporting abuse.¹⁸⁷ A 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 FBI fingerprint background checks for all employees, contractors, and volunteers who have regular contact with Indian children.¹⁸⁸ This creates an increased risk that an individual with a disqualifying criminal history in a different State could be hired into a position with 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 that may compromise the safety and well-being of Indian children who receive treatment at IHS-funded Tribal health programs.¹⁸⁹

Patient Safety Organizations (PSOs) are designed to reduce the risk associated with patient care by establishing an environment where clinicians and health care organizations can voluntarily report and analyze data. The Agency for Healthcare Research and Quality's (AHRQ's) voluntary PSO program is the first and only nationwide program that offers legal protections for providers to disclose and learn from patient safety events. Many hospitals that participate in the PSO program find that it has improved patient safety. However, challenges to progress remain, including with AHRQ communication with stakeholders, such as provider associations, professional societies, and risk management organizations.¹⁹⁰

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.

ENDNOTES

- ¹ *OIG, Selected Health Care Coalitions Increased Involvement in Whole Community Preparedness But Face Developmental Challenges Following New Requirements in 2017*, OEI-04-18-00080, April 2020. Available at <https://oig.hhs.gov/oei/reports/oei-04-18-00080.pdf>.
- ² *OIG, State and Local Pandemic Influenza Preparedness: Medical Surge, September 2009*, OEI-02-08-00210. Available at <https://oig.hhs.gov/oei/reports/oei-02-08-00210.pdf>.
- ³ *OIG, HHS Did Not Always Efficiently Plan and Coordinate Its International Ebola Response Efforts*, A-04-16-03567, August 2019. Available at <https://oig.hhs.gov/oas/reports/region4/41603567.pdf>.
- ⁴ *OIG, Toolkit: Insights for Health Care Facilities From OIG's Historical Work on Emergency Response*, August 2020. Available at <https://oig.hhs.gov/reports-and-publications/featured-topics/response/toolkit-healthcare.asp>.
- ⁵ *OIG, Gaps Continue to Exist in Nursing Home Emergency Preparedness and Response During Disasters: 2007–2010*, April 2012. Available at <https://oig.hhs.gov/oei/reports/oei-06-09-00270.pdf>.
- ⁶ *OIG, Hospitals Reported Improved Preparedness for Emerging Infectious Diseases After the Ebola Crisis*, OEI-06-15-00230, October 2018. Available at <https://oig.hhs.gov/oei/reports/oei-06-15-00230.pdf>.
- ⁷ *OIG, Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020*, OEI-06-20-00300. Available at: <https://oig.hhs.gov/oei/reports/oei-06-20-00300.pdf>.
- ⁸ *FDA, Fact Sheet: FDA at a Glance*, October 2019. Available at <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance>.
- ⁹ *FDA, Safeguarding Pharmaceutical Supply Chains in a Global Economy*, October 2019. Available at: <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>; *FDA, Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program*, December 2019. Available at: <https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019>.
- ¹⁰ *OIG, Drug Supply Chain Security: Wholesalers Exchange Most Tracing Information*, OEI-05-14-00640, September 2017. Available at <https://oig.hhs.gov/oei/reports/oei-05-14-00640.pdf>. *OIG, Drug Supply Chain Security: Dispensers Received Most Tracing Information*, OEI-05-16-00550, March 2018. Available at <https://oig.hhs.gov/oei/reports/oei-05-16-00550.pdf>.
- ¹¹ *FDA, Cybersecurity*, August 2020. Available at <https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity#guidance>.
- ¹² *OIG, FDA Should Further Integrate Its Review of Cybersecurity Into the Premarket Review Process for Medical Devices*, OEI-09-16-00220, September 2018. Available at: <https://oig.hhs.gov/oei/reports/oei-09-16-00220.pdf>. *OIG, The Food and Drug Administration's Policies and Procedures Should Better Address Postmarket Cybersecurity Risk to Medical Devices*, A-18-16-30530, October 2018. Available at <https://oig.hhs.gov/oas/reports/region18/181630530.pdf>.
- ¹³ *CDC, CDC and Food Safety*, June 2020. Available at <https://www.cdc.gov/foodsafety/cdc-and-food-safety.html/>.

¹⁴ FDA, *What does FDA regulate?* August 2020. Available at: <https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate>.

¹⁵ OIG, *Challenges Remain in FDA's Inspections of Domestic Food Facilities*, OEI-02-14-00420, September 2017. Available at <https://oig.hhs.gov/oei/reports/oei-02-14-00420.pdf>. OIG, *The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply*, A-01-16-01502, December 2017. Available at <https://oig.hhs.gov/oas/reports/region1/11601502.pdf>.

¹⁶ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health*, August 2019. Available at <https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf>.

¹⁷ CDC, *Drug Overdose Deaths*, March 2020. Available at <https://www.cdc.gov/drugoverdose/data/statedeaths.html>, citing Hedegaard H, Miniño AM, Warner M, *Drug overdose deaths in the United States, 1999–2018*, NCHS Data Brief, no. 356, National Center for Health Statistics, 2020. Available at <https://www.cdc.gov/nchs/products/databriefs/db356.htm>.

¹⁸ Hedegaard H, Miniño AM, Warner M, *Drug overdose deaths in the United States, 1999–2018*, NCHS Data Brief, no. 356, National Center for Health Statistics, 2020. Available at <https://www.cdc.gov/nchs/products/databriefs/db356.htm>.

¹⁹ HHS, *Combating an Epidemic: Legislation to Help Patients with Substance Use Disorder*, Testimony before the House Subcommittee on Health of the Committee on Energy and Commerce, March 3, 2020. Available at https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Testimony-Giroir_Brandt-Opioid%20Legislative%20Hearing_030320.pdf.

²⁰ NIH, *COVID-19: Potential Implications for Individuals with Substance Use Disorders*, April 2020. Available at <https://www.drugabuse.gov/about-nida/noras-blog/2020/04/covid-19-potential-implications-individuals-substance-use-disorders>.

²¹ Ibid.

²² OIG, *Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look*, OEI-02-19-00130, May 2020. Available at <https://oig.hhs.gov/oei/reports/oei-02-19-00130.pdf>.

²³ OIG, *IHS Needs To Improve Oversight of Its Hospitals' Opioid Prescribing and Dispensing Practices and Consider Centralizing Its Information Technology Functions*, A-18-17-11400, July 2019. Available at <https://oig.hhs.gov/oas/reports/region18/181711400.pdf>.

²⁴ FDA, *Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework Guidance for Industry*, June 2019. Available at <https://www.fda.gov/media/128150/download>. FDA's 2018 Strategic Policy Roadmap, January 2018. Available at <https://www.fda.gov/media/110587/download>.

²⁵ FDA, *Opioid Medications*, August 2020. Available at <https://www.fda.gov/drugs/information-drug-class/opioid-medications>. FDA, *Information about Medication-Assisted Treatment (MAT)*, February 2019. Available at: <https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat>.

²⁶ NIH funds \$945 million in research to tackle the national opioid crisis through NIH HEAL Initiative. Available at <https://www.nih.gov/news-events/news-releases/nih-funds-945-million-research-tackle-national-opioid-crisis-through-nih-heal-initiative>.

²⁷ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health*, August 2019. Available at <https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf>.

²⁸ OIG, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder*, OEI-12-17-00240, January 2020. Available at <https://oig.hhs.gov/oei/reports/oei-12-17-00240.pdf>.

²⁹ OIG, *States' Use of Grant Funding for a Targeted Response to the Opioid Crisis*, OEI-BL-18-00460, March 2020. Available at <https://oig.hhs.gov/oei/reports/oei-BL-18-00460.pdf>.

³⁰ OIG, *HRSA's Monitoring Did Not Always Ensure Health Centers' Compliance with Federal Requirements for HRSA's Access Increases In Mental Health and Substance Abuse Services Supplemental Grant Funding*, A-02-18-02010, July 2020. Available at <https://oig.hhs.gov/oas/reports/region2/21802010.asp>.

³¹ USASpending.gov, Agency Spending Profile. <https://www.usaspending.gov/agency>.

³² CMS, *CMS Fast Facts*, July 2020. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts>.

³³ CMS, *Financial Report, FY 2019*. Available at <https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2019>.

³⁴ CMS, *CMS Fast Facts*, July 2020. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts>.

³⁵ CMS, *Trustees Report & Trust Funds*, April 2020. Available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds>.

³⁶ HHS, *Budget in Brief, FY 2021*. Pg. 19. Available at <https://www.hhs.gov/sites/default/files/fy-2021-budget-in-brief.pdf>.

³⁷ HHS Tracking Accountability in Government Grants System (TAGGS), Grants by OPDIV report. Available at <https://taggs.hhs.gov/ReportsGrants/GrantsByOPDIV>.

³⁸ As of August 31, 2020, HHS awarded \$160.7 billion for contractual services and supplies. USASpending.gov, Contractual services and supplies spending. Available at: https://www.usaspending.gov/explorer/object_class.

³⁹ According to the 2020 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, the Trustees stated that the Federal Hospital Insurance Trust Fund is expected to be depleted in 2026. Available at <https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf>.

⁴⁰ GAO, *U.S. Government's 2019 and 2018 Consolidated Financial Statement*. Available at <https://www.gao.gov/products/GAO-20-315R>.

⁴¹ OIG, *Medicare Could Have Saved Billions at Critical Access Hospitals if Swing-Bed Services Were Reimbursed Using the Skilled Nursing Facility Prospective Payment System Rates*, A-05-12-00046, March 2015. Available at <https://oig.hhs.gov/oas/reports/region5/51200046.asp>.

⁴² CMS, *National Health Expenditures by type of service and source of funds*, CY 1960-2018, December 2019. Available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>.

⁴³ OIG, *Increases in Reimbursement for Brand Name Drugs in Part D*, OEI-03-15-00080, June 2018. Available at <https://oig.hhs.gov/oei/reports/oei-03-15-00080.asp>.

⁴⁴ The specific drugs at issue were inhalation drugs administered through DME and supplying fees for immunosuppressive drugs associated with an organ transplant, oral anticancer chemotherapeutic drugs and oral antiemetic drugs used as a part of an anticancer chemotherapeutic regimen. See OIG, *Medicare Part B Prescription Drug Dispensing and Supplying Fee Payment Rates Are Considerably Higher Than the Rates Paid by Other Government Programs*, A-06-12-00038, September 2014. Available at <https://oig.hhs.gov/oas/reports/region6/61200038.asp>.

⁴⁵ OIG, *Issue Brief: Excluding Noncovered Versions When Setting Payment for Two Part B Drugs Would Have resulted in Lower Drug Costs for Medicare and its Beneficiaries*, OEI-12-17-00260, November 2017. Available at <https://oig.hhs.gov/oei/reports/oei-12-17-00260.pdf>.

⁴⁶ 31 USC § 3351(4)

⁴⁷ GAO, *Payment Integrity: Federal Agencies' Estimates of FY 2019 Improper Payments*. Available at <https://www.gao.gov/assets/710/705016.pdf>.

⁴⁸ HHS, *2019 Agency Financial Report*. Available at <https://www.hhs.gov/sites/default/files/fy2019-hhs-agency-financial-report.pdf>.

⁴⁹ CMS, *2019 Medicare Fee-for-Service Supplemental Improper Payment Data*. Available at <https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programscertcert/2019-medicare-fee-service-supplemental-improper-payment-data>.

⁵⁰ OIG, *Online Portfolio: Home Health*, February 2016. Available at <https://oig.hhs.gov/reports-and-publications/portfolio/home-health/>. OIG, *Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio*, OEI-02-16-00570, July 2018. Available at <https://oig.hhs.gov/oei/reports/oei-02-16-00570.asp>. OIG, *CMS Improperly Paid Millions of Dollars for Skilled Nursing Facility Services When the Medicare 3-Day Inpatient Hospital Stay Requirement Was Not Met*, A-05-16-00043, February 2019. Available at <https://oig.hhs.gov/oas/reports/region5/51600043.pdf>. OIG, *Medicare Improperly Paid Suppliers for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Provided to Beneficiaries During Inpatient Stays*, A-09-17-03035, November 2018. Available at <https://oig.hhs.gov/oas/reports/region9/91703035.pdf>. OIG, *Medicare Improperly Paid Providers for Items and Services Ordered by Chiropractors*, A-07-17-03002, July 2018. Available at <https://oig.hhs.gov/oas/reports/region9/91602033.pdf>. OIG, *Medicare Improperly Paid Hospitals Millions of Dollars for Intensity-Modulated Radiation Therapy Planning Services*, A-09-16-02033, August 2018. Available at <https://oig.hhs.gov/oas/reports/region9/91602033.pdf>.

⁵¹ OIG, *Billions in Estimated Medicare Advantage Payments From Chart Reviews Raise Concerns*, OEI-03-17-00470, December 2019. Available at <https://oig.hhs.gov/oei/reports/oei-03-17-00470.asp>.

⁵² OIG, *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials*, OEI-09-16-00410, September 2018. Available at <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>.

⁵³ CMS, *2019 PERM Medicaid Improper Payment Rates*. Available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicaid-and-CHIP-Compliance/PERM/PERMErrorRateFindingsandReport>.

⁵⁴ CMS, *Fiscal Year (FY) 2019 Medicare Fee-For-Service Improper Payment Rate is Lowest Since 2010 while data points to concerns with Medicaid eligibility*. Available at <https://www.cms.gov/newsroom/press-releases/fiscal-year-fy-2019-medicare-fee-service-improper-payment-rate-lowest-2010-while-data-points>.

⁵⁵ OIG, *Vulnerabilities Exist in State Agencies' Use of Random Moment Sampling To Allocate Costs for Medicaid School-Based Administrative and Health Services Expenditures*, December 2018. Available at <https://oig.hhs.gov/oas/reports/region7/71804107.asp>. OIG, *Michigan Did Not Always Comply With Federal and State Requirements for Claims Submitted for the Nonemergency Medical Transportation Brokerage Program*, A-5-16-00021, June 2018. Available at <https://oig.hhs.gov/oas/reports/region5/51600021.asp>. OIG, *Minnesota Did Not Always Comply With Federal and State Requirements for Claims Submitted for the Nonemergency Medical Transportation Brokerage Program*, A-05-15-00026, September 2017. Available at <https://oig.hhs.gov/oas/reports/region5/51500026.asp>. OIG, *Oklahoma Did Not Adequately Oversee Its Medicaid Nonemergency Medical Transportation Program*, A-06-16-00007, August, 2017. Available at <https://oig.hhs.gov/oas/reports/region6/61600007.asp>. OIG, *Work Plan: Medicaid Targeted Case Management*, 2020. Available at <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000235.asp>. OIG, *Personal Care Services Portfolio*. Available at <https://oig.hhs.gov/newsroom/media-materials/2016/mpcs.asp>.

⁵⁶ OIG, *Featured Topic: Unaccompanied Children*, August 2020. Available at <https://oig.hhs.gov/reports-and-publications/featured-topics/uac/>.

⁵⁷ OIG, *Recommendation Followup: Vulnerabilities Continue To Exist in the HHS Small Business Innovation Research Program*, OEI-04-18-00230, March 2019. Available at <https://oig.hhs.gov/oei/reports/oei-04-18-00230.asp>.

⁵⁸ 31 USC §§ 3351-3358.

⁵⁹ OIG, *U.S. Department of Health and Human Services Met Many Requirements of the Improper Payments Information Act of 2002 but Did Not Fully Comply for Fiscal Year 2019*, A-17-20-52000, May 2020. Available at <https://oig.hhs.gov/oas/reports/region17/172052000.asp>.

⁶⁰ Congressional Research Service, *The Temporary Assistance for Needy Families (TANF) Block Grant: Responses to Frequently Asked Questions*, July 2020. Available at: <https://fas.org/sfp/crs/misc/RL32760.pdf>.

⁶¹ OIG, *The Centers for Medicare & Medicaid Services Did Not Identify and Report Potential Antideficiency Act Violations for 12 Contracts Used To Establish the Federal Marketplace Under the Affordable Care Act*, A-03-16-03001, February 2020. Available at <https://oig.hhs.gov/oas/reports/region3/31603001.asp>.

⁶² OIG, *CMS Did Not Administer and Manage Strategic Communications Services Contracts in Accordance With Federal Requirements*, A-12-19-20003, July 2020. Available at <https://oig.hhs.gov/oas/reports/region12/121920003.asp>.

⁶³ HHS, *CARES Act Provider Relief Fund: General Information*. Available at <https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/general-information/index.html#timeline>.

⁶⁴ HHS, Coronavirus (COVID-19) Grant Opportunities and Guidance. Available at <https://www.hhs.gov/coronavirus/grants/index.html#covid19>.

⁶⁵ CMS, *Medicaid Managed Care Enrollment and Program Statistics, 2017*. Available at <https://www.medicaid.gov/medicaid/managed-care/downloads/enrollment/2017-medicaid-managed-care-enrollment-report.pdf>.

⁶⁶ OIG, *Weaknesses Exist in Medicaid Managed Care Organizations' Efforts To Identify and Address Fraud and Abuse*, OEI-02-15-00260, July 2018. Available at <https://oig.hhs.gov/oei/reports/oei-02-15-00260.asp>.

⁶⁷ OIG, *Billions in Estimated Medicare Advantage Payments From Chart Reviews Raise Concerns*, OEI-03-17-00470, December 2019. Available at <https://oig.hhs.gov/oei/reports/oei-03-17-00470.asp>.

⁶⁸ OIG, *Billions in Estimated Medicare Advantage Payments From Diagnoses Reported Only on Health Risk Assessments Raise Concerns*, OEI-03-17-00471, September 2020. Available at <https://oig.hhs.gov/oei/reports/oei-03-17-00471.asp>.

⁶⁹ OIG, *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials*, OEI-09-16-00410, September 2018. Available at <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>.

⁷⁰ OIG, *CMS's Encounter Data Lack Essential Information That Medicare Advantage Organizations Have the Ability to Collect*, OEI-03-19-00430, August 2020. Available at <https://oig.hhs.gov/oei/reports/OEI-03-19-00430.asp>.

⁷¹ OIG, *Medicare Advantage Encounter Data Show Promise for Program Oversight, But Improvements Are Needed*, OEI-03-15-00060, January 2018. Available at <https://www.oig.hhs.gov/oei/reports/oei-03-15-00060.asp>.

⁷² OIG has found that some Tribes and Tribal organizations have not adequately protected funds under the Indian Self-Determination and Education Assistance Act and other programs, resulting in embezzlement and theft of Federal funds.

⁷³ HHS codified the Uniform Guidance at 45 CFR part 75, which prescribes instructions and other pre-award matters for the granting agency to use in the announcement and application process for awards made on or after December 26, 2014. The Uniform Guidance stipulates that the use of certain sections is required only for competitive Federal awards but may also be used by the HHS awarding agency for non-competitive awards where appropriate or required by Federal statute.

⁷⁴ OIG, *Key Medicare Tools To Safeguard Against Pharmacy Fraud and Inappropriate Billing Do Not Apply to Part D*, OEI-02-15-00440, March 2020. Available at <https://oig.hhs.gov/oei/reports/oei-02-15-00440.asp>.

⁷⁵ OIG, *Two Indian Health Service Hospitals Had System Security and Physical Controls for Prescription Drug and Opioid Dispensing but Could Still Improve Controls*, A-18-1630540, November 2017. Available at <https://oig.hhs.gov/oas/reports/region18/181630540.pdf>.

⁷⁶ See, e.g., *Examining Efforts to Prevent Opioid Overutilization and Misuse in Medicare and Medicaid*, Testimony of Maureen Dixon, pp. 4–5, May 2019. Available at <https://oig.hhs.gov/testimony/docs/2018/dixon-testimony052918.pdf>.

⁷⁷ OIG, *The Centers for Medicare & Medicaid Services Could Improve Performance Measures Associated With the Fraud Prevention System*, A-01-15-00509, September 2017. Available at <https://oig.hhs.gov/oas/reports/region1/11500509.pdf>.

⁷⁸ OIG, *Problems Remain for Ensuring That All High Risk Medicaid Providers Undergo Criminal Background Checks*, July 2019. Available at <https://oig.hhs.gov/oei/reports/oei-05-18-00070.asp>.

⁷⁹ OIG, *Twenty-Three States Reported Allowing Unenrolled Providers To Serve Medicaid Beneficiaries*, OEI-05-19-00060, March 2020. Available at <https://oig.hhs.gov/oei/reports/oei-05-19-00060.asp>.

⁸⁰ OIG, *States Could Do More To Prevent Terminated Providers From Serving Medicaid Beneficiaries*, OEI-03-19-00070, March 2020. Available at <https://oig.hhs.gov/oei/reports/oei-03-19-00070.asp>.

⁸¹ OIG, *U.S. Department of Health and Human Services Met the Requirements of the Digital Accountability and Transparency Act of 2014, With Areas That Require Improvement*, A-17-19-54000, October 2019. Available at <https://oig.hhs.gov/oas/reports/region17/171954000.asp>.

⁸² HHS, *2019 Agency Financial Report*. Available at <https://www.hhs.gov/sites/default/files/fy2019-hhs-agency-financial-report.pdf>.

⁸³ Ibid.

⁸⁴ This TMC focuses on Medicare and Medicaid. The Department funds other vital health services, such as IHS, substance abuse treatment facilities, and Federally Qualified Health Centers, which are addressed in other TMCs.

⁸⁵ CMS, *CMS Innovation Center COVID-19 Flexibilities*, June 2020. Available at <https://innovation.cms.gov/innovation-models/covid-19-flexibilities>.

⁸⁶ The Healthcare Payment Learning & Action Network, *APM Measurement: Progress of Alternate Payment Models Methodology and Results Report*, 2019, <http://hcp-lan.org/workproducts/apm-methodology-2019.pdf>. Pursuant to the LAN framework, the higher figure represents categories 2, 3, and 4 models and the lower figure represents only categories 3 and 4. The report also includes data for Medicare Advantage and commercial insurance.

⁸⁷ HHS, *2019 Agency Financial Report*. Available at <https://www.hhs.gov/sites/default/files/fy2019-hhs-agency-financial-report.pdf>.

⁸⁸ CMS, *2019 PERM Medicaid Improper Payment Rates*. Available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicaid-and-CHIP-Compliance/PERM/PERMErrorRateFindingsandReport>.

⁸⁹ Speech: Remarks by Administrator Seema Verma at the 2019 CMS Quality Conference, January 29, 2019. Available at <https://www.cms.gov/newsroom/press-releases/speech-remarks-administrator-seema-verma-2019-cms-quality-conference>.

⁹⁰ HHS, *National Health Quality Roadmap*, May 2020. Available at <https://www.hhs.gov/about/leadership/eric-d-hargan/quality-roadmap/index.html>. The authors note that some project timelines in the Roadmap will be pushed back due to the COVID-19 pandemic.

⁹¹ OIG, *ACOs' Strategies for Transitioning to Value-Based Care: Lessons From the Medicare Shared Savings Program*, OEI-02-15-00451, July 2019. Available at <https://oig.hhs.gov/oei/reports/oei-02-15-00451.pdf>.

⁹² 84 Fed. Reg. 55766 (Oct. 17, 2019); 84 Fed. Reg. 55694 (Oct. 17, 2019); 85 Fed. Reg. 42986 (July 15, 2020); 83 Fed. Reg. 64302 (Dec. 14, 2018).

⁹³ OIG, *Registered Nurses Did Not Always Visit Medicare Beneficiaries' Homes at Least Once Every 14 Days to Assess Quality of Care and Services Provided by Hospice Aides*, A-09-18-03022, November 2019. Available at <https://oig.hhs.gov/oas/reports/region9/91803022RIB.pdf>.

⁹⁴ OIG, *Using Health IT for Care Coordination: Insights From Six Medicare Accountable Care Organizations*, OEI-01-16-00180, May 2019. Available at <https://oig.hhs.gov/oei/reports/oei-01-16-00180.pdf>.

⁹⁵ OIG, *Many Medicaid-Enrolled Children Treated for ADHD Did Not Receive Recommended Followup Care*, OEI-07-17-00170, August 2019. Available at <https://oig.hhs.gov/oei/reports/oei-07-17-00170.pdf>.

⁹⁶ OIG, *2019: Vulnerabilities in Hospice Care*. Available at <https://oig.hhs.gov/newsroom/media-materials/2019/hospice/>.

⁹⁷ OIG, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090, November 2010. Available at <https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf>.

OIG, *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*, OEI-06-11-00370, February 2014. Available at <https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf>.

OIG, *Adverse Events in Inpatient Rehabilitation Facilities (IRF): National Incidence Among Medicare Beneficiaries*, OEI-06-14-00110, July 2016. Available at <https://oig.hhs.gov/oei/reports/oei-06-14-00110.pdf>.

OIG, *Adverse Events in Long-term Care Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-14-00530, November 2018. Available at <https://oig.hhs.gov/oei/reports/oei-06-14-00530.pdf>.

⁹⁸ OIG, *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm*, OEI-06-09-00091, January 2012. Available at <https://oig.hhs.gov/oei/reports/oei-06-09-00091.asp>.

⁹⁹ OIG, *Adverse Events In Hospitals: National Incidence Among Medicare Beneficiaries—10-Year Update*, OEI-06-18-00400, estimated November 2020.

¹⁰⁰ OIG, *Hospice Deficiencies Pose Risks to Medicare Beneficiaries*, OEI-02-17-00020, July 2019. Available at https://oig.hhs.gov/oei/reports/oei-02-17-00020.asp?utm_source=mmpage&utm_medium=web&utm_campaign=OEI-02-17-00020.

¹⁰¹ OIG, *Corporate Integrity Agreement*. Available at https://oig.hhs.gov/fraud/cia/agreements/Vanguard_Healthcare_LLC_Vanguard_Healthcare_Services_LLC_Boulevard_Terrace_LLC_Glen_Oaks_LLC_Imperial_Gardens_Health_and_Rehabilitation_Vanguard_of_Manchester_%20LC_Vanguard_Financial_Svcs_LLC_et al_01092019.pdf.

¹⁰² OIG, *Indian Health Service Hospitals: More Monitoring Needed to Ensure Quality Care*, OEI-06-14-00010, October 2016. Available at <https://oig.hhs.gov/oei/reports/oei-06-14-00010.pdf>. OIG, *Longstanding Challenges Warrant Focused Attention To Support Quality Care*, OEI-06-14-00011, October 2016. Available at <https://oig.hhs.gov/oei/reports/oei-06-14-00011.pdf>.

¹⁰³ IHS, *Quality at IHS*. Available at <https://www.ihs.gov/quality/>.

¹⁰⁴ OIG, *Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio*, OEI-02-16-00570, July 2018. Available at <https://www.oig.hhs.gov/oei/reports/oei-02-16-00570.pdf>.

¹⁰⁵ OIG, *CMS Guidance to State Survey Agencies on Verifying Correction of Deficiencies Needs To Be Improved To Help Ensure the Health and Safety of Nursing Home Residents*, A-09-18-02000, February 2019. Available at <https://oig.hhs.gov/oas/reports/region9/91802000.pdf>.

¹⁰⁶ OIG, *Indian Health Service Hospitals: More Monitoring Needed to Ensure Quality Care*, OEI-06-14-00010, October 2016. Available at <https://oig.hhs.gov/oei/reports/oei-06-14-00010.pdf>.
OIG, *Longstanding Challenges Warrant Focused Attention To Support Quality Care*, OEI-06-14-00011, October 2016. Available at <https://oig.hhs.gov/oei/reports/oei-06-14-00011.pdf>.
OIG, *Rosebud Hospital, Indian Health Service Management of Emergency Department Closure and Reopening, A Case Study*, OEI-06-17-00270, July 2019. Available at <https://oig.hhs.gov/oei/reports/oei-06-17-00270.pdf>.

¹⁰⁷ OIG, *Separated Children Placed in Office of Refugee Resettlement Care*, OEI-BL-18-00511, January 2019. Available at <https://www.oig.hhs.gov/oei/reports/oei-BL-18-00511.pdf>.

¹⁰⁸ OIG, *The Tornillo Influx Care Facility: Concerns About Staff Background Checks and Number of Clinicians on Staff*, A-12-19-20000, November 27, 2018. Available at <https://oig.hhs.gov/oas/reports/region12/121920000.pdf>.

¹⁰⁹ OIG, *Unaccompanied Alien Children Program Care Provider Facilities Do Not Include All Required Security Measures in Their Checklists*, OEI-05-19-00210, June 2020. Available at <https://oig.hhs.gov/oei/reports/oei-05-19-00210.pdf>.

¹¹⁰ OIG, *The Office of Refugee Resettlement's Incident Reporting System Is Not Effectively Capturing Data to Assist Its Efforts to Ensure the Safety of Minors in HHS Custody*, OEI-09-19-00430, June 2020. Available at <https://oig.hhs.gov/oei/reports/oei-09-18-00430.pdf>.

¹¹¹ DOJ, U.S. Attorney's Office, District of Montana, *White House Announces Presidential Task Force on Protecting Native American Children in the Indian Health Service System*, March 26, 2019. Available at <https://www.justice.gov/usao-mt/pr/white-house-announces-presidential-task-force-protecting-native-american-children-indian>.

¹¹² Presidential Task Force on Protecting Native American Children in the Indian Health Service System. Report, July 23, 2020. Available at <https://www.whitehouse.gov/wp-content/uploads/2020/07/Task-Force-Report-Protecting-Native-American-Children-in-the-Indian-Health-Service-System-April-2020.pdf>.

¹¹³ OIG, *Indian Health Service Has Strengthened Patient Protection Policies but Must Fully Integrate Them Into Practice and Organizational Culture*, OEI-06-19-00330, December 2019. Available at <https://oig.hhs.gov/oei/reports/oei-06-19-00330.pdf>.

¹¹⁴ OIG, *The Tornillo Influx Care Facility: Concerns About Staff Background Checks and Number of Clinicians on Staff*, A-12-19-20000, November 27, 2018. Available at <https://oig.hhs.gov/oas/reports/region12/121920000.pdf>.

¹¹⁵ OIG, *All Six States Reviewed Had Partially Implemented New Criminal Background Check Requirements for Childcare Providers, and Five of the States Anticipate Full Implementation by Fiscal Year 2020*, A-05-19-00015, August 2019. Available at <https://oig.hhs.gov/oas/reports/region5/51900015.asp>.

¹¹⁶ OIG, *Tribal Health Programs: Concerns About Background Verifications for Staff Working With Indian Children*, A-01-20-01500, August 2020. Available at: <https://oig.hhs.gov/oas/reports/region1/12001500.asp>.

¹¹⁷ OIG, *National Background Check Program for Long-Term-Care Providers: Assessment of State Programs Concluded in 2017 and 2018*, OEI-07-18-00290, August 2019. Available at <https://oig.hhs.gov/oei/reports/oei-07-18-00290.asp>. See also: OIG, *National Background Check Program for Long-Term-Care Providers: Assessment of State Programs Concluded Between 2013 and 2016*, OEI-07-16-00160, April 2019. Available at <https://oig.hhs.gov/oei/reports/oei-07-16-00160.asp>.

¹¹⁸ CMS, *CMS Fast Facts*, July 2019. Available at <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/cms-fast-facts/index.html>.

¹¹⁹ OIG, *Joint Report: Ensuring Beneficiary Health and Safety in Group Homes Through State Implementation of Comprehensive Compliance Oversight*, January 2018. Available at <https://oig.hhs.gov/reports-and-publications/featured-topics/group-homes/group-homes-joint-report.pdf>.

¹²⁰ OIG, *Incidents of Potential Abuse and Neglect at Skilled Nursing Facilities Were Not Always Reported and Investigated*, A-01-16-00509, June 2019. Available at <https://oig.hhs.gov/oas/reports/region1/11600509.pdf>.

¹²¹ OIG, *CMS Could Use Medicare Data To Identify Instances of Potential Abuse or Neglect*, A-01-17-00513, June 2019. Available at <https://oig.hhs.gov/oas/reports/region1/11700513.pdf>.

¹²² CMCS Informational Bulletin: Health and Welfare of Home and Community Based Services (HCBS) Waiver Recipients, June 2018. Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/cib062818.pdf>.

¹²³ OIG, *A Resource Guide for Using Diagnosis Codes in Health Insurance Claims to Help Identify Unreported Abuse or Neglect*, A-01-19-00502, July 2019. Available at https://oig.hhs.gov/oas/reports/region1/11900502.asp?utm_source=website&utm_medium=asp&utm_campaign=abuse-neglect-guide.

¹²⁴ OIG, *Medicaid Data Can Be Used To Identify Instances of Potential Child Abuse Or Neglect*, A-01-19-00001, July 2020. Available at <https://oig.hhs.gov/oas/reports/region1/11900001.pdf>.

¹²⁵ *The Foundation for Evidence Based Policymaking Act of 2018*, P.L. 111-435 (Jan. 14, 2019); Federal Data Strategy 2020 Action Plan. Available at <https://strategy.data.gov/assets/docs/2020-federal-data-strategy-action-plan.pdf>.

¹²⁶ *RelImagine HHS* is a transformation effort to improve the Department's ability to enhance the health and wellbeing of all Americans. In spring 2017, OMB released Memorandum M-17-22, requiring all Cabinet-level agencies to develop a plan to become more effective, efficient, and accountable. In response, HHS formed *RelImagine HHS*.

¹²⁷ Office of the Chief Technology Officers, *Leveraging Data for the Nation's Health: A vision for inter-agency data sharing for the U.S. Department of Health and Human Services*, December 2019. Available at <https://www.hhs.gov/sites/default/files/master-future-state-508.pdf>. *Federal Data Strategy: Principles and Practices*. Available at <https://strategy.data.gov/>.

¹²⁸ HHS Protect: *Frequently Asked Questions*, July 2020. Available at <https://www.hhs.gov/about/news/2020/07/20/hhs-protect-frequently-asked-questions.html>.

¹²⁹ CMS IFC Rule release on August 25, 2020 (<https://www.cms.gov/files/document/covid-ifc-3-8-25-20.pdf>). Will update once rule is in Federal Register and cite to hospital reporting requirements.

¹³⁰ The COVID-19 Tracking Project, August 2020. Available at <https://covidtracking.com/blog/hospitalization-data-reported-by-the-hhs-vs-the-states-jumps-drops-and-other>.

¹³¹ Office of the Assistant Secretary for Planning and Evaluation, *Improving Data for Decision Making: HHS Data Collection Strategies for a Transformed Health System*, December 2011. Available at <https://aspe.hhs.gov/basic-report/improving-data-decision-making-hhs-data-collection-strategies-transformed-health-system>.

¹³² Office of the Chief Technology Officer, *The State of Data Sharing at the U.S. Department of Health and Human Services* (Sept. 2018). Available at https://www.hhs.gov/sites/default/files/HHS_StateofDataSharing_0915.pdf.

¹³³ HHS Protect: *Frequently Asked Questions*, July 2020. Available at <https://www.hhs.gov/about/news/2020/07/20/hhs-protect-frequently-asked-questions.html>.

¹³⁴ Remarks by CDC Director Robert Redfield and HHS Chief Information Officer Jose Arrieta on COVID-19 Data Collection, July 2020. Available at <https://www.hhs.gov/about/news/2020/07/15/prepared-remarks-from-hhs-media-call-cdc-director-redfield-cio-arrieta-covid-19-data-collection.html>.

¹³⁵ HHS, *COVID-19 Guidance for Hospital Reporting and FAQs For Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting*, July 2020. Available at <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf>.

¹³⁶ *Foundations for Evidence-Based Policymaking Act of 2018*, P.L. 111-435 (Jan. 14, 2019). Enterprise data governance is one of the four areas that is part of the Federal Data Strategy. Available at <https://strategy.data.gov/>. The Federal Data Strategy Action Plan requires all Federal agencies to make several data governance improvements, including establishing a data governance body. Action 12: Constitute a Diverse Data Governance Body. Available at <https://strategy.data.gov/action-plan/#action-12-constitute-a-diverse-data-governance-body>.

¹³⁷ *HHS Strategic Plan FY 2018–2022, Strategic Goal 5: Promote Effective and Efficient Management and Stewardship*. Available at https://www.hhs.gov/about/strategic-plan/strategic-goal-5/index.html#obj_5_3. *Digital Strategy at HHS*. Available at <https://www.hhs.gov/web/governance/digital-strategy/index.html>.

¹³⁸ Office of the Chief Technology Officer, *Leveraging Data for the Nation's Health: A vision for inter-agency data sharing for the U.S. Department of Health and Human Services*, December 2019. Available at <https://www.hhs.gov/sites/default/files/master-future-state-508.pdf>.

¹³⁹ The CARES Act appropriated \$500 million to the CDC for public health data surveillance and analytics infrastructure modernization.

¹⁴⁰ T-MSIS is a joint effort by the States and CMS to build a national Medicaid data set that addresses identified problems with prior Medicaid data sets. CMS intends for T-MSIS to provide States and the Federal Government with a national Medicaid data repository that would, among other functions, support program management, financial management, and program integrity. CMS, State Health Official Letter, SHO #18-008, August 10, 2018. Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/sho18008.pdf>.

¹⁴¹ OIG, *National Review of Opioid Prescribing in Medicaid is Not Yet Possible*, OEI-05-18-00480, August 2019. Available at <https://oig.hhs.gov/oei/reports/oei-05-18-00480.pdf>.

¹⁴² OIG work has shown that databases such as ACFs Program Information Report, FDA's Food Facility Registry and its National Drug Code Directory, HRSAs 340B covered-entity database, and IHS's Health Service Directory contain incomplete and inaccurate data.

¹⁴³ *The Foundation for Evidence Based Policymaking Act of 2018* mandates HHS improve its capacity for using data for evidence building purposes; Federal Data Strategies, *Promoting Efficient and Appropriate Data Use: Practices 27-40*. Available at <https://strategy.data.gov/practices/>. U.S. Department of Health and Human Services, *2018 HHS Data Strategy: Enhancing the HHS Evidence-Based Portfolio*.

¹⁴⁴ CDC, Data Modernization Initiative, *A Roadmap of Activities and Expected Outcomes*. Available at https://www.cdc.gov/surveillance/pdfs/318212-A_DMI_LogicModel_July23b-508.pdf.

¹⁴⁵ Most HHS data that can be shared are in machine-readable formats, but some data are not. Without structured data that can be automatically read and formatted, sharing and use of data may require resource intensive preparation work. Office of the Chief Technology Officer, *The State of Data Sharing at the U.S. Department of Health and Human Services*, page 12, September 2018. Available at https://www.hhs.gov/sites/default/files/HHS_StateofDataSharing_0915.pdf#:~:text=The%20State%20of%20Data%20Sharing%20at%20the%20U.S.,gives%20us%20their%20data%2C%20they%20lose%20all%20control.

¹⁴⁶ The Clinical Response through Emerging Technology. Available at <https://www.hhs.gov/sites/default/files/cret-document.pdf>. Available at <https://www.hhs.gov/cto/blog/2019/1/17/top-health-tech-sprint-unleashes-the-power-of-open-data-and-ai.html>. HHS Reimagine Acquisitions, *BuySmarter*. Available at <https://www.hhs.gov/sites/default/files/hhs-buysmarter-journey.pdf>.

¹⁴⁷ Examples of HHS stakeholders include Medicare providers, State Medicaid agencies, public health entities, researchers, universities, and other entities that may have similar missions or interests to that of the Department and its programs.

¹⁴⁸ *The Foundations for Evidence-Based Policymaking Act of 2018* created a default presumption that Government data assets be available to the public in a machine-readable, open format, and under open licenses, and encouraging public use. P.L. 111-435 § 202 (Jan. 2019). The third Federal Data Strategy Principle is promoting transparency: articulate the purposes and uses of federal data to engender public trust. Comprehensively document processes and products to inform data providers and users. Available at <https://strategy.data.gov/principles/>. The 2018 HHS Data strategy Priority 1 is improving access to HHS data. Available at <https://aspe.hhs.gov/system/files/pdf/261591/2018HHSDataStrategy.pdf>.

¹⁴⁹ Office of the Chief Technology Officer, *The State of Data Sharing at the U.S. Department of Health and Human Services*, September 2018. Available at https://www.hhs.gov/sites/default/files/HHS_StateofDataSharing_0915.pdf.

¹⁵⁰ HHS, COVID-19 Guidance for Hospital Reporting and FAQs For Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting, July 2020. Available at <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf>.

¹⁵¹ CMS, COVID-19 Nursing Home Data. Available at <https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/>.

¹⁵² NIH, *All of Research Hub – Workbench*. Available at <https://www.researchallofus.org/workbench/>.

¹⁵³ FDA, *FDA's Technology Modernization Action Plan*, September 2019. Available at <https://www.fda.gov/about-fda/reports/fdas-technology-modernization-action-plan>.

¹⁵⁴ HHS Secretary Priorities, *Value-Based Care*. Available at <https://www.hhs.gov/about/leadership/secretary/priorities/index.html#value-based-healthcare>.

¹⁵⁵ ONC, *State of Interoperability among U.S. Non-federal Acute Care Hospitals in 2018*, March 2020. Available at <https://www.healthit.gov/sites/default/files/page/2020-03/State-of-Interoperability-among-US-Non-federal-Acute-Care-Hospitals-in-2018.pdf>.

¹⁵⁶ Ibid.

¹⁵⁷ ONC, *Interoperability for COVID-19 Novel Coronavirus Pandemic*. Available at <https://www.healthit.gov/isa/covid-19>.

¹⁵⁸ 85 Fed. Reg. 25642 (May 1, 2020). Available at <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>.

¹⁵⁹ 85 Fed. Reg. 25510, May 1, 2020. Available at <https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and>.

¹⁶⁰ CMS, *Fact Sheet on MyHealthEData*, March 2020. Available at <https://www.cms.gov/About-CMS/Story-Page/MyHealthEData-fact-sheet.pdf>.

¹⁶¹ ONC, *A Look Ahead: Year Two for ONC and the Recognized Coordinating Entity for TEFCA*, May 2020. Available at: <https://www.healthit.gov/buzz-blog/health-it/a-look-ahead-year-two-for-onc-and-the-recognized-coordinating-entity-for-tefca>.

¹⁶² HHS, *Voice of HHS Podcast*, Eric Hargan: De-regulation, Taiwan, and the Return to Washington, August 2020. Available at <https://www.hhs.gov/podcasts/voices-of-hhs/learning-curve-12-eric-hargan-de-regulation-taiwan-and-the-return-to-washington.html>.

¹⁶³ CISA, HHS, and FBI, *Ransomware Activity Targeting the Healthcare and Public Health Sector*, October 2020. Available at <https://us-cert.cisa.gov/ncas/alerts/aa20-302a>.

¹⁶⁴ OIG, *Review of the Department of Health and Human Services' Compliance with Federal Information Security Modernization Act of 2014 for Fiscal Year 2019*, A-18-19-11200, April 2020. Available at <https://oig.hhs.gov/oas/reports/region18/181911200.asp>.

¹⁶⁵ OIG, *Summary Report for Office of Inspector General Penetration Testing of Eight HHS Operating Division Networks*, A-18-18-08500, March 2019. Available at <https://oig.hhs.gov/oas/reports/region18/181808500.asp>.

¹⁶⁶ NIH, *ACD Working Group for Foreign Influences on Research Integrity*, December 2018. Available at https://acd.od.nih.gov/documents/presentations/12132018ForeignInfluences_report.pdf.

¹⁶⁷ OIG, *Opportunities Exist for the National Institutes of Health to Strengthen Controls in Place to Permit and Monitor Access to Its Sensitive Data*, A-18-18-09350, February 2019. Available at <https://oig.hhs.gov/oas/reports/region18/181809350.pdf>.

¹⁶⁸ HHS Press Release, *HHS Announces the Official Opening of the Health Sector Cybersecurity Coordination Center*, October 2018. Available at <https://www.hhs.gov/about/news/2018/10/30/hhs-announces-official-opening-health-sector-cybersecurity-coordination-center.html>.

¹⁶⁹ FDA, *Cybersecurity Safety Communications*. Available at <https://www.fda.gov/medical-devices/digital-health/cybersecurity>.

¹⁷⁰ 84 Fed. Reg. 55766 and 55694 (October 17, 2019). Available at <https://www.federalregister.gov/documents/2019/10/17/2019-22027/medicare-and-state-healthcare-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the> and <https://www.federalregister.gov/documents/2019/10/17/2019-22028/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>.

¹⁷¹ OCR, HIPAA and COVID-19. Available at <https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html>.

¹⁷² OCR, *Resources for Mobile Health Apps Developers*, September 2020. Available at <https://www.hhs.gov/hipaa/for-professionals/special-topics/health-apps/index.html>.

¹⁷³ OIG, *Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020*, OEI-06-20-00300, April 2020. Available at <https://oig.hhs.gov/oei/reports/oei-06-20-00300.pdf>.

¹⁷⁴ OIG, *Hospitals Reported Improved Preparedness for Emerging Infectious Diseases After the Ebola Outbreak*, OEI-06-15-00230, October 2018. Available at <https://www.oig.hhs.gov/oei/reports/oei-06-15-00230.pdf>.

¹⁷⁵ Dr. Nora Volkow, Director, National Institute on Drug Abuse, National Institutes of Health, *COVID-19: Potential Implications for Individuals with Substance Abuse Disorders*, April 6, 2020. Accessed at <https://www.drugabuse.gov/about-nida/noras-blog/2020/04/covid-19-potential-implications-individuals-substance-use-disorders> on April 9, 2020.

¹⁷⁶ OIG, *States' Oversight of Opioid Prescribing and Monitoring of Opioid Use*. July 20, 2020. Available at <https://oig.hhs.gov/oas/opioid-oversight-map/oversight.asp>.

¹⁷⁷ HHS, *Strategy to Combat Opioid Abuse, Misuse, and Overdose: A Framework Based on the Five Point Strategy*. Available at <https://www.hhs.gov/opioids/sites/default/files/2018-09/opioid-fivepoint-strategy-20180917-508compliant.pdf>

¹⁷⁸ OIG, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder*, OEI-12-17-00240, January 2020. Available at: <https://oig.hhs.gov/oei/reports/oei-12-17-00240.asp>.

¹⁷⁹ OIG, *Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look*, OEI-02-19-00130, May 2020. Available at <https://oig.hhs.gov/oei/reports/oei-02-19-00130.pdf>.

¹⁸⁰ OIG, *Communication and Management Challenges Impeded HHS's Response to Zero-Tolerance Policy*, OEI-BL-18-00510, March 2020. Available at <https://oig.hhs.gov/oei/reports/oei-BL-18-00510.pdf>.

¹⁸¹ OIG, *Unaccompanied Alien Children Care Provider Facilities Generally Conducted Required Background Checks but Faced Challenges in Hiring, Screening, and Retaining Employees*, A-12-19-20001, September 2019. Available at <https://oig.hhs.gov/oas/reports/region12/121920001.pdf>.

¹⁸² OIG, *Ohio Did Not Ensure the Accuracy and Completeness of Psychotropic and Opioid Medication Information Recorded in Its Child Welfare Information System for Children in Foster Care*, A-05-18-00007, July 2020. Available at <https://oig.hhs.gov/oas/reports/region5/51800007.asp>.

¹⁸³ OIG, *Kansas Did Not Ensure That Group Homes for Children in Foster Care Complied With All State Health and Safety Requirements*, A-07-19-06087, July 2020. Available at <https://oig.hhs.gov/oas/reports/region7/71906087.asp>.

¹⁸⁴ OIG, *Missouri Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety and Emergency Preparedness*, A-07-18-03230, March 2020. Available at <https://oig.hhs.gov/oas/reports/region7/71803230.pdf>. OIG, *Florida Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety and Emergency Preparedness*, A-04-18-08065, March 2020. Available at <https://oig.hhs.gov/oas/reports/region4/41808065.pdf>. OIG, *Life Safety and Emergency Preparedness Deficiencies Found at 18 of 20 Texas Nursing Homes*, A-06-19-08001, February 2020. Available at <https://oig.hhs.gov/oas/reports/region6/61908001.pdf>. OIG, *California Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety and Emergency Preparedness*, A-09-18-02009, November 2019. Available at <https://oig.hhs.gov/oas/reports/region9/91802009.pdf>. OIG, *New York Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety and Emergency Preparedness*, A-02-17-01027, August 2019. Available at <https://oig.hhs.gov/oas/reports/region2/21701027.pdf>.

¹⁸⁵ Christopher Weaver and Dan Frosch, "A Pedophile Doctor Drew Suspicion for 21 Years. No One Stopped Him," *PBS Frontline* in partnership with *The Wall Street Journal*, February 9, 2019. Accessed at <https://www.pbs.org/wgbh/frontline/article/patrick-stanley-weber-sexual-abuse-pine-ridge-blackfeet-reservation/> on September 19, 2019.

¹⁸⁶ Christopher Weaver, "Former U.S. Indian Health Service Doctor Is Found Guilty of Abusing Boys," *The Wall Street Journal*, September 27, 2019. Accessed at <https://www.wsj.com/articles/former-u-s-indian-health-service-doctor-is-found-guilty-of-abusing-boys-11569624911> on October 1, 2019.

¹⁸⁷ OIG, *Report: Indian Health Service Has Strengthened Patient Protection Policies but Must Fully Integrate Them Into Practice and Organizational Culture*, OEI-06-19-00330, December 2019. Available at <https://oig.hhs.gov/oei/reports/oei-06-19-00330.pdf>.

¹⁸⁸ <https://oig.hhs.gov/oas/reports/region1/12001500.pdf>.

¹⁸⁹ https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/2020_Letters/DTLL_09252020.pdf.

¹⁹⁰ OIG, *Patient Safety Organizations: Hospital Participation, Value, and Challenges*, OEI-01-00420, September 2019. Available at <https://oig.hhs.gov/oei/reports/oei-01-17-00420.pdf>.