

2022

Top Management & Performance Challenges Facing HHS



U.S. Department of Health and Human Services
OFFICE OF INSPECTOR GENERAL

Introduction

The *Top Management and Performance Challenges Facing HHS* is an annual publication of the Department of Health and Human Services (HHS or the Department), Office of Inspector General (OIG). In this edition, OIG has identified six top management and performance challenges (TMCs) that the Department faces as it strives to fulfill its mission to enhance the health and well-being of all Americans.

In selecting these TMCs, OIG considered our oversight, enforcement, data analytics, and risk analysis work, as well as Department information and developments in law and HHS's responsibilities.

The Department continues to face challenges in responding to Public Health Emergencies (PHEs), such as the COVID-19 pandemic and the monkeypox PHE. Challenges related to the Department's COVID-19 and monkeypox responses are primarily addressed in [TMCs 1](#) and [6](#) on public health. However, responses to PHEs affect nearly every aspect of Department operations, and related challenges are addressed in other TMCs.

Management and performance challenges are inherently crosscutting. Multiple HHS Staff Divisions (StaffDivs) and Operating Divisions (OpDivs) must address these pressing issues. Furthermore, the challenges themselves intersect. For example, the challenge of safeguarding the well-being of people served by HHS programs highlighted [in TMC 4](#) intersects with the challenge of delivering value, quality, and improved outcomes in Medicare and Medicaid, which is the subject of [TMC 3](#). Some priority issues, such as improving nursing home care, raise multiple challenges. Improving nursing home care is primarily addressed in TMC 4 because of serious, persistent quality-of-care vulnerabilities, but elements of this issue appear in other TMCs. Given that challenges cross internal HHS boundaries and externally with Federal and State agencies, coordination among HHS divisions, with Tribal governments, and across the Government sector at all levels is integral to addressing these challenges, as set out [in TMC 6](#).

The six TMCs are not the only challenges that confront HHS. OIG reports are a key resource that highlight additional opportunities to improve HHS programs and operations. OIG also maintains a list of significant and unimplemented OIG recommendations, including legislative recommendations, that address vulnerabilities. If implemented, these recommendations would, in OIG's view, positively affect HHS programs in terms of cost savings, program effectiveness and efficiency, and public health and safety.

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

HIGHLIGHT: Challenge Implementing New Legislation

The Department must efficiently and effectively implement the provisions of new legislation, including most recently the *Bipartisan Safer Communities Act* and the *Inflation Reduction Act of 2022*. This includes ensuring HHS has appropriate resources, data, technologies, and expertise. The Department should consider program integrity when implementing and operating new requirements and expanded programs.

2022

Top Management & Performance Challenges Facing HHS

1

Safeguarding Public Health

4

Safeguarding the Well-Being of HHS Beneficiaries

2

Ensuring the Financial Integrity of HHS Programs

5

Harnessing and Protecting Data and Technology To Improve the Health and Well-Being of Individuals

3

Delivering Value, Quality, and Improved Outcomes in CMS Programs

6

Strengthening Coordination for Better Programs and Services

Table of Contents

Introduction.....	1
1: Safeguarding Public Health.....	5
2: Ensuring the Financial Integrity of HHS Programs	11
3: Delivering Value, Quality, and Improved Outcomes in CMS Programs	18
4: Safeguarding the Well-Being of HHS Beneficiaries	24
5: Harnessing and Protecting Data and Technology To Improve the Health and Well-Being of Individuals.....	31
6: Strengthening Coordination for Better Programs and Services	36
ENDNOTES	39



Acronyms

ACF	Administration for Children and Families	IJA	Infrastructure Investment and Jobs Act
ADHD	Attention Deficit/Hyperactivity Disorder	IRA	Inflation Reduction Act
AI/AN	American Indian/Alaska Native	IT	Information Technology
AMP	Average Manufacturer Price	MA	Medicare Advantage
API	Application Programming Interface	MAO	Medicare Advantage Organization
APTC	Advance Premium Tax Credit	NIH	National Institutes of Health
ASP	Average Sales Price	OIG	Office of Inspector General
ASPR	Administration for Strategic Preparedness and Response	OMB	Office of Management and Budget
CCDF	Child Care and Development Fund	OpDiv	Operating Division
CDC	Centers for Disease Control and Prevention	ORR	Office of Refugee Resettlement
CHIP	Children's Health Insurance Program	OTP	Opioid Treatment Program
CIO	Chief Information Officer	OD	Opioid Use Disorder
CMS	Centers for Medicare & Medicaid Services	PERM	Payment Error Rate Measurement
DHS	Department of Homeland Security	PHE	Public Health Emergency
DME	Durable Medical Equipment	PMTA	Premarket Tobacco Product Application
EIS	Emergency Intake Sites	PRF	Provider Relief Fund
EO	Executive Order	REMS	Risk Evaluation and Mitigation Strategy
EUA	Emergency Use Authorization	SAMHSA	Substance Abuse and Mental Health Services Administration
FAR	Federal Acquisition Regulation	SFC	Sanitation Facilities Construction
FDA	Food and Drug Administration	SNF	Skilled Nursing Facility
FFE	Federally Facilitated Exchange	StaffDiv	Staff Division
FFS	Fee-for-Service	TANF	Temporary Assistance for Needy Families
FY	Fiscal Year	TEFCA	Trusted Exchange Framework and Common Agreement
GAO	Government Accountability Office	TMC	Top Management and Performance Challenge
HAC	Hospital Acquired Condition	T-MSIS	Transformed Medicaid Statistical Information System
HHS	Department of Health and Human Services	UC	Unaccompanied Children
HIPAA	Health Insurance Portability and Accountability Act of 1996	UIP	Uninsured Program
HRSA	Health Resources and Services Administration		
IHS	Indian Health Service		

1: Safeguarding Public Health

Key Takeaways

Relevant Agencies

- All HHS

Elements of the Challenge

- Strengthening emergency preparedness and response capabilities
- Providing adequate oversight of FDA-regulated products
- Addressing the mental health and drug overdose crises

Outbreaks of COVID-19 and monkeypox in 2020–22 tested the Department’s capacity to safeguard public health. As of October 4, 2022, the United States had reported more than 96.25 million cases of COVID-19, losing more than 1.05 million people to the disease,¹ and had confirmed more than 26,194 cases of monkeypox.² In addition to infectious diseases, the United States continues to experience a variety of emergencies that require Federal assistance due to hurricanes, extreme heat, flooding, and wildfires. HHS must be able to foresee and combat major outbreaks and provide public health and medical emergency assistance while effectively operating a range of programs and services that are essential to protecting individuals and communities. This work includes effectively preparing for future emergencies while advancing response capabilities, ensuring that products regulated by the Food and Drug Administration (FDA) are safe and effective, and combating the mental health and drug overdose crises. To operate effective public health programs, the Department must ensure that its OpDivs and StaffDivs coordinate efforts internally as well as with partners at all levels of Government and with other stakeholders. ([See TMC 6](#) for more information on the challenge the Department faces in coordinating with internal and external partners.)

Strengthening emergency preparedness and response capabilities

Public health emergencies can severely strain public health and medical infrastructure as well as lead to serious illness and loss of life. According to the Centers for Disease Control and Prevention (CDC), from 2020 to 2021 life expectancy in the United States declined from 77.0 to 76.1 years—its lowest level since 1996. Declines in life expectancy since 2019 were driven largely by the COVID-19 pandemic.³ Pandemics such as COVID-19 are so extensive that they impact every aspect of every American’s life and alter the fabric of our society, with greater harm inflicted on vulnerable populations, such as those who are marginalized at a pandemic’s outset, have been historically disadvantaged, have less access to health care, or are dependent on health and social services, including those who reside in congregate care settings such as nursing homes. There have been pronounced racial and ethnic disparities in COVID-19 infections, hospitalizations, death rates, and vaccination rates.⁴ HHS programs must address racial, socioeconomic, geographic, and other types of disparities, and the effects that such disparities have on public health. ([See TMCs 3 and 4](#) for additional information related to equity and health disparities, including in nursing homes.)

HHS has a leading role in preparing for, responding to, and recovering from the adverse health effects of PHEs including those related to infectious disease outbreaks, natural disasters, and chemical, biological, radiological, and nuclear events. HHS is uniquely positioned to provide technical assistance, guidance, funding, and coordination to assist State, Tribal, local, and Territorial leaders to effectively and equitably plan for and respond to emergencies, as well as support sustained recovery and resilience-building efforts. As we look to the future, disasters are becoming more frequent and intense because of climate change, and occurrences of disease outbreaks are projected to increase.⁵ Recent experiences—including the spread of COVID-19 and monkeypox, and weather events

such as wildfires, winter storms, and hurricanes—underscore that HHS must be prepared to address multiple emergencies simultaneously with different response needs and challenges.

A key challenge for HHS is having adequate planning and mechanisms in place prior to an emergency so that assets and relief can be deployed efficiently and rapidly to those in need of HHS resources and assistance. This includes planning for controls and strategies to mitigate disaster preparedness and response risk.⁶ For instance, a 2021 OIG report looking at CMS's emergency preparedness guidance for hospitals found that CMS's controls were well-designed and implemented, but CMS's authority was insufficient for it to fulfill its responsibility to ensure that accredited hospitals would maintain quality and safety during an emerging infectious disease emergency.⁷ OIG is also assessing hospital compliance with CMS's emergency preparedness requirements including preventive measures hospitals are taking to minimize the spread of COVID-19 and monkeypox.⁸ Furthermore, OIG continues to conduct multiple reviews of nursing homes' infection prevention and emergency preparedness. Nursing homes have been acutely challenged in the face of both infectious disease and natural disaster emergencies. OIG recently excluded seven Louisiana nursing homes and their owner from participating in Federal health care programs; the homes evacuated residents to a warehouse where they suffered inhumane and squalid conditions, and seven residents died.⁹ ([See TMC 4](#) for more information related to nursing homes.)

In addition, an effective emergency response requires a prepared public health workforce. The *American Rescue Plan Act of 2021* provided HHS with additional funds including \$7.6 billion to establish, expand, and sustain the public health workforce.¹⁰ HHS must use these resources effectively to support the public health workforce and build the capacity for addressing current and future emergencies.

For infectious disease emergencies, multiple HHS divisions play critical roles in identifying, acquiring, developing, distributing, and administering medical countermeasures including vaccines, therapeutics, and diagnostics. Playing particularly critical roles among HHS's divisions are the CDC, Administration for Strategic Preparedness and Response (ASPR),¹¹ National Institutes of Health (NIH), Office of Global Affairs, and FDA. For example, CDC is responsible for understanding outbreaks and implementing appropriate, equitable, and immediate early interventions and prevention strategies. FDA may use its Emergency Use Authorization (EUA) authority and accelerated approval pathways to facilitate the availability of medical countermeasures during PHEs, as it did for COVID-19 diagnostics, vaccines, and therapeutics.

HHS and its divisions have been subjected to public criticism for their handling of recent emergencies. In January 2022, the Government Accountability Office (GAO) identified HHS's leadership and coordination of PHEs as at high risk due to persistent deficiencies in HHS's leadership role in preparing for and responding to PHEs.¹² ([See TMC 6](#) for more information on the challenge of coordination when preparing for and responding to PHEs.) Subsequently, CDC acknowledged that it had made mistakes over the past few years, lost public trust, and needed to transform while refocusing on public health needs.¹³

OIG work on prior outbreaks of communicable disease illustrates the importance of ongoing HHS readiness to detect, assess, and respond to new disease outbreaks and other emergencies. For instance, an 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 PHEs.¹⁴ HHS concurred with the recommendations in the report but has not yet taken the actions necessary to implement them.

In addition to coordinating emergency planning and response efforts with its program offices, HHS works with States, localities, and Tribes to facilitate planning and preparedness to address a wide range of health and human service needs, including the management and distribution of medical supplies, establishment of alternative care sites, and distribution of vaccines and antiviral drugs. In an OIG survey of hospitals conducted in March 2021, hospitals reported that operating in "survival mode" for an extended period had created challenges with health care delivery, staffing, vaccinations, supplies, and finances. Hospitals reported that the emergency exacerbated longstanding challenges in health care delivery, access, and health outcomes.¹⁵ Prior OIG work identified opportunities for health care facilities to improve emergency preparedness and response planning during infectious disease outbreaks and disasters.¹⁶ HHS should continue to support the development and maturation of health care coalitions as entities in

this diverse group—including hospitals, public health agencies, emergency medical services, nursing facilities, and emergency management entities—work together to plan and coordinate emergency response.^{17, 18}

HHS must rely on up-to-date information to sustain and strengthen its emergency response, and provide effective health guidance to the American public while building the public's trust. As the COVID-19 emergency continues to evolve and the spread of monkeypox heightens concerns, new data provides a deeper understanding of topics such as transmission, testing, therapeutics, vaccines, vaccination programs, public health communication, and short- and long-term health effects. HHS faces the challenge of ensuring that as an organization it is continuously learning, charged with gathering data about threats that may be evolving and complex, evaluating the data, and using the data to inform emergency responses and guide the public.

Hospitals reported operating in 'survival mode' for an extended period created challenges with health care delivery, staffing, vaccinations, supplies, and finances, exacerbating longstanding challenges in health care delivery, access, and health outcomes.

Providing adequate oversight of FDA-regulated products

FDA is charged with ensuring the safety, effectiveness, quality, 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 within FDA's purview.¹⁹ FDA has the added challenge of facilitating emergency response efforts related to PHEs including, for example, reviewing scientific evidence and issuing EUAs and approvals for COVID-19 vaccines and other medical products; providing surveillance of medical product safety, effectiveness, and quality; and updating guidance based on emerging science.²⁰

Drugs, biologics, and medical devices

FDA helps to ensure the safety, effectiveness, and quality of medical products through a number of activities, which include evaluating manufacturing facilities; reviewing drugs, devices, and biologics for safety, effectiveness, and quality; authorizing the use of investigational medical products; and conducting postmarket surveillance. The public relies on FDA to be expeditious, independent, unbiased, and evidence-based when evaluating products and making decisions regarding approval for marketing in the United States. OIG found more than one-third of drugs approved through the accelerated approval pathway have incomplete confirmatory trials.²¹ OIG work also illustrates FDA's challenge of balancing availability and quality in its EUA processes.²² FDA's task of assessing complex products has become more difficult as science and technology have evolved. The drug, biologic, and medical device supply chain is becoming increasingly complex, and many of the products used in the United States are manufactured overseas or are dependent on raw materials that are produced overseas. For all FDA-regulated drugs, 73 percent of the manufacturing facilities producing active pharmaceutical ingredients and 52 percent of the manufacturing facilities producing finished dosage forms of human drugs were located outside of the United States in 2022. In addition, OIG found that FDA could improve its for-cause drug inspection process and recommended that FDA identify and implement ways to improve the timeliness of these inspections.²³

The rapid evolution of science and technology presents new oversight challenges for FDA, as does managing cybersecurity risks associated with increasing numbers of networked devices. ([See TMC 5](#) for additional information on the challenge of managing cybersecurity risks.)

Food and infant formula

The 2022 identification of *Cronobacter sakazakii* infections associated with infant formula and the corresponding recall resulted in supply shortages and the ongoing challenge of providing families access to a safe and adequate supply of infant formula. The infant formula outbreak demonstrates the importance of FDA managing a robust food safety program.

Foodborne illness is a largely preventable threat to public health. An estimated 1 in 6 Americans gets sick, 128,000 are hospitalized, and 3,000 die from contaminated foods each year.²⁴ FDA is responsible for overseeing the Nation's increasingly diverse and complex food system and supply chain. The American public relies on FDA, which works in collaboration with other Federal agencies and State, local, and Territorial partners to help ensure the safety of both human and animal food.²⁵ FDA's current approach to food safety includes goals to "enhance traceability, improve predictive analytics, respond more rapidly to outbreaks, address new business models, reduce food contamination, and foster the development of stronger food safety cultures."²⁶ FDA must continue to modernize the food safety system and respond effectively and efficiently when issues are identified. FDA should conduct risk-based inspections of domestic and foreign food facilities within the timeframes required by the *Food Safety Modernization Act*, identify instances of failure to comply with good manufacturing practices, and take necessary steps when health risks are identified, including administrative and enforcement actions when warranted.²⁷ FDA has made organizational changes to improve incident response through, for example, its Coordinated Outbreak Response and Evaluation Network and should continue to improve the timeliness and effectiveness of its processes, such as food recalls. OIG is assessing whether FDA followed the inspections and recall process for infant formula per Federal requirements.²⁸

Tobacco

Tobacco use is the leading cause of preventable death and disease in the United States.²⁹ FDA regulates the manufacturing, marketing, sale, and distribution of tobacco products to protect public health and has committed to reducing harm from tobacco products, particularly among youth. CDC's 2021 National Youth Tobacco Survey indicates that youth tobacco product use remains a public health threat, with approximately 1 in 4 students (24.1 percent) ever using a tobacco product, and approximately 1 in 10 students (9.3 percent) using a tobacco product during the previous 30 days.³⁰ In 2021, e-cigarettes were the most-used tobacco product among both middle and high school students.³¹ FDA must continue efforts to reduce harm amid increasing concerns surrounding the use and detrimental health effects of electronic nicotine delivery systems, such as e-cigarettes and vape pens, that contain tobacco-derived nicotine and non-tobacco, or synthetic, nicotine. OIG is assessing FDA's Premarket Tobacco Product Application (PMTA) process for electronic nicotine delivery systems.³² Through the PMTA process, FDA must determine whether a new tobacco product is appropriate for the protection of public health, taking into account the increased or decreased likelihood that existing users of tobacco products will stop using such products, and the increased or decreased likelihood that those who do not use tobacco products will start using such products.

While 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 manufacture, marketing, sale, and distribution, including premarket reviews and health warnings on packaging and advertisements. OIG is assessing FDA's Tobacco Retailer Compliance Check Inspection program under which FDA contractors (generally States) carry out undercover-buy inspections of tobacco retailers to ensure compliance with restrictions on sales to minors.³³

Addressing the mental health and drug overdose crises

Mental health crisis

The United States faces a mental health crisis. In 2020, 21 percent of all adults experienced mental illness.³⁴ During the pandemic, that number is thought to have trended upward, with more than 30 percent of adults in the United States reporting symptoms of anxiety and/or depressive disorder.³⁵ Additionally, more than 20 percent of school-aged children have experienced worsened mental or emotional health since the pandemic began.³⁶ According to CDC, the United States had one death by suicide every 11 minutes in 2020.

Many who experience mental health illness do not obtain treatment, and it is critically important that the crisis care system in America is transformed and people are provided timely access to quality help.³⁷ HHS has committed resources toward enhancing the mental health workforce and connecting people to treatment, such as through Substance Abuse and

Mental Health Services Administration's (SAMHSA's) launch of 988—the three-digit phone number for the National Suicide Prevention Lifeline. OIG is currently evaluating the availability of behavioral health care in Medicare fee-for-service (FFS), Medicare Advantage (MA), and Medicaid managed care.³⁸ Under the *Bipartisan Safer Communities Act*, HHS is responsible for administering \$800 million in new grant funding to address the mental health care needs of adults and children. As described [in TMC 2](#), sound financial management of these grant funds is important to ensure that the government gets the quality of services and outcomes for which it is paying.³⁹

Overdose crisis

In recent years illicit opioids, largely driven by fentanyl and its analogues, have become key contributors to the overdose crisis. Other controlled substances, including benzodiazepines and stimulants (particularly methamphetamine), are also being used in combination with opioids. Since 2017, HHS has declared an ongoing opioid PHE nationwide, and in the past few years our country has experienced heightened concerns about the prevalence and detrimental effects of substance use disorders, including those involving alcohol, tobacco, opioids, and other drugs. Provisional data from CDC show that drug overdose deaths attributable to opioids as well as other categories of drugs have significantly increased since the start of the COVID-19 pandemic.⁴⁰ For the 12-month period ending in March 2022, there were 104,671 reported drug overdose deaths, which was a 40-percent increase from the 74,679 reported drug overdose deaths during the 12-month period ending in March 2020.⁴¹ In early fiscal year (FY) 2022, HHS released an overdose prevention strategy.⁴² Current Federal priorities for drug policy include expanding access to evidence-based treatment for substance use disorder, advancing racial equity in the approach to drug policy, and reducing the supply of illicit substances.⁴³

Opioids prescribed by licensed medical professionals and paid for, in part, with Federal funds have contributed to the opioid crisis. Moreover, OIG has found that opioid-related fraud encompasses a broad range of criminal activity, from prescription drug diversion to substance use disorder treatment schemes. OIG investigations show that opioid drug diversion—the redirection of drugs prescribed for medical use to nonmedical purposes—is on the rise. Diverted opioid drugs present a high risk of inappropriate use and cause significant harm, such as overdoses. Also, potentiator drugs (drugs that exaggerate euphoria and escalate the potential for misuse when combined with opioids) and drugs indicated to treat Opioid Use Disorders (OUDs) (including buprenorphine and methadone) are at high risk for diversion.

More than 43,000 people enrolled in Medicare Part D overdosed on prescription opioids or illicit opioids during 2020. Overall, 1 in 4 Medicare patients enrolled in Part D received opioids during 2020.⁴⁴ Unlike recent years, there was no growth in the number of people receiving prescriptions through Part D for the opioid overdose-reversal drug, naloxone. Access to naloxone is important: Naloxone used in response to an overdose can save a life. Additionally, growth in the number of people receiving drugs through Part D to treat OUDs slowed. Ensuring sufficient access to treatment is particularly important as we do not yet know the full extent to which the stressors of the COVID-19 pandemic may have increased both the prevalence of OUDs and the need for these treatments.

The Department should continue to use the tools available across its divisions to address the ongoing overdose crisis while being mindful of patients' needs to access appropriate management for acute and chronic pain, which may include the use of opioid analgesics. FDA has key roles in ensuring the safe use of opioid analgesics including, for example, evaluating proposed new opioid analgesics and approving them for marketing in the United States only if their benefits outweigh risks.⁴⁵ FDA also employs tools to mitigate risks associated with opioid analgesics, including requiring product labeling changes and Risk Evaluation and Mitigation Strategies (REMS) as needed.⁴⁶ An OIG evaluation found that data quality issues made it challenging for FDA to determine whether two REMS for opioid analgesics had been effective and that REMS may not be well-suited to quickly address the opioid crisis.⁴⁷ FDA must work to ensure that strategies it uses to mitigate the misuse and abuse of opioids achieve their intended impacts. CMS and States should continue to follow up with prescribers with questionable prescribing patterns to ensure that Medicare Part D and Medicaid are not paying for unnecessary drugs being diverted for resale or recreational use. 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.⁴⁸

Ensuring access to effective substance use disorder treatment, especially in regions with greater risk for opioid misuse and overdose, remains crucial to combating the overdose crisis.⁴⁹ Measures to address COVID-19 have further challenged access to treatment. In a survey of 143 opioid treatment programs (OTPs), OIG identified various challenges OTPs encountered during the COVID-19 pandemic including maintaining pre-pandemic service levels, managing impacts on facility operations, and maintaining patient participation in opioid treatment program activities, among others.⁵⁰ To ensure access to effective treatment, HHS needs data to continue building its ability to monitor access and unmet needs. An OIG evaluation identified opportunities to enhance information about access and the need for medication to treat OUD through the Buprenorphine Waiver Program, one of the SAMHSA's key initiatives for combating the overdose crisis by expanding treatment services.⁵¹ In spring 2021, HHS released new buprenorphine practice guidelines designed to expand access to evidence-based treatment for OUD.⁵²

In addition, HHS must ensure that funding to address the overdose crisis is efficiently and effectively spent for its intended purpose. In a series of OIG audits of Medicaid payments for OTP services, OIG found that Medicaid reimbursements for OTP services in some States did not meet Federal and State requirements.^{53, 54} Another OIG audit of a SAMHSA grant to combat OUD found that the recipient did not meet its goal for the number of naloxone kits distributed, nor could the recipient ensure that the naloxone kits were distributed to targeted populations.⁵⁵

2: Ensuring the Financial Integrity of HHS Programs

Key Takeaways

Relevant Agencies

- All HHS

Elements of the Challenge

- Controlling costs by ensuring prudent payments for goods and services
- Preventing, reducing, and recovering improper payments
- Combating fraud, waste, and abuse
- Monitoring and reporting on the integrity of HHS programs

HHS is the largest civilian agency in the Federal government, with \$2.9 trillion in budgetary resources.^{56, 57} Sound stewardship that ensures the transparency and accountability of HHS funds is paramount to making sure people served by HHS and the American public benefit from this substantial financial investment.⁵⁸

HHS's Medicare program is the Nation's largest health insurer by expenditures and handles more than 1 billion claims per year. Medicaid is the largest health insurer in terms of lives covered, with nearly 89 million individuals enrolled in Medicaid and the Children's Health Insurance Program (CHIP) as of May 2022.⁵⁹ Spending for the Medicare and Medicaid programs (including State spending) represents 38 cents of every dollar spent on health care annually in the United States.⁶⁰ Medicare expenditures totaled \$857.1 billion and Medicaid expenditures totaled \$521.8 billion in 2021.⁶¹ HHS is the largest grantmaking and second-largest contracting agency in the Federal government. In FY 2021, HHS awarded \$236.4 billion in grants (excluding CMS grants) and \$38.9 billion in contracts.⁶²

The Department must protect the fiscal integrity of HHS funds and ensure that beneficiaries have access to the services they need. This is a growing challenge due to, among other factors, looming financial shortfalls in the Medicare program,^{63, 64} growth in the number of people enrolled in Medicaid, and massive COVID-19 funds that HHS is responsible for distributing and overseeing via grants and other mechanisms. HHS must manage the efficient and effective use of funds internally and oversee the use of Federal funds by hundreds of thousands of external funding recipients.

Controlling costs by ensuring prudent payments for goods and services

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

Prescription drug programs

The Medicaid, CHIP, and Medicare programs accounted for 42 percent (\$147 billion) of total U.S. prescription drug expenditures in 2020.⁶⁵ The Medicare Part D program had net costs of \$79.8 billion for FY 2021, and 48 million people relied on Part D for prescription drug coverage.^{66, 67}

A top management challenge for HHS is implementation of the *Inflation Reduction Act* (IRA), which makes several changes to Medicare and provides certain complex new authorities. Under IRA, CMS must negotiate prices on selected Medicare Part B and Part D brand-name drugs that account for the greatest program spending. IRA also mandates rebates for Part B or Part D drugs for which prices increased at a rate exceeding the rate of inflation. The law also changes the structure of the Part D program and caps annual out-of-pocket costs at \$2,000 per enrollee. Portions of the statute take effect as soon as January 2023. OIG's prior work looking at drug spending in areas such as biosimilars and hepatitis drugs suggests that the Part D reforms could have a substantial impact. Administering new and complex programs creates challenges and risks for CMS, including those tied to managing technical and regulatory complexity, meeting required timeframes, managing resources efficiently, issuing clear guidance, delivering program outcomes, designing and providing effective oversight, and preventing and detecting fraud and abuse. More specifically with respect to implementing prescription drug provisions, OIG work has identified challenges in calculating inflation-indexed rebates in Part B and ensuring the completeness and accuracy of measures, such as average sales price (ASP) and average manufacturer price (AMP). Furthermore, OIG work suggests that CMS must be attuned to ensuring accurate and complete reporting of manufacturer data, such as ASP and AMP data, required for effective and efficient program operations. CMS must also provide effective oversight and, where appropriate, enforcement of manufacturer compliance with new program requirements.

The way that Medicare and Medicaid pay and reimburse for drugs can impact prescription drug prices and costs for people and programs. For example, 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.⁶⁸ Also, OIG looked at the impact of the least costly alternative policy in Part B, which based the payment amount for a group of clinically comparable products on that of the least costly product, on costs for certain prostate cancer drugs. OIG found that when the least costly alternative policy was rescinded there was an increase in costs for the studied drugs.

Furthermore, OIG work on the Part D program has raised concerns about whether the program design encourages the use of the highest value drugs. OIG found that although there was a 17 percent decrease in Medicare Part D prescriptions for brand-name drugs between 2011 and 2015, there was a 77 percent increase in total reimbursements for these drugs, leading to greater overall Part D spending and higher enrollee out-of-pocket costs.⁶⁹ OIG work looking at the use of lower cost biosimilar drugs that are clinically equivalent to their higher cost reference biological drugs found that the program and its enrollees could realize significant savings if biosimilar use were to increase, but the lack of biosimilar coverage on Part D formularies may limit increased use.⁷⁰

Additionally, manufacturers' uses of reasonable assumptions when calculating AMPs and best prices—a practice OIG's work has established as common—represents a vulnerability in drug pricing for thousands of drugs used in the Medicaid program.⁷¹ HHS must endeavor to limit the impact of high prices on programs and beneficiaries while protecting access to medically necessary drugs. The Department also should be prepared to address the coverage and reimbursement challenges of emerging technologies.

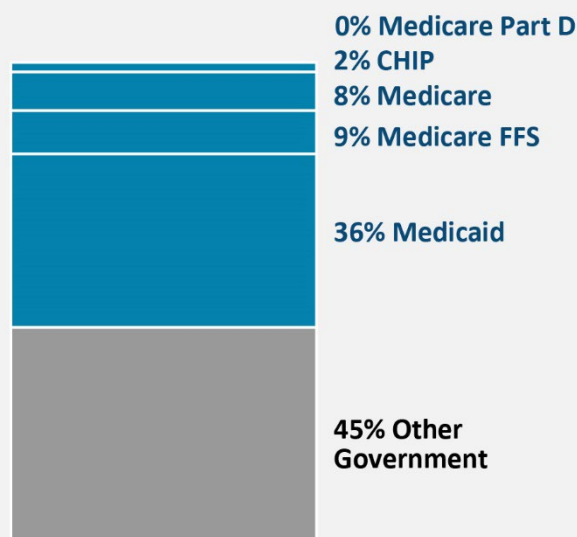
Preventing, reducing, and recovering improper payments

An improper payment is any payment that does not meet statutory, contractual, administrative, or other legally applicable requirements, and that may be an overpayment or underpayment.⁷² Reducing improper payments—such as payments to ineligible recipients or duplicate payments—is critical to safeguarding Federal funds. Due in part to their size and in part to some programs having error rates that exceed statutory benchmarks, HHS programs account for some of the largest estimated improper payments in the Federal Government. Medicare, Medicaid, and CHIP together accounted for 55 percent, or \$153.7 billion, of all governmentwide estimated improper payments reported in FY 2021.⁷³ Furthermore, insufficient HHS oversight of grant programs and contracts poses risks of significant improper payments.

Medicare

Original Medicare FFS and Medicare Part D (also known as Medicare Prescription Drug) accounted for \$26.4 billion, or 17 percent, of the estimated improper payments that HHS reported in FY 2021.⁷⁴ Notably, the Medicare FFS improper payment rate estimate during the past 3 years has decreased from 7.3 percent (\$28.9 billion) in FY 2019, to 6.3 percent (\$25.0 billion) in FY 2021.⁷⁵ The improvements in Medicare FFS estimated improper payments represent positive momentum on which the Department and CMS can build. However, some types of providers and suppliers pose heightened risks to the financial security of Medicare. For instance, OIG and CMS have identified especially high rates of improper payments for home health, hospice, and skilled nursing facility (SNF) care; durable medical equipment (DME); drug testing services; and certain hospital services.⁷⁶ CMS has taken corrective actions for Medicare FFS by focusing on specific service areas with high improper payment rates. But more must be done. The reduction in the improper payment rate was driven primarily by reductions in Part B and DME claims. CMS should take further action to reduce improper payments among providers and suppliers.

Medicaid and Medicare programs accounted for 55% of all 2021 governmentwide estimated improper payments.



Graphic adapted from [PaymentAccuracy.gov](https://www.paymentaccuracy.gov/).

CMS must ensure appropriate billing for Medicare services and must monitor for indications that hospitals may be engaging in inappropriate billing practices, such as upcoding.⁷⁷ For example, OIG found that hospitals increasingly billed for inpatient stays under Medicare severity diagnosis-related groups at the highest severity—and most expensive—level from FY 2014 through FY 2019. CMS should also ensure that it is prepared to detect and prevent improper payments in areas with growing utilization, such as telehealth and genetic testing. When improper payments are identified, such as through OIG audits, CMS should continue its efforts to recover collectible overpayments. OIG has recommended additional steps CMS could take to improve its ability to recover misspent funds.⁷⁸

MA allows people to receive Medicare benefits through private managed care plans. HHS pays plans in part by adjusting the per-person amount to account for health status differences between enrolled people in order to determine the monthly payment amount, which means that plans receive higher payments for enrollees reported to have a poorer than average health status, and lower payments for enrollees reported to have better than average health status. HHS reported an improper payment rate of 10.28 percent for MA, accounting for \$23.2 billion, or 15 percent of the estimated improper payments HHS reported in FY 2021.⁷⁹ As it exceeds 10 percent, the FY 2021 rate is not in compliance with the *Payment Integrity Information Act*. As disclosed in the FY 2021 Agency Financial Report (AFR), contributing to the increase in the error rate was the rebasing of the measure to exclude MA payments not related to risk adjustment from the calculation. Nevertheless, the amount of improper payments in MA indicates further scrutiny is needed, especially considering the incentive to receive higher payments by misreporting diagnoses. HHS should evaluate critical and feasible action steps to assist MA organizations with compliance efforts, specifically with organizations that have significant improper payments year-over-year to ensure that medical record documentation is sufficient and substantiates clinical diagnoses.

Medicaid

Medicaid is a Federal-State partnership through which the 50 States, District of Columbia, and 5 Territories each offers its own program, within certain Federal parameters, reflecting State and local needs and preferences. CMS's Payment Error

Rate Measurement (PERM) program measures improper payments in Medicaid and CHIP, and produces a national improper payment rate for each program. The estimated Medicaid improper payment rate increased from 21.4 percent in FY 2020 to 21.7 percent in FY 2021, while CHIP increased from 27.0 percent to 31.8 percent.⁸⁰ These increases were largely due to the continued re-introduction of beneficiary eligibility errors into the error rate calculation; inclusion of these errors had previously been paused while CMS updated the PERM eligibility component.⁸¹ Medicaid accounted for approximately \$98.7 billion in estimated improper payments in FY 2021. CMS attributes these increases to high levels of eligibility errors, such as those occurring when States maintain insufficient documentation to substantiate that income and other information were appropriately verified, failures in conducting timely and appropriate annual redeterminations, as well as errors when beneficiaries are claimed under incorrect eligibility categories that provide a Federal matching rate higher than appropriate.⁸²

OIG has long identified eligibility determinations as a significant risk area. Medicaid expansion under the *Affordable Care Act* and mandated changes to Medicaid eligibility rules led to a significant increase in applications for Medicaid coverage. More recently, the *Families First Coronavirus Response Act* temporarily increased the Federal Government's share of Medicaid costs, with the condition that States accepting the additional funds are prohibited from making their Medicaid eligibility requirements more restrictive and from terminating people's coverage during the COVID-19 PHE. After the COVID-19 PHE ends, States will need to conduct renewals of eligibility for all individuals enrolled in Medicaid and CHIP, which could affect millions of people.

Prior OIG audits found that some States did not always determine Medicaid eligibility for some beneficiaries per Federal and State requirements. We determined that both human and system errors, as well as a lack of policies and procedures, contributed to improper or potentially improper payments. We estimated that 4 States we audited made Federal Medicaid payments totaling almost \$1.4 billion for more than 700,000 people whose eligibility could be considered because of the *Affordable Care Act* expansion but who did not meet or may not have met eligibility requirements. Furthermore, States made Federal Medicaid payments totaling more than \$5 billion on behalf of 5 million individuals who fit traditional Medicaid coverage groups but who did not meet or may not have met eligibility requirements. As with Medicare, CMS faces other fiscal integrity challenges with Medicaid, such as collecting overpayments from State Medicaid agencies. As of April 2022, CMS had not collected about \$1.5 billion in overpayments identified in OIG audit reports.⁸³

Advanced Premium Tax Credit

The risk assessment process that HHS uses to estimate improper payments determined that the APTC program is susceptible to significant improper payments. HHS has started the improper payment measurement program for the Federally Facilitated Exchange (FFE) and anticipates reporting an improper payment estimate for the FFE in the FY 2022 AFR. HHS continues to develop the improper payment measurement methodology for State-based exchanges and will continue to update AFR with the measurement program development status.

Grants and contracts

Administering grant programs and contracts requires that HHS implement oversight and guidance to ensure that program goals are met and funds are used appropriately. HHS is responsible for providing guidance and up-to-date policies to grant recipients and helping States and other grantees address financial management and internal control issues. Without proper internal controls at the grantee level, funds may be misspent, duplication of services may occur, and subrecipients may not be adequately monitored. OIG has identified grantee-level concerns in several HHS programs. For example, OIG found that most NIH grantees failed to meet at least one Federal requirement related to investigators' foreign interests and support and lacked oversight practices to ensure that all materials submitted to NIH were accurate. OIG has identified a range of other problems with grants and contracts oversight. For example, some grantees of the Office of Refugee Resettlement (ORR) Unaccompanied Children (UC) Program reported unallowable rental, construction, subcontractor, or other costs,⁸⁴ and ORR did not award or sufficiently manage a sole source contract in accordance with Federal requirements.⁸⁵ Additionally, it remains the responsibility of individual organizations within HHS to administer the Small Business Innovation

Research (SBIR) program. OIG made two recommendations to address vulnerabilities in the SBIR program: (1) HHS should ensure awardee compliance with SBIR eligibility requirements and (2) HHS should improve procedures to check for duplicative awards.⁸⁶

HHS must track and report improper payment rates for its risk-susceptible grant programs and thus adhere to the *Payment Integrity Information Act of 2019*.⁸⁷ 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. HHS stated in its FY 2021 AFR that it did not report an improper payment estimate for TANF because statutory limitations preclude HHS from requiring States to participate in a TANF improper payment measurement. The Office of Management and Budget (OMB) identified TANF as a risk-susceptible program that must report estimated error rates and amounts. HHS must continue to pursue legislative or other remedies to develop an appropriate methodology for measuring TANF payment accuracy and report an improper payment estimate for TANF.⁸⁸

Although HHS has taken steps to improve the contract management and closeout processes, the Department in terms of its oversight of contracts needs to take additional actions to ensure that it is meeting other Federal requirements. For example, OIG found that, while some Federal Acquisition Regulation (FAR) were met, FDA did not always identify contracts eligible for closeout and did not always follow the FAR requirements for closing contracts in a timely manner.⁸⁹ HHS must also improve its use and management of other transaction agreements, which carry a higher risk than traditional awards. OIG found that NIH did not fully comply with Federal requirements for awarding and administering other transactions. NIH implemented the OIG recommendations to strengthen its internal controls.⁹⁰

COVID-19 funding

Congress appropriated \$484.0 billion to HHS for the COVID-19 response.⁹¹ This includes the Provider Relief Fund (PRF) to support health care providers affected by the COVID-19 pandemic and the Uninsured Program (UIP) to reimburse health care providers that have conducted COVID-19 testing, administered vaccines, or provided treatment for uninsured individuals with a COVID-19 primary diagnosis.^{92, 93} Both programs are administered by the Health Resources and Services Administration (HRSA). PRF and UIP had to be rolled out quickly, which presented challenges and vulnerabilities in administering the programs. A recent OIG audit found that HHS's and HRSA's controls related to selected PRF program requirements could be improved. OIG found that HHS and HRSA did not have certain procedures related to supporting documentation, calculation of nonautomatic payments, and return of rejected payments. Other procedures had weaknesses. OIG recommended, and HRSA concurred, that HRSA seek repayment of overpayments and strengthen efforts as it fully implements postpayment quality control review processes.⁹⁴ OIG is currently conducting additional audits and evaluations of PRF and UIP distributions, including PRF distributions made to nursing homes.⁹⁵

Combating fraud, waste, and abuse

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. The Department should apply a robust variety of program integrity strategies to protect HHS programs, including implementing systems and processes to detect and prevent fraud, as well as plans for addressing fraud when it occurs. (For an additional discussion on combating fraud, waste, and abuse in CMS programs, [see TMC 3.](#))

Fraud Schemes

- Billing for services not provided
- Identity theft
- Kickbacks
- Improper prescribing
- Deceptive marketing
- Money laundering

COVID-19 funds

OIG has identified serious concerns related to fraud schemes that would divert funds intended for the COVID-19 response and recovery. Law enforcement investigations have included allegations of providers falsely attesting to their eligibility for funds and providers using relief funds for impermissible personal expenses. OIG has identified other serious fraud schemes that threaten programs and people. These include schemes in which fraudsters offer unapproved and illegitimate COVID-19 tests and fake vaccination cards, often in exchange for personal details, including information that can be used to falsely bill Medicare or other payers. HHS must apply effective internal controls and efficiently manage the collection, maintenance, and analysis of relevant data that are key to ensuring COVID-19 funds are used for their intended purposes.

Furthermore, as with all HHS grant programs, it will be critical that the Department provide up-to-date policies to COVID-19-related grant recipients and help States and other grantees address their own financial management and internal control issues. Without proper internal controls, funds may be misspent, duplication of services may occur, and subrecipients may lack adequate monitoring. ([See TMC 3](#) for additional details regarding COVID-19 flexibilities and the challenge of terminating these flexibilities at the end of the PHE.)

Grants and Contracts

Without adequate oversight and internal controls, HHS grants and contracts are vulnerable to fraud schemes including embezzlement and theft.⁹⁶ HHS has worked to strengthen some of its program integrity efforts focused on grant programs. For instance, HHS issued guidance and developed tools to help its awarding OpDivs examine prospective grantee risk prior to awarding grants.⁹⁷ This information enhanced awarding OpDivs' assessments of prospective grant recipients' integrity and potential performance. Suspension and debarment programs help protect the integrity of Federal grants and contracts. Most suspension and debarment referrals resulted in actions to protect funds. Furthermore, most of the referrals came from HHS non-awarding entities, while many HHS awarding agencies made no referrals during the 5-year period we reviewed. This suggests there were missed opportunities for additional referrals among these awarding agencies. HHS has since made improvements in strengthening program integrity for its suspension and debarment programs. HHS implemented two of OIG's four recommendations to strengthen suspension and debarment programs by issuing the Discretionary Suspension and Debarment Handbook for Contracts and Grants and conducting ongoing training across the Department to encourage the use of suspension and debarment as a viable administrative remedy.⁹⁸

Provider enrollment screening processes

An effective provider enrollment screening process is an important tool for preventing Medicaid and Medicare fraud. Such a process plays a vital role in identifying and preventing unscrupulous providers from enrolling in Medicaid and Medicare. OIG found that Medicaid is vulnerable to being defrauded by high-risk providers that were not properly screened.⁹⁹ We also found that unscrupulous providers could exploit loopholes in the provider enrollment process to enroll in State Medicaid programs without undergoing these checks.¹⁰⁰ In addition, OIG found 23 States had not enrolled all providers serving Medicaid beneficiaries in their respective Medicaid programs, exposing enrollees to potentially harmful providers that had not been screened for fraud and abuse.¹⁰¹ Despite legislative requirements in the *21st Century Cures Act* designed to strengthen Medicaid program integrity, terminated providers continue to serve people enrolled in Medicaid. We recommended that CMS: (1) ensure that all States fully implement fingerprint-based criminal background checks for high-risk Medicaid providers and (2) work with States to ensure that they have the controls required to prevent unenrolled providers from participating 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 in and external to the Federal Government. Responsible stewardship of HHS programs is vital to operating a financial management and administrative infrastructure that employs appropriate safeguards to minimize risk and provide oversight to protect resources. Although HHS continues to maintain a clean opinion on its basic financial statements and has addressed most severe weaknesses in

financial management systems, OIG recommends that HHS focus on refreshing OpDivs' understanding of departmental guidance and identifying those areas for which OpDiv training would be developed to prevent and detect future accuracy issues related to performance dates, award types, and award descriptions.

In addition, financial management systems help OpDivs and StaffDivs ensure operational effectiveness and efficiency, financial reporting reliability, and compliance with applicable laws and regulations. OIG continues to find deficiencies in internal controls over segregation of duties, configuration management for approved changes to HHS financial systems, and access to HHS financial systems.¹⁰² These deficiencies collectively constitute a significant deficiency in internal controls. HHS must take additional actions to address and resolve these issues, including continuing to work to control user access, ensuring proper approval of and documentation supporting system changes, and ensuring appropriate segregation of duties.¹⁰³

3: Delivering Value, Quality, and Improved Outcomes in CMS Programs

Key Takeaways

Relevant Agency

- CMS

Elements of the Challenge

- Aligning program incentives with quality, equity, and health outcomes
- Strengthening program integrity
- Ensuring smooth transitions when PHE waivers and flexibilities end

CMS is tasked with administering the two largest Federal health care programs, Medicare and Medicaid, as well as CHIP and the Health Insurance Marketplaces. More than 147 million people (43 percent of Americans) rely on Medicare and Medicaid for their health insurance including senior citizens, individuals with disabilities, low-income families and individuals, and individuals with end-stage renal disease.¹⁰⁴

Effectively and efficiently managing this complex suite of programs is a top HHS challenge. These programs use multiple delivery models (including FFS, managed care, and value-based care); cover a broad array of health conditions, providers, services, settings, and insurance plans; and operate pursuant to intricate statutory directives and regulatory schemes. Spending on these programs is massive, totaling \$1.3 trillion in FY 2021.¹⁰⁵ CMS's task is further complicated by the fact that it must administer portions of these programs collaboratively with States and private insurance companies. For example, Medicaid is functionally more than 50 different Federal-State partnerships, with substantial State customization and variation in benefits and payment methodologies. CMS programs rapidly change and evolve. Most recently, for example, IRA enacted major changes including a new requirement to negotiate prescription drug prices for certain expensive Medicare Part B or Part D drugs, and an extension of subsidies available to purchasers of marketplace plans. (For more information about implementing IRA, [see TMC 2.](#))

Administering these programs comes with an array of operational and program integrity risks and challenges, as well as promising opportunities for better care and health outcomes, improved access and health equity, lower costs, more transparency and choices for consumers, and reduced administrative burden.¹⁰⁶ (Additional information regarding challenges related to costs and quality of care can be found in [TMCs 2](#) and [4.](#)) To achieve better care at lower cost, HHS must maintain a steady focus on developing and refining effective, innovative, and evidence-driven payment and delivery models. At the same time, CMS must be proactive in preventing and detecting fraud, waste, and abuse, including abuse and neglect in nursing homes and other care settings. HHS must pay special attention to effectiveness and program integrity in nascent areas such as expanded benefits addressing social determinants of health and new uses of digital technology. This is vitally important given the current and anticipated growth in the costs and numbers of people enrolled 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 increases in program costs in coming decades and improving the lives and health outcomes of the people they serve.

Aligning program incentives with quality, equity, and health outcomes

Developing effective incentives, policies, and safeguards to drive better quality, equity, and health outcomes is a significant challenge given the complexities of health care, the evolving science of quality measurement, the broad range of providers and others who furnish services, and the varying needs and circumstances of the populations served by CMS programs. One of the main ways that CMS tests potential quality incentives is through the CMS Innovation Center. In a report to Congress, CMS estimated that more than 27.8 million people enrolled in Medicare and Medicaid and individuals with private insurance in multipayer model tests had been included in Innovation Center models and initiatives as of September 30, 2020.¹⁰⁷ Estimated payments for model tests and initiatives (excluding reimbursement for covered services) totaled about \$13 billion for FY 2010–20.

Reforming health care payment and delivery models gives rise to risk-management challenges in CMS programs. CMS must maintain a steady focus on quality of care and health outcomes. This is particularly true during a PHE if normal guardrails and conditions are adjusted to address exigent public health circumstances and if providers may temporarily be unable to meet optimal care guidelines. ([See TMC 4](#) for further discussion of quality-of-care challenges.)

Quality measurement

The Department is undertaking initiatives to streamline, improve, and target quality measures more precisely and to move from process measures to outcome measures. In March 2021, CMS launched Meaningful Measures 2.0: Moving from Reduction to Modernization to “reduce the number of measures in its programs” and “further shape the entire ecosystem of quality measures that drive value-based care.”¹⁰⁸ CMS recently announced its first set of quality measures for Medicaid-funded home and community-based services.¹⁰⁹

Moving forward, HHS should ensure that its programs use effective, evidence-based measures to monitor 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 HHS divisions that use quality measurements to enhance efficiency and strengthen quality measurement. CMS outlined a range of steps it is taking in its 2021 annual report to Congress on Identification of Quality Measurement Priorities.¹¹⁰

Aligning payment incentives

In managing its portfolio of FFS, managed care, and value-based payment models, CMS must ensure that payment mechanisms are driving high-quality, efficient care. OIG work has identified many opportunities for better alignment of incentives and outcomes. For example, an OIG report examined inpatient rehabilitation facility (IRF) transfer payment policy for early discharges to home health and found that CMS’s transfer payment policy was not aligned with costs, which may have provided IRFs with a financial incentive to admit patients inappropriately.¹¹¹ In response, CMS reported to OIG that it is developing an IRF Review Choice Demonstration and collaborating with ASPE to develop a prototype and recommendations for a

unified, post-acute care payment system to more closely align Medicare post-acute care payments with the post-acute care needs of Medicare beneficiaries. Some policies result in Medicare and enrollees paying more for care provided in certain settings than for the same care provided in other settings. A 2021 study found that Medicare and enrollees who receive outpatient services and then are admitted for inpatient care for the same condition shortly afterward pay more if the outpatient services provider is affiliated with the admitting hospital than if the outpatient service provider is wholly owned by the admitting hospital.¹¹² CMS should be attentive to nursing home payments to ensure appropriate incentives to deliver high-quality care. For example, understanding SNF costs is crucial to understanding the factors that contribute to

In managing its portfolio of FFS, managed care, and value-based payment models, CMS must ensure that payment mechanisms are driving high-quality, efficient care.

nursing home performance and how nursing homes deliver care to beneficiaries. OIG is assessing whether SNFs are reporting related-party costs as per Federal regulations and will determine whether SNF allocations of Medicare funds could impact beneficiary care, such as whether overhead costs might have increased while allocations for patient care decreased, potentially reducing care.

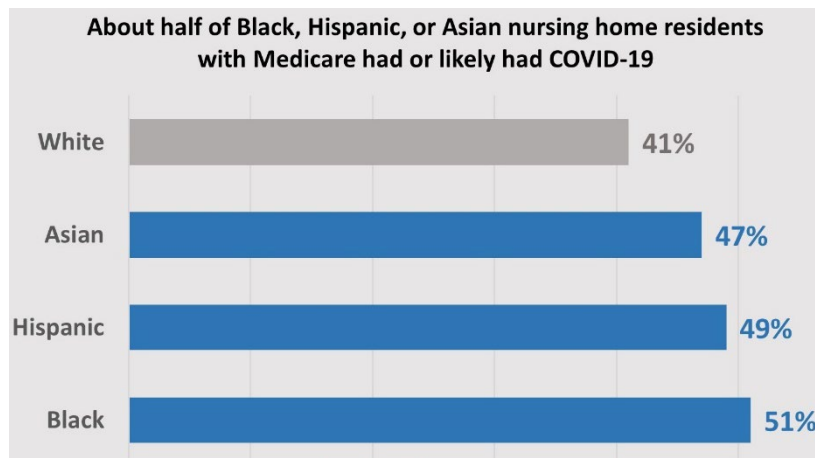
Another recent OIG report, discussed in more detail [in TMC 4](#), revealed continued high rates of patient harm in hospitals and recommended that CMS broaden its lists of hospital-acquired conditions (HACs) to capture common, preventable, and high-cost harm events.¹¹³ This expansion would have the effect of reducing payments for a broader array of HACs, thus more appropriately aligning payment with quality of care. CMS has observed challenges in aligning payment and desired outcomes in some models being tested by the Innovation Center. In a July 2022 analysis of certain acute and specialty care models, CMS noted that generous financial incentive payments spurred robust participation in the models but made it difficult for many models to demonstrate net savings.¹¹⁴ CMS must continue to monitor the results of its range of models and remain attuned to opportunities to better align payments with quality and efficient care.

Nontraditional services

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

Equity

Access to care and health equity are longstanding challenges that have been exacerbated by the COVID-19 pandemic. OIG work has long identified access issues in Medicare and Medicaid. For example, a report examining provider shortages and limited availability of behavioral health services in New Mexico's Medicaid managed care program provides insights into challenges likely shared by other States. Identified challenges included an uneven distribution of licensed providers across the State, staff retention, poor care coordination, and a lack of transportation and broadband services. Promising initiatives to increase availability of behavioral health services included open-access scheduling, a "treat first" clinical model, care integration, and telehealth.¹¹⁵



Graphic adapted from OIG report [COVID-19 Had A Devastating Impact on Beneficiaries in Nursing Homes During 2020](#).

Ensuring that programs have accurate demographic and other data is a requisite step in identifying, understanding causes of, and addressing health disparities. An OIG analysis of Medicare claims data showed that in 2020 the COVID-19 pandemic did not affect nursing home residents equally. About half of Black, Hispanic, and Asian nursing home residents had or likely had COVID-19, compared to 41 percent of White residents.¹¹⁶ OIG also found that dually eligible, Black, Hispanic, and older beneficiaries were disproportionately hospitalized with COVID-19 during surges in six localities. Another OIG report found that inaccuracies in Medicare’s race and ethnicity data hinder CMS’s ability to assess health disparities and recommended steps CMS should take to improve this data.¹¹⁷

Strengthening program integrity

HHS must be attentive across its programs to combating fraud, waste, and abuse. The nature of fraud and abuse risk differs depending on how Medicare and Medicaid pay for services. Traditional FFS risks, arising from volume-sensitive payments, include inappropriate increased utilization, increased program costs, and improper patient steering. In managed care, a capitated payment system could lead to potential risks such as: (1) stinting on care to reduce costs; (2) discriminating against expensive patients; or (3) manipulating or falsifying data used to measure performance, outcomes, acuity, or diagnoses for risk adjustment. In addition, 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. 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 value-based program or model, CMS must consider the range of incentives in the model.

Managed care

HHS faces a significant challenge in conducting oversight of managed care programs and protecting against fraud, waste, and abuse. Managed care is the primary delivery system for Medicaid, covering at least some services for more than 80 percent of all enrollees.¹¹⁸ In Medicare, nearly half of beneficiaries are currently enrolled in Medicare Advantage Organizations (MAOs).

The MA program is vulnerable to fraud, waste, and abuse perpetrated by MAOs to inappropriately inflate payments they receive from Medicare or inappropriately deny care they are obligated to provide. For example, OIG has found risk-adjustment data that MAOs submitted to CMS for use in the risk-adjustment program were not always supported by medical records. OIG has recommended that certain MAOs refund overpayments and enhance their policies and procedures to prevent, detect, and correct noncompliance with Federal requirements.¹¹⁹ OIG also found that billions of dollars in estimated MA risk-adjusted payments supported solely through chart reviews or diagnoses reported only on health risk assessments raise concerns about the completeness of payment data submitted to CMS, the validity of diagnoses on chart reviews and health risk assessments, and the quality of care provided to beneficiaries.^{120, 121} OIG has recommended CMS improve its oversight of MAOs so that MAOs will ensure practices drive better care—not just higher profits—as well as enact policies and procedures to improve the integrity and usefulness of payment data. ([See TMC 2](#) for additional information on program integrity related to managed care and Medicaid eligibility determinations.)

Additionally, significant concerns have been raised that the capitated payment model used in MA may provide a potential incentive for MAOs to inappropriately deny access to services and payments to increase their profits. Recent OIG work showed that MAOs sometimes delayed or denied enrollees access to medical services, even though the requested care was medically necessary and met Medicare coverage rules. These denials likely prevented or delayed needed care for beneficiaries.¹²² OIG also found that high numbers of overturned denials upon appeal and performance problems identified by CMS audits raise concerns that some beneficiaries and providers may not be getting services and payments that MAOs are required to provide.¹²³

Value-based models

In testing and implementing value-based models, CMS must continue to focus on program integrity risks, incorporating safeguards to reduce and strategies to correct these risks. Focusing on program integrity risk is especially important for

models that introduce new payment incentives, which could lead to new fraud schemes, and for models for which customary payment, coverage, or fraud and abuse laws do not apply due to waivers, exceptions, or safe harbors. Additional risks may arise from novel flexibilities granted because of the COVID-19 PHE.

Many value-based models promote care in home and community settings through in-person home visits, remote monitoring, and other technologies. These services are often preferred by patients. OIG work in areas such as hospice care, home health, and personal care services consistently demonstrates that patients may be vulnerable to fraud and abuse in home and community-based settings. Ensuring that home-based services meet quality of care requirements remains important. ([See TMC 4](#) for further information on quality of care.)

Marketplaces

The Department must be attuned to ensuring that payments for advance premium tax credits (APTCs) for consumers enrolled in marketplace insurance are accurate. There was an estimated 20 percent increase in people eligible for subsidized marketplace coverage after passage of the *American Rescue Plan Act of 2021* and an estimated \$35.5 billion increase in premium tax credits.¹²⁴ With passage of the IRA, a further increase in the volume of APTC is possible. OIG work has found weaknesses in State and Federal marketplace systems for ensuring correct eligibility determinations and accurate APTC payments. For example, a recent OIG audit determined that APTC payments were paid on behalf of enrollees who did not make required premium payments and recommended improvements to processes and data collection and sharing with the Internal Revenue Service.¹²⁵

Additional risks to program integrity across Medicare and Medicaid are covered in more detail in other TMCs.

Ensuring smooth transitions when PHE waivers and flexibilities end

When the President declares a national emergency or major disaster and the Secretary declares a PHE, the Secretary is authorized under section 1135 of the *Social Security Act* to temporarily modify or waive certain Medicare, Medicaid, CHIP, and *Health Insurance Portability and Accountability Act of 1996* (HIPAA) requirements to ensure sufficient health care items and services are available to meet the needs of beneficiaries and to ensure providers of such items and services in good faith may be reimbursed and exempted from sanctions. In some cases, the Department can issue blanket waivers; in others, providers or States ask for individual waivers. In implementing, administering, and terminating waivers and flexibilities, CMS must strive to ensure timeliness, continuity, and quality of care, as well as to ensure equity for people served by its programs.

CMS implemented hundreds of waivers and flexibilities addressing coverage and payment for items and services in response to the COVID-19 PHE. For example, CMS suspended or reduced the scope of many program integrity safeguards, such as provider enrollment screening, in an effort to ensure access to care in exigent circumstances. However, these waivers and flexibilities also raised the risk of fraud, waste, or abuse. CMS should take steps to ensure that funds are paid only to eligible recipients—in correct amounts—and used per program requirements.

CMS must plan for and manage risks associated with termination of these waivers and flexibilities when the COVID-19 PHE ends. CMS must be attuned to the impacts of unwinding on enrollees, providers, State agencies, and health care delivery, as well as on program payments, effectiveness, and outcomes. The Department has indicated that it will provide at least 60 days notice before terminating the PHE. Even with such notice, as a practical matter States, providers, contractors, and others may be challenged to shift business operations rapidly and effectively. They will need clear, timely guidance from CMS.

As a condition for receiving a temporary increase in Medicaid funding as authorized under the *Families First Coronavirus Response Act* (FFCRA), States must maintain enrollments of most people enrolled in Medicaid as of March 18, 2020, through the end of the month in which the PHE ends. In large part due to this condition, Medicaid and CHIP enrollment increased between February 2020 and May 2022 by 25.9 percent.¹²⁶ After the COVID-19 PHE ends, States will be required to redetermine eligibility for millions of people covered through Medicaid and CHIP during the PHE. CMS has issued guidance giving States up to 12 months to initiate and

14 months after the end of the PHE to complete all redeterminations, and OIG is planning oversight of this process. A 50-State survey of State Medicaid and CHIP officials in January 2022 found that many State Medicaid programs had not made key decisions on how to resume eligibility determinations, and only half of the States had a plan for doing so.¹²⁷ States reported wide variances among anticipated approaches. In April 2022, CMS published best and promising practices from States based on discussions with every State and Territory related to renewal planning and preparation for unwinding. In June 2022, CMS published *Top 10 Fundamental Actions to Prepare for Unwinding and Resources to Support State Efforts*.¹²⁸ The stakes are high for this transition because of the risk of unnecessary disruptions in insurance coverage and patient care. CMS has indicated that it plans to streamline Medicaid and marketplace enrollment to ensure individuals can receive coverage in the program for which they are eligible.¹²⁹ At the conclusion of the PHE, it will be important for CMS to ensure that States complete pending eligibility and enrollment actions per CMS requirements. ([See TMC 2](#) for additional discussion of Medicaid eligibility determinations and improper payments.)

Also challenging may be the termination of waivers and flexibilities through which CMS expanded Medicare access to a wide range of services that could be delivered by telehealth. These waivers and flexibilities proved effective in aiding providers and patients in furnishing and obtaining health care beyond the more limited range of telehealth services ordinarily covered by Medicare. To the extent possible, CMS must ensure that new, post-PHE telehealth policies—including any extensions of existing waivers or flexibilities—are designed to improve care and enhance access while also protecting patients and programs from fraud and abuse. A new OIG evaluation found that certain people enrolled in Medicare, such as urban residents and Hispanic people, were more likely than others to use telehealth during the first year of the COVID-19 pandemic.¹³⁰ This report concluded that as CMS, HHS, Congress, and other stakeholders consider permanent changes to Medicare telehealth services, it is important to balance concerns about issues such as access, quality of care, health equity, and program integrity. The report recommended CMS take appropriate steps to enable a successful transition from current pandemic-related flexibilities to well-considered long-term policies for the use of telehealth. ([See TMC 5](#) for additional information on telehealth.)

Looking forward, to the extent flexibilities and waivers are needed to address new or existing PHEs, CMS should mitigate risks by incorporating guardrails into their design, monitor implementation of flexibilities for any abuse, and take prompt action to correct problems and hold wrongdoers accountable.

4: Safeguarding the Well-Being of HHS Beneficiaries

Key Takeaways

Relevant Agencies

- ACF, CMS, IHS, HRSA, SAMHSA

Elements of the Challenge

- Promoting health and safety in nursing homes
- 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

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

Promoting health and safety in nursing homes

The administration has prioritized improving nursing home care and the Department continues efforts to improve the quality of services and the information available to beneficiaries and their families when selecting a care provider.¹³¹ A longstanding Department effort is CMS's Five-Star Quality Rating System that is intended to facilitate informed comparisons of nursing homes. CMS also issued guidance to improve safety and quality of care for long-term care residents, including measures such as steps to reduce crowding.¹³² As the Nation strives to recover from the COVID-19 pandemic, it is important that residents and their families have accurate and timely information about infection rates in nursing homes and the vaccination status of staff.

The COVID-19 pandemic—the first in a century for which a nationwide PHE was declared—posed unprecedented challenges to the Department's and other stakeholders' efforts to protect the health and safety of nursing home residents. Nursing home residents were prioritized for COVID-19 vaccinations, but this vulnerable population sustained an outsized toll from the disease, especially early in the pandemic. In 2020, 42 percent of Medicare nursing home residents were diagnosed with or likely had COVID-19, with rates of disease even higher for Black, Hispanic, and Asian residents.¹³³ The COVID-19 pandemic also highlighted the importance of good infection control practices for COVID-19 and other infectious diseases. Quality Improvement Organizations have conducted education and outreach to nursing homes in ways such as by providing assistance with COVID-19 infection control and promoting vaccinations for residents and staff. Initiatives to vaccinate nursing home staff against COVID-19 have resulted in a vaccination rate above 90 percent.¹³⁴

As the COVID-19 pandemic has taken a heavy toll on nursing home residents, longstanding staffing and quality-of-care concerns remain pressing. Staffing issues have long complicated nursing homes' ability to provide safe and high-quality care, and CMS now includes additional staffing data in nursing homes inspections. As part of the administration's priority focus on improving quality of nursing home care, CMS launched a new effort to establish minimum staffing requirements which included issuing a Request for Information and conducting a study it plans to issue in spring 2023.¹³⁵

Planned revisions to the nursing home survey process aim to improve complaint investigations and facility-reported incidents.¹³⁶ Additionally, nursing homes were charged with implementing new infection control imperatives needed to maintain operations during natural disasters, utility service disruptions, and other occurrences that complicate delivery of care. OIG is continuing its series of audits to assess nursing home compliance with health and safety regulations. An 8-State review identified more than 2,200 areas of potential noncompliance with life safety and emergency preparedness requirements after unannounced visits to 150 nursing homes.¹³⁷

An 8-State review identified more than 2,200 areas of noncompliance with life safety and emergency preparedness requirements after unannounced visits to 150 nursing homes.

Ensuring effective front-line oversight of nursing homes by State survey agencies is another longstanding challenge that was exacerbated by the COVID-19 pandemic. In the early months of the COVID-19 PHE, CMS directed State agencies to focus on infection control surveys and serious complaint investigations and halt comprehensive standard surveys. However, these infection control surveys identified few deficiencies despite significant COVID-19 outbreaks at many nursing homes during that timeframe, and backlogs of standard surveys mounted.^{138, 139} These rising backlogs put further pressure on an already strained system, as many States were failing to investigate serious complaints in a timely manner even before the pandemic.¹⁴⁰ Furthermore, appropriate surveyor oversight has long been a concern, with just over half of the States failing to meet survey performance measures in 3 or 4 consecutive years from FY 2015 to FY 2018.¹⁴¹ CMS has expressed its commitment to clearing these backlogs. OIG has recommended CMS safeguard the health and safety of nursing home residents by ensuring facility correction of deficiencies.¹⁴² Government enforcement actions have stopped some poorly performing nursing homes from rendering deficient services. One nursing home chain charged with rendering grossly substandard care to people enrolled in Medicare and Medicaid agreed to repay \$18 million and abide by the terms of a corporate integrity agreement to ensure that it delivers appropriate care going forward.¹⁴³

Pressing changes are needed to nursing home care beyond those associated with the COVID-19 pandemic. For example, OIG continues looking at the use of antipsychotic drugs and recommended improved data to better ensure that patients do not receive inappropriate medications.¹⁴⁴ OIG has also evaluated facility-initiated discharges and will continue to urge further attention to ensure adequate safeguards against inappropriately moving residents against their wishes or interests.¹⁴⁵ In June 2022, CMS released updated long-term care surveyor guidance and training related to facility-initiated discharge.¹⁴⁶

Looking forward, CMS will need to consider the full range of potential contributors to poor nursing home performance including, for example, the potential impacts of private equity and other ownership structures and fragmented reimbursement for nursing home care. Ensuring that nursing homes prioritize quality of care and quality of life for residents remains important. CMS must continue to take steps to ensure that it and the States can detect problems at nursing homes quickly and insist on rapid remediation. Improving nursing home care will require partnerships and sustained commitment from Government and private stakeholders to achieve positive change. OIG is prioritizing improving nursing home care and continuing to conduct a substantial number of audits and evaluations addressing an array of nursing home topics.

Ensuring safety and quality of care for people enrolled in Federal health care programs

Federal health care programs cover specific health care services that may include hospital care, physician services, prescription drugs, immunizations, hospice care, home and community-based care, DME, and skilled nursing care.

Delivering covered services

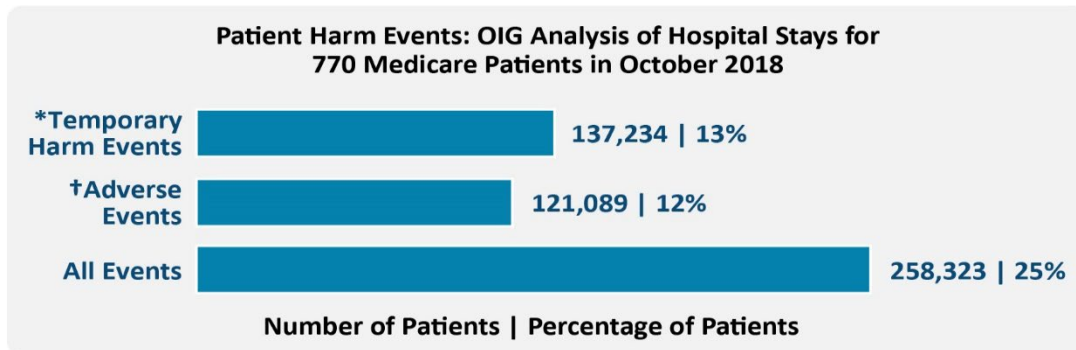
Ensuring access to and use of care that meets quality and safety standards remains a challenge. Even when Federal health care programs cover care, many people do not actually receive the care they need. For example, OIG found that more than 500,000 children with attention deficit/hyperactivity disorder (ADHD) who were Medicaid-enrolled did not receive timely followup care, and that more than 50,000 such children did not receive behavioral therapy as recommended by professional guidelines.¹⁴⁷ Moreover, hospice care is a growing health care sector serving people and their families at an extremely vulnerable time near end-of-life. OIG found that more than 80 percent of hospice providers had quality-of-care deficiencies.¹⁴⁸

Additionally, fixed daily payment structures may incentivize hospices to enroll people for longer time periods but provide insufficient care. At times, the greatest barrier to care derives from a person's own behavior and beliefs. The Department is currently working to overcome substantial vaccine hesitancy that has hampered COVID-19 vaccination efforts, despite ample supplies of and an adequate ability to distribute and administer multiple, safe, and effective vaccines.¹⁴⁹

OIG found more than 500,000 children with ADHD who were Medicaid-enrolled did not receive timely followup care, and more than 50,000 such children did not receive behavioral therapy as recommended by professional guidelines.

Improving quality of care

Although the Department has made progress, more work remains to improve access to and quality of all types of care. Oversight work revealed that patients experience significant rates of adverse events (patient harm as a result of medical care) in health care facilities. Specifically, in a series of studies looking at patient care from 2010 to 2014, OIG found that 25 percent of people enrolled in Medicare were harmed during stays in acute-care hospitals (2010), 33 percent in SNFs (2011), 29 percent in rehabilitation hospitals (2012), and 46 percent in long-term care hospitals (2014).¹⁵⁰ OIG also found that hospitals did not identify when harm occurred in their facilities, in part due to confusion over guidance from HHS and other Government agencies regarding how to define and report adverse events.¹⁵¹ OIG re-examined the harm rate for Medicare beneficiaries in hospitals in 2018 and found that the rate was similar to that in OIG’s prior study for 2010.¹⁵²



Source: OIG analysis of hospital stays for 770 Medicare patients in October 2018.

* The rate and number of patients who experienced temporary harm events involve patients who experienced at least one temporary harm event and no adverse events.

† The rate and number of patients who experienced adverse events involve patients who experienced at least one adverse event. Four percent of patients (41,708) in this group also experienced temporary harm.

[Indian Health Service \(IHS\)](#). To address longstanding quality-of-care concerns in IHS-operated hospitals,¹⁵³ IHS created a Quality Framework and Office of Quality to provide better guidance and oversight to its facilities and clinical staff.¹⁵⁴ IHS is also working to establish a nationwide compliance program to address several OIG recommendations and improve care for people receiving benefits. However, some longstanding challenges, such as recruiting and retaining qualified staff, persist. IHS continues efforts to combat the longstanding problem of OUD and can take additional steps to better protect people receiving benefits.¹⁵⁵ There is also a pressing need to protect patients—especially children—from predators who may be within the ranks of health care and service providers. To continue improvements at IHS, OIG has recommended IHS prioritize developing and implementing a staffing program to ensure sufficient qualified staff at facilities, enhance training for staff and hospital leaders, intervene quickly and effectively when quality problems are identified, and establish better procedures, including improved external communications.¹⁵⁶ ([See TMC 6](#) for more information on crosscutting Government efforts to keep patients safe).

Protecting the health and safety of children served by HHS programs

HHS operates or funds many programs that provide child care, education, and residential care in addition to health care for children, including some especially vulnerable children such as children living in foster care and children in the UC Program. The Head Start program—administered by the Administration for Children and Families (ACF)—promotes school readiness for nearly 900,000 children in low-income families,¹⁵⁷ and the Child Care and Development Fund (CCDF) provides child care assistance for about 1.5 million children in low-income families.¹⁵⁸ The importance of properly vetting program staff to ensure child safety is discussed below.

Operating the UC Program

By law, UC who enter the United States without lawful immigration status are referred to the care and custody of ORR. ORR's UC Program merits specific discussion as it is uniquely mandated to assume care and custody of children. Through the UC Program, ORR places children in shelters and other facilities operated by grantees or contractors. These facilities provide food and shelter as well as medical and mental health care and other services. Children remain in these placements until a sponsor (usually a parent or family member) is found to whom the child may be safely released, the child's immigration status is resolved, or the child turns 18 years old and ages out of the program. Since ORR began operating the UC Program in 2002, it has served more than 410,000 children.¹⁵⁹ As of April 20, 2022, more than 9,800 UC were in HHS custody.¹⁶⁰

During the previous administration, ORR was called upon to care for more children who were separated from parents or guardians by the Department of Homeland Security (DHS) at or after arriving in the United States. OIG's work has shown that neither ORR care provider facilities nor DHS had kept adequate records about separated families, impeding efforts to identify and reunite them. Prior to recent reform efforts, OIG found that ORR and DHS were not able to systemically automate, collect, or reconcile information about separated children across both agencies.¹⁶¹ Limitations in data about separated children complicate HHS's ability to ensure appropriate placement and may cause children to spend more time in HHS custody. Issues related to identifying and vetting appropriate sponsors may also contribute to the amount of time children spend in HHS care facilities. During a 2018 audit, OIG found two key vulnerabilities with Influx Care Facilities (ICFs): (1) limited staff background checks and (2) insufficient clinical staff to serve children's mental health needs.¹⁶² In prior evaluations of the UC Program, OIG also found: (1) a lack of routine oversight concerning whether facilities' regular use of inspection checklists ensuring required physical security measures were present and working¹⁶³ and (2) that ORR's incident reporting system lacked designated fields to capture information to protect the safety of children.¹⁶⁴ OIG also found areas for improvement in HHS intra-agency coordination and communication with ORR about UC.¹⁶⁵ (See TMC 5 for information about the UC portal.)

The number of children entering the United States fluctuates. The Department prepares to serve additional children at times of increased need. In response to approximately 122,000 referrals of UC in FY 2021, compared to 16,000 referrals in FY 2020, ORR opened 1 ICF and 14 Emergency Intake Sites (EISs) to provide services and additional space when the capacity of standard shelters was exceeded. ORR opened these facilities in an effort to avoid having children spend prolonged periods of time in border facilities operated by DHS. ORR established these facilities during a time when ORR's total available bed capacity across its standard care provider network had been reduced by up to 40 percent due to COVID-19 mitigation measures and staffing shortages. At the same time, nearly 6,000 children were in DHS custody awaiting transfer to and placement in an ORR facility, with more than 4,000 of these transfers exceeding the 72-hour limit (for an average of 138 hours). OIG found that operational challenges within ORR and the ORR EIS at Fort Bliss hindered case management for children.¹⁶⁶ Although HHS has closed or transitioned all EIS to ICFs, OIG has recommended ORR take a number of measures to help ensure children receive quality case management services that prioritize their safety and well-being, including during an influx.

The Department must work to ensure that UC Program-funded facilities meet all safety requirements, including infection control priorities related to COVID-19, and provide adequate medical and mental health care. As discussed below, HHS must also enhance efforts to ensure that all staff with unsupervised and direct 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 people. Thousands of HHS-funded providers hold positions of trust that bring them into close contact with individuals, often behind closed doors and at especially vulnerable times. The vast

majority of providers seek to serve people's best interests. However, some providers may harm people, and HHS must protect people enrolled in its programs from abuse and neglect. For example, a former IHS pediatrician is currently serving a prison sentence for sexually assaulting boys he treated as patients. This disturbing case commanded extensive attention, and the Department committed to collaborating with a Presidential Task Force on Protecting Native American Children in the IHS system established in March 2019.¹⁶⁷ The task force released a report in July 2020 detailing its investigation of institutional and systemic breakdowns that resulted in failure to protect children from abuse.¹⁶⁸ ([See TMC 6](#) regarding protecting IHS patients.) Better attention to protecting vulnerable people of all ages in all HHS care settings is also needed.

Vetting providers and staff

Although even the most thorough vetting may not completely prevent all potential predators from abusing Federal programs to gain access to victims, background checks remain a useful prevention tool. OIG identified a lack of uniformity across UC facilities in conducting all required background checks for staff whose jobs entailed direct access to and supervision of children.¹⁶⁹ OIG is currently reviewing whether the UC Program's ICFs and previously instituted EISs, which are not State-licensed and are established during periods of UC influx, conducted required background checks before hiring employees. This review also seeks to determine whether mitigation strategies have since been implemented to ensure the safety and well-being of children.¹⁷⁰

Conducting adequate background checks has been a problem in other HHS-funded child care programs as well. In several audits, OIG found that some States have not fully implemented CCDF requirements to conduct comprehensive criminal background checks on current and prospective staff.¹⁷¹ Additionally, some IHS-funded, Tribe-run health centers failed to conduct required background checks on employees working with American Indian children.¹⁷² Implementing background checks for long-term care providers remains a challenge as well.¹⁷³ 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 only staff who have passed required background checks have access to patients in various health care settings and to children in the UC Program and CCDF-funded programs. The Department is working to support States implementing 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 allowable timelines described in the CCDF Final Rule.¹⁷⁴

Identifying and reporting abuse and neglect

People in all care settings are at risk of abuse and neglect. Home and community-based services allow many Medicaid beneficiaries opportunities to avoid undesired facility care. However, some beneficiaries have been abused or neglected by individuals such as family members who were paid by Federal health care programs to care for the beneficiary at home. Group homes provide care to many especially vulnerable people, including adults with developmental disabilities. OIG's work found extensive failures in the proper handling of critical incidents, including the suspected abuse and neglect of group home residents.¹⁷⁵ The Department, in coordination with OIG, has created several resources to better address the abuse and neglect of residents in group homes. These resources include model practices for: (1) State incident management and investigation, (2) State incident management audits, (3) State mortality reviews, and (4) State quality assurance.¹⁷⁶ CMS has also published additional resources and training materials regarding health and welfare issues in Medicaid home and community-based services.¹⁷⁷

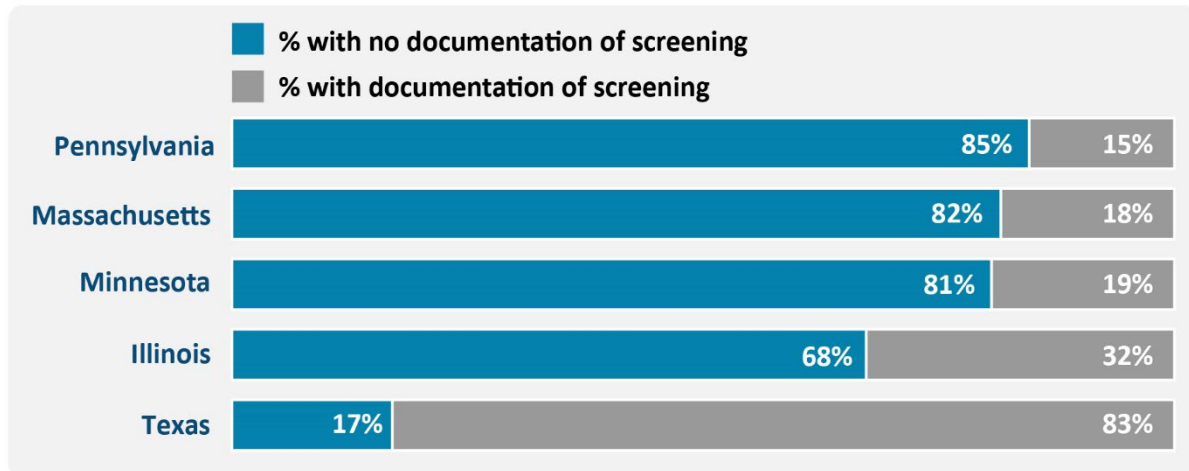
About 1.8 million people enrolled in Medicare receive care in SNFs each year.¹⁷⁸ OIG has identified cases of substantial failure to report incidents of potential abuse or neglect of Medicare beneficiaries living in SNFs who require treatment in hospital emergency departments.¹⁷⁹ CMS's June 2022 Updated Guidance for Nursing Home Resident Health and Safety clarifies reporting requirements.¹⁸⁰ In addition, OIG work identified cases of potential abuse of people enrolled in Medicare who were in hospice care and for whom hospices failed to act in some instances.¹⁸¹ These cases revealed vulnerabilities in

beneficiary protections that CMS must address to better ensure that beneficiary harm is identified, reported, addressed, and ultimately prevented.

All States have enacted mandatory reporting laws that require certain individuals, such as schoolteachers or nursing home staff, to report suspected abuse or neglect targeting vulnerable individuals. Despite State and Federal requirements, many instances of abuse and neglect go unreported, making it harder to help victims and hold wrongdoers accountable.¹⁸²

Failure to conduct adequate screening, including failure to adequately screen for sex trafficking children who went missing from foster care, may also cause abuse and neglect to go undetected.¹⁸³

The case files of many children in OIG's review had no documentation of a screening to identify whether they were victims of sex trafficking, as required.



Source: OIG analysis of documentation in foster care case files, 2022. Our review included 74 children from Pennsylvania, 91 children from Minnesota, 88 children from Massachusetts, 62 children from Illinois, and 98 children from Texas.

It is important to prevent harm by identifying providers and facilities that are subjecting beneficiaries to abuse or neglect. States and other partners should use claims data to better identify unreported abuse and neglect. OIG created a resource guide to help accomplish this goal.¹⁸⁴ OIG has also explored Medicaid claims data as an additional way to identify potential child abuse and neglect.¹⁸⁵ Additional efforts would help 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 work to ensure that its reporting requirements sufficiently protect individuals in all care settings and are adequately enforced. Protecting people from abuse and neglect is a critical responsibility requiring attention and cooperation from all stakeholders.

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

Key Takeaways

Relevant Agencies

- All HHS

Elements of the Challenge

- Expanding and improving HHS's capacity to collect, use, and exchange data to support evidence-based policymaking, management, and program improvement
- Securing HHS data and systems to positively impact the cybersecurity posture of HHS and the sectors HHS influences

The Department continues to improve how it collects, manages, shares, and secures its data. In parallel, HHS is refining its approach to influence and shape how other entities use technology. Yet HHS faces significant challenges to both protect data and technology from persistent cybersecurity threats and improve how the Department and related entities share large amounts of critical data from disparate sources, including public health data, on an unprecedented scale. The importance of managing these challenges is highlighted by critical issues such as addressing inequities across health and human service programs, which often requires foundational improvements to data collection and analysis to better understand the effects on disadvantaged individuals and communities. Continued modernization of HHS data and technology capabilities is needed for HHS and its divisions to fulfill their missions, improve situational awareness, and better prepare for future public health threats and emergencies.

HHS's authorities and policies also shape how technology and individuals' data are used and protected by other private and public entities. These authorities are increasingly important in a technology-enabled health and human services delivery system. HHS has made progress; however, the ability to access quality data quickly and easily remains a challenge within the Department and in the health care and public health systems. Data collection challenges also hinder better understanding of racial and geographical population disparities. ([See TMC 3](#) for more information on longstanding access to care and health equity challenges.) Continued progress on these challenges must happen as the Department continues to respond to multiple, simultaneous emergencies and while the quantity, frequency, and sophistication of cybersecurity risks rapidly increase.

Expanding and improving HHS's capacity to collect, use, and share data to support evidence-based policymaking, management, and program improvement

Data are central to every HHS program, and the Department and its programs are continually seeking to improve their ability to collect, use, and exchange data from disparate sources. Collecting large amounts of data does not automatically translate to efficient and effective use, particularly as much of HHS's data is unstructured and not standardized. The Department is finalizing its HHS Data Strategy, which is intended to focus on addressing challenges related to data sharing, security, privacy, and governance.

Improving HHS data governance and standardization is critical for effective program operations

Improving the governance, standardization, and structure of data collected and used by HHS is fundamental to making HHS programs more effective and efficient. However, data governance practices are not consistent across HHS. HHS's need to improve data governance is not unique to the Department and is a requirement for all Federal agencies.¹⁸⁶ Although progress has been made, the Department must effectively operationalize its data governance plans. Hurdles HHS must overcome include the continued effect of data silos and legacy technology that do not easily support modern data governance and standardization.

Most significantly, HHS faces challenges in how it manages and leverages data across its programs. Most HHS divisions primarily collect data to administer their own programs. The ability of OpDivs and StaffDivs to quickly access and use actionable data from other programs remains a challenge because data are often housed within a single HHS division's data silo.¹⁸⁷ Eliminating or reducing data silos within the Department and within HHS programs, ensuring that standardized data sets are developed, and increasing appropriate access across programs are essential to improving program management, evidence-based decision making, and benefiting from new technologies. ([See TMC 6](#) for more information on HHS's coordination challenges.)

The effect of these data silos was seen during the response to the pandemic, limiting how HHS and its partners gained insight about COVID-19. Achieving a mature, public health reporting system that can respond to future public health threats requires extensive collaboration among Federal, State, local, and Tribal entities. It requires interoperability and security across a range of systems to allow for the exchange of data in a timely fashion and data collection that is accurate, timely, and efficient to track and thwart emerging health threats. To address these challenges, CDC is taking steps to modernize its operations, including developing new internal systems, processes, and policies to enhance bidirectional communication.¹⁸⁸

Some HHS programs rely on decades-old, legacy IT systems with limited data capabilities, which may exacerbate the effect of data silos.¹⁸⁹ Legacy systems can limit operational effectiveness by acting as a significant barrier to modern data analysis and sharing tools. These are often custom software projects that require significant manual work to communicate with other systems. In the ORR UC Program, deficiencies with the UC Portal's search capabilities impeded case managers' ability to reliably determine whether potential sponsors were sponsoring other children, and ORR staff have had to engage in significant efforts to receive and reconcile data from other Federal agencies.^{190, 191} ([See TMC 4](#) for more information on challenges associated with the UC Program.) While HHS is making progress in updating its critical legacy systems, these efforts are complex and can take years. However, failure to take on these projects poses a greater long-term risk, and HHS must continue to invest in the long-term modernization of its IT systems.

Improving access to HHS data

Although much of HHS's data are publicly available, some are not easy to use or barriers, such as a lack of standardization, limit access, understanding, or use of the data by stakeholders and the public.¹⁹² These barriers hinder public access to and use of data vital for public health and welfare and data that may lead to innovation and improvement in health and human service systems. HHS external stakeholders rely on effective dissemination of data collected by departmental programs. Currently, in many instances HHS does not use contemporary approaches, such as application programming interfaces (APIs), to provide users access to actionable data from HHS systems. Some OpDivs, in collaboration with the private sector, have deployed the Fast Healthcare Interoperability Resources API, which enables health data to be quickly and efficiently exchanged to support a more seamless flow and integration of data across systems.

HHS must ensure any progress made in improving access and use of its internally generated data also applies to data generated by external entities and received and managed by the Department. CMS has made significant improvements to the national Medicaid data set, the Transformed Medicaid Statistical Information System (T-MSIS).¹⁹³ Now that all States report in T-MSIS, CMS is able to leverage T-MSIS for programmatic insights, including insight about COVID-19 treatment and

testing and how the PHE affected Medicaid service utilization.¹⁹⁴ Although CMS has made public some T-MSIS information (mainly metrics on State data quality and some research files), additional work is needed to make T-MSIS an effective data tool for States and other stakeholders.¹⁹⁵

Encouraging data sharing among health care providers, patients, and payers

The health care system and patients in general have not fully realized and benefited from contemporary approaches to the seamless flow of electronic health information. Two key goals of HHS's Information Technology Strategic Plan aim to improve health information exchange. The goals are to enhance data and interoperability, and to improve IT management and governance.¹⁹⁶ The potential is great for HHS to improve the availability and interoperability of electronic health information by updating regulations that advance certified electronic health record technology. Although there are signs of recent progress in improving interoperability and access, routine and robust health information exchange among providers remains a challenge across the health care system.¹⁹⁷ In May 2020, CMS published the Interoperability and Patient Access final rule that continued to build on and expand the use of health IT standards to emphasize improving health information exchange and facilitating appropriate and necessary patient, provider, and payer access to information in health records. In January 2022, the Office of the National Coordinator for Health Information Technology published the Trusted Exchange Framework and Common Agreement (TEFCA), which outlines a common set of principles, terms, and conditions to facilitate network-to-network electronic health information sharing in a timely and secure manner. HHS is faced with translating TEFCA's authorities and other initiatives into more widespread improvements across the health care industry and public health systems. This will require further engagement and efforts to ensure progress is not limited to those health care entities with resources to implement modern technologies and data practices, which would only serve to broaden the digital divide.

Securing HHS data and systems to positively impact the cybersecurity posture of HHS and the sectors HHS influences

As HHS expands its technological capabilities, increases data sharing among HHS programs and the public, and improves data interoperability in the broader health care and public health systems, it must take crucial steps to modernize its approach to cybersecurity. The importance of improving cybersecurity posture across the Federal Government has been recognized by the President, such as in the May 2021 Executive Order (EO) Improving the Nation's Cybersecurity, which directed Federal agencies to fundamentally and systemically change their approach to cybersecurity. In support, the HHS Office of Information Security is finalizing its Strategic Plan. HHS efforts will require significant investments in resources as well as cultural and organizational change. To operationalize the EO, OMB directed agencies including HHS to meet specific cybersecurity standards and objectives by the end of FY 2024. These include adopting a "zero trust" security architecture approach. This method requires meaningful organizational change in how HHS implements security across its divisions and programs so that the Department protects the enterprise "anytime, anywhere" regardless of where its assets and resources are located.¹⁹⁸

Persistent and growing cybersecurity threats exacerbate the challenges facing HHS associated with data and technologies used to carry out the vital health and human service missions of HHS divisions. These threats, if not mitigated, can put critical HHS program operations at risk and potentially impact the health and welfare of individuals served by HHS. It is common practice for adversaries to continuously conduct reconnaissance for discovering new systems under development, often to gain understanding of the underlying technologies, data, and potential vulnerabilities that may be exploited.

This challenge is multifaceted and complex because program needs and timeliness often compete with cybersecurity controls and capabilities. To overcome this challenge, HHS will need to ensure that its divisions and programs establish and use a risk-based approach to rapid system development and deployment. This includes understanding the value of protecting technology and data and the risk presented by cybersecurity threats.

Cybersecurity challenges in a federated environment

Although the Department continues to improve its overall cybersecurity posture, OIG and GAO have identified challenges and systemic weaknesses. One persistent challenge is the federated nature of IT and cybersecurity environments across HHS with its vast network of interdependent, increasingly digital health, social, and administrative services. The large scale of HHS's mission and IT environments dictates that the Department must simultaneously address a range of dynamic cybersecurity requirements along with the specific data and technological needs for each division or program. For example, 24 of NIH's 28 entities receive individual funding from Congress and administer their own budgets. Each NIH entity designates its own chief information officer (CIO) who coordinates with the NIH CIO.¹⁹⁹ IHS also has a decentralized environment with a headquarters, area offices, and individual hospitals and clinics that often have additional health care mandates because they provide direct patient care. This type of environment poses challenges to IHS's ability to assess, manage, and respond to cybersecurity threats, as well as modernize cybersecurity approaches in order to become resilient in the face of persistent threats.²⁰⁰

The challenges posed by HHS's federated nature are exacerbated by the complexity of ensuring that thousands of HHS contractors, grantees, and other partners have appropriate cybersecurity capabilities and implement the best-of-breed security solutions. For many HHS grant programs, both an OpDiv and a grantee have responsibilities for protecting sensitive data, such as data generated from research that is the intellectual property of the United States. As datasets continue to grow, the ability to prevent bad actors from directly and indirectly inferring personally identifiable information is a challenge. Ownership of data (whether the owner is Federal or a grantee) in some cases is unclear, resulting in some challenges regarding the applicability of specific data protections. However, both HHS and its grantees have faced challenges to consistently adopting controls to address the growing cybersecurity risks facing these programs. HHS and its divisions must make additional progress to ensure grantees, as well as other HHS contractors and partners, have adequate data protections in place and are developing a risk-based approach that can be effectively implemented across a wide range of OpDiv and StaffDiv missions.

Maintaining vigilance is critical to protecting HHS and health system infrastructure security

HHS's cybersecurity defenses continue to be tested as cyberthreats persist and adversaries continue to increase their levels of sophistication and maliciousness. In 2022, HHS OpDivs experienced numerous sophisticated phishing and business email compromise attacks on employees. In response, HHS issued an Advisory Notification to mitigate risk for the entire Department. The Department as well as the health care and public health sectors must maintain vigilance. Future sophisticated and novel methods of social engineering, coupled with technical threats, will present cybersecurity challenges and opportunities for cyberattacks.

In 2021, 45 million people were affected by cyberattacks on health care providers and related entities, up from 34 million in 2020.²⁰¹ The average total cost of a breach in the health care industry increased almost 10 percent from \$9.2 million in 2021 to \$10.1 million in 2022.²⁰² Threat communication has improved through public-private partnerships spearheaded by the HHS Healthcare Cybersecurity and Coordination Center and the Department of Homeland Security Cybersecurity and Infrastructure Security Agency. These partnerships have increased the health care sector's awareness of the impacts ransomware could have on operations, including having to move patients to other facilities, loss of access to electronic health records, potential fraud, and the compromising of electronic health information and other sensitive information.

This challenge is widely expected to increase as new technologies are developed and introduced into the market. These technologies include the expansion of telehealth and other remote patient monitoring modalities, AI, precision medicine technologies, and future digital treatments and therapies. In particular, FDA and the health care industry must continue to improve cybersecurity for networked medical devices (such as infusion pumps and pacemakers that use internet connectivity).²⁰³ To address cybersecurity threats and reduce patient risks, FDA has issued guidance to help support premarket and postmarket processes related to cybersecurity impacts for devices. Additionally, FDA has sought additional funding and authorities to support its ongoing efforts to help device manufacturers and the ecosystem combat

cybersecurity threats.²⁰⁴ FDA should continue to take steps to enhance its ability to receive relevant information as well as securely share information with key stakeholders.²⁰⁵ HHS may have additional options to assess the cybersecurity of devices once in use by health care providers; however, there has been limited progress to assess this issue as part of the existing oversight mechanisms, such as the survey and certification process for Medicare-participating hospitals.²⁰⁶

The Department plays a significant role in ensuring the privacy of individual data such as personal health information, genetic information, and other sensitive data. The HIPAA Privacy Rule's requirements, established nearly 20 years ago, may not adequately address current issues related to privacy concerns. Patients and providers continue to have questions about how best to protect data while navigating the requirements and constraints of HIPAA. The Department's challenge is to be responsive to changes in the health care industry, including nontraditional health care delivery approaches that may impact patient privacy. Moving in this direction, the Office for Civil Rights has begun data collection to learn from the health care community which changes are needed to enable HIPAA to support present-day requirements.

6: Strengthening Coordination for Better Programs and Services

Key Takeaways

Relevant Agencies

- All HHS

Elements of the Challenge

- Preparing for and responding to PHEs
- Reducing health disparities in American Indian and Alaska Native communities
- Protecting children
- Keeping patients safe

The importance of HHS's mission and the breadth of its programs and authorities put the Department at the center of some of the largest and most complex problems facing the Nation. To solve these problems—and address issues on the horizon—HHS needs to coordinate, collaborate, and communicate effectively across HHS programs and with other Federal agencies as well as outside the Federal Government with Tribal, State, and local Governments, international entities, industry, and other stakeholders.

Strengthening HHS's coordination, collaboration, and communication can help Americans receive more efficient, higher quality health programs and human services and benefit from greater advances in the sciences underlying them. Interagency efforts led by the Department such as the HHS Task Force to Prevent Human Trafficking and the Behavioral Health Coordinating Council provide opportunities for HHS programs to work more efficiently and in closer alignment.^{207, 208} Collaboration among HHS experts also helps the Department bring forward the best evidence to develop multifaceted strategies, such as the HHS Overdose Prevention Strategy.²⁰⁹ Proactive engagement with integrity partners, such as OIG, can help HHS programs consider practices that mitigate risks of fraud, waste, and abuse when launching new or expand programs.^{210, 211}

Effective partnerships with other Federal agencies help ensure that critical initiatives and resources, such as those for emergency preparedness and response or law enforcement investigations, are working in concert. Established networks of information exchange with State, Tribal, and local Governments can better allow HHS programs to reflect community needs and support culturally responsive public health efforts.²¹² HHS's capacity to mitigate drug overdose risk through its Opioid Rapid Response Program, for example, relies on timely communication and coordination across OpDivs and StaffDivs and with State public health agencies.²¹³

Engagement with HHS's vast array of nongovernmental stakeholders—from health care providers to food and drug manufacturers, health systems, nursing homes, hospices, professional associations, scientists, consumers, and community nonprofits, 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. HHS's initiatives to ensure that the U.S. supply of safe and nutritionally adequate infant formula meets demand, for example, requires new engagements with companies that import, sell, and distribute infant formula, and those seeking to enter the formula market for the first time.²¹⁴ HHS's efforts to strengthen and protect the public health supply chain and industrial base cannot be accomplished without an array of industry partners, as well as strategic coordination among Federal, Tribal, State, Territorial, and local entities to prevent the maldistribution of critical resources in an emergency, such as personal

protective equipment, diagnostics, vaccines, and therapeutics.²¹⁵ HHS's ability to ensure that callers to 988, the National Suicide Prevention Lifeline, receive appropriate help at times of crisis requires collaboration with local organizations as well as States.²¹⁶

Preparing for and responding to PHEs

In January 2022, GAO identified HHS's leadership and coordination of PHEs as a high-risk area in need of transformation. Although the unprecedented nature of the COVID-19 pandemic presented new coordination challenges—from medical supply shortages to the distribution of funds through new programs and large-scale vaccination programs—GAO's designation stemmed from deficiencies in HHS's emergency preparation and response leadership for more than a decade including during the H1N1 influenza pandemic, Zika, Ebola, and extreme weather emergencies, as well as during the COVID-19 pandemic. The GAO report pointed to HHS's coordination challenges as impediments to its leadership, specifically in establishing roles and responsibilities, communicating effectively with partners and the public at large, and understanding the parameters of its partners' capabilities.²¹⁷ In July 2022, HHS elevated leadership for emergency preparedness and response from StaffDiv, ASPR, to OpDiv, ASPR.²¹⁸ An early responsibility of the new agency was making vaccines available through the Strategic National Stockpile to mitigate the spread of monkeypox as the Nation confronted the monkeypox PHE.²¹⁹ Using lessons learned from COVID-19, CDC announced in August 2022 a reorganization designed to, among other goals, improve collaboration and communication and focus on a customer-centric structure.²²⁰

Decades of OIG reports have identified challenges to HHS's emergency preparedness and response and have provided recommendations to address these challenges.²²¹ A June 2022 OIG report found that some of the same challenges related to communication with partners and partner capabilities as identified by GAO heightened the risk of exposure to COVID-19 in facilities providing care to unaccompanied children.²²² Deficiencies in safety procedures occurred, in part, because the ORR was rapidly expanding capacity, setting up new emergency intake facilities, and developing COVID-19 protocols and guidance for their use. However, ORR did not have a process in place for widely disseminating the guidance and frequent updates to appropriate staff.

Information sharing across public health entities can lead to better decisions. Ensuring appropriate data access across HHS stakeholders is especially important in emergencies. Without access to data, public health decisionmakers lack timely information to develop the most effective response and allocate scarce resources. The *Tribal Health Data Improvement Act of 2021* required HHS to establish a strategy for providing access to public health care data to Indian Tribes and Tribal epidemiology centers.²²³ During the COVID-19 pandemic, however, Tribal epidemiology centers were unable to readily access critical data maintained by HHS. Both GAO and OIG have recommended that HHS address issues blocking Tribal epidemiology centers from timely access to all public health data to which they are entitled.^{224, 225}

Reducing health disparities in American Indian and Alaska Native communities

Ensuring Tribal epidemiology centers have access to data is key not only to an effective pandemic response but also to addressing health disparities affecting American Indian and Alaska Native (AI/AN) communities, which were disproportionately negatively impacted by COVID-19.^{226, 227} Health disparities are health status differences across various socioeconomic, ethnic, and racial groups. People of color experience disparities in areas such as access to care and quality of care.²²⁸ Such disparities have profound implications for the health and well-being of these individuals.

Access to safe drinking water and adequate waste disposal facilities are essential for healthy populations as these prevent disease. To address sanitation deficiencies in AI/AN communities, the *Infrastructure Investment and Jobs Act* (IIJA) allocated \$3.5 billion to the IHS Sanitation Facilities Construction (SFC) Program.²²⁹ Through effective collaboration and communication with Tribal entities and other stakeholders, HHS has an opportunity to assist AI/AN communities in addressing challenges associated with managing the rapid increase in SFC funding provided under the IIJA, and ultimately to reduce disparities in access for AI/AN communities to adequate sanitation and in health outcomes.

Protecting children

As described in [TMC 4](#), a Top Management Challenge for HHS is safeguarding the well-being of people served by HHS programs, including children. Recent OIG reviews highlight areas in which better collaboration, coordination, and communication could help address program vulnerabilities that put children at risk.

OIG reviews of children missing from foster care demonstrate opportunities for better collaboration between HHS and State agencies to improve outcomes for the thousands of children missing from their placements nationwide and reduce episodes of missing children and associated risk, including the risk of being trafficked.^{230, 231, 232} A 2022 OIG evaluation found a lack of communication among HHS divisions regarding unaccompanied children during the development and early implementation of CDC's Title 42 order to suspend the entries of certain persons into the United States due to COVID-19 risks. Based on this finding, as well as prior findings related to the UC Program,²³³ OIG recommended that HHS take steps to improve internal coordination and communication about unaccompanied children and ensure that CDC coordinates with ORR when making future decisions that could affect the number of unaccompanied children placed in ORR's care.²³⁴

Keeping patients safe

OIG reports have identified issues with HHS coordination with, and outreach to, external partners that may leave patients at risk of harm. For example, OIG found that more than half of the States repeatedly failed to meet one or more performance measures—most commonly, timeliness requirements—for conducting nursing home surveys. Nevertheless, CMS rarely reached out to senior State officials, such as Governors or health department directors, to raise concerns about State survey performance. OIG recommended that CMS engage with senior State officials earlier and more frequently when it identifies persistent or egregious performance problems. Earlier and more frequent contact may underscore the importance of requirements for protecting the health and safety of nursing home residents, build a greater understanding of the urgency to resolve performance problems and their implications for nursing home residents, and provide opportunities for State officials or other stakeholders to develop solutions before problems become critical.²³⁵ ([See TMC 4](#) for more information on nursing homes and patient safety.)

HHS coordination internally and with medical organizations is a key recommendation in an OIG review that found children enrolled in Medicaid in five States did not receive important blood lead screening tests on schedule. Specifically, more than one-third of the 1 million children who were required to receive a 12-month and a 24-month blood lead screening test received neither test. The OIG review recommended that CMS coordinate with Federal agencies, such as CDC, and medical organizations, such as the American Academy of Pediatrics, to develop educational materials for State Medicaid agencies that clearly communicate Medicaid's requirements and testing schedule, and highlight the current actionable blood lead reference value.²³⁶

As described in [TMC 1](#), OIG work raises concerns about people enrolled in Medicare receiving treatment for OUD. OIG has recommended several collaborative approaches to increase the number of people receiving treatment, such as CMS outreach to enrollees, engagement to increase the number of providers and opioid treatment programs, and assisting SAMHSA with data.²³⁷

Conclusion

To run effective and efficient programs, HHS must consider issues and impacts outside a single program or mission for any one of its agencies. Barriers to coordination include navigating a wide breadth of HHS stakeholders with different goals and authorities and varying logistic, economic, and workforce pressures, as well as the scope and complexity of the problems for which HHS needs partnerships to resolve and the ever-changing landscape of the health and human services sectors. Overcoming these barriers requires HHS to engage in intentional, sustained, and forward-looking efforts toward building strategic partnerships both domestically and internationally, communicating effectively, managing collaborative work, and maintaining accountability.

ENDNOTES

¹ CDC, *COVID Data Tracker*. Available at <https://covid.cdc.gov/covid-data-tracker>.

² CDC, *2022 U.S. Map & Case Count*. Available at <https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html>.

³ CDC, *Life Expectancy in the U.S. Dropped for the Second Year in a Row in 2021*, August 2022. Available at https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/20220831.htm.

⁴ ASPE, *Health Disparities by Race and Ethnicity during the COVID-19 Pandemic: Current Evidence and Policy Approaches*. Available at <https://aspe.hhs.gov/reports/health-disparities-race-ethnicity-during-covid-19-pandemic-current-evidence-policy-approaches>. Additionally, an OIG report found that dually eligible people—those enrolled in Medicare and Medicaid—as well as Black, Hispanic, and older Medicare enrollees have been disproportionately hospitalized with COVID-19. See OIG, *Medicare Beneficiaries Hospitalized With COVID-19 Experienced a Wide Range of Serious, Complex Conditions*, OEI-02-20-00410, August 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-02-20-00410.asp>.

⁵ According to the National Oceanic and Atmospheric Administration (NOAA), in 2021 there were 20 weather or climate disaster events affecting the United States with losses exceeding \$1 billion. During 1980–2021, there were 7.4 events on average per year; however, the annual average for the most recent 5 years (2017–21) increased to 17.2 events. NOAA, National Centers for Environmental Information, *Billion-Dollar Weather and Climate Disasters*. Available at <https://www.ncdc.noaa.gov/billions/>. The United Nation's 2021 Intergovernmental Panel on Climate Change Report projects climate change will result in increases in extreme events. Intergovernmental Panel on Climate Change Sixth Assessment Report, *Climate Change 2021: The Physical Science Basis*. Available at: <https://www.ipcc.ch/report/ar6/wg1/>. Additionally, some researchers have conducted work that suggests increased occurrence of outbreaks may be expected in the future. Baker, R.E., et al., *Infectious disease in an era of global change*, *Nature Reviews Microbiology* 20, October 13, 2021. Available at <https://doi.org/10.1038/s41579-021-00639-z>. Marani Marco, et. al., *Intensity and frequency of extreme novel epidemics*. Proceedings of the National Academy Sciences, August 23, 2021. Available at <https://www.pnas.org/doi/10.1073/pnas.2105482118>.

⁶ OIG, *The Substance Abuse and Mental Health Services Administration Generally Had Controls and Strategies for Mitigating Disaster Preparedness and Response Risks*, A-04-20-02026, May 2021. Available at <https://oig.hhs.gov/oas/reports/region4/42002026.asp>.

⁷ OIG, *CMS's Controls Related to Hospital Preparedness for an Emerging Infectious Disease Were Well-Designed and Implemented but Its Authority Is Not Sufficient for It To Ensure Preparedness at Accredited Hospitals*, A-02-21-01003, June 2021. Available at <https://www.oig.hhs.gov/oas/reports/region2/22101003.asp>.

⁸ OIG, *CMS's Internal Controls Over Hospital Preparedness for Emerging Infectious Disease Epidemics Such as Coronavirus Disease 2019*. Available at <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000455.asp>.

⁹ OIG, *HHS-OIG Issues Notice of Exclusion to Owner of 7 Louisiana Nursing Homes*, May 23, 2022. Available at <https://oig.hhs.gov/newsroom/news-releases-articles/nursing-home-exclusion/>.

¹⁰ 117th Congress (2021–2022), *H.R.1319 - American Rescue Plan Act of 2021*. Available at <https://www.congress.gov/bill/117th-congress/house-bill/1319/text>.

¹¹ ASPR was formerly known as the Office of the Assistant Secretary for Preparedness and Response.

¹² GAO, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*. Available at <https://files.gao.gov/reports/GAO-22-105291/index.html#appendix18>.

¹³ PBS, *CDC director discusses efforts to reform the agency amid COVID, monkeypox criticisms*, August 25, 2022. Available at <https://www.pbs.org/newshour/show/cdc-director-discusses-efforts-to-reform-the-agency-amid-covid-monkeypox-criticisms>.

¹⁴ 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.asp>.

¹⁵ OIG, *Hospitals Reported That the COVID-19 Pandemic Has Significantly Strained Health Care Delivery*, OEI-09-21-00140, March 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-09-21-00140.asp>.

-
- ¹⁶ OIG, *Toolkit: Insights for Health Care Facilities From OIG's Historical Work on Emergency Response*, July 2022. Available at <https://oig.hhs.gov/reports-and-publications/featured-topics/response/toolkit-healthcare.asp>.
- ¹⁷ OIG, *The Puerto Rico Department of Health's Implementation of Its Emergency Preparedness and Response Activities Before and After Hurricane Maria Was Not Effective*, A-02-18-02002, July 2021. Available at <https://oig.hhs.gov/oas/reports/region2/21802002.asp>.
- ¹⁸ 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.asp>.
- ¹⁹ FDA, *Fact Sheet: FDA at a Glance*. Available at <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance>.
- ²⁰ FDA, *COVID-19 Vaccines, Emergency Use Authorization—Vaccines*. Available at <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines#eua-vaccines>.
- ²¹ OIG, *Delays in Confirmatory Trials for Drug Applications Granted FDA's Accelerated Approval Raise Concerns*, OEI-01-21-00401, September 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-01-21-00401.pdf>.
- ²² OIG, *FDA Repeatedly Adapted Emergency Use Authorization Policies To Address the Need for COVID-19 Testing*, OEI-01-20-00380, September 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-01-20-00380.pdf>.
- ²³ OIG, *The Food and Drug Administration's Foreign For-Cause Drug Inspection Program Can Be Improved To Protect the Nation's Drug Supply*, A-01-19-01500, June 2022. Available at <https://oig.hhs.gov/oas/reports/region1/11901500.asp>.
- ²⁴ FDA, *What You Need to Know about Foodborne Illnesses*. Available at <https://www.fda.gov/food/consumers/what-you-need-know-about-foodborne-illnesses>.
- ²⁵ FDA, *What does FDA regulate?* Available at <https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate>.
- ²⁶ FDA, *New Era of Smarter Food Safety Frequently Asked Questions*. Available at <https://www.fda.gov/food/new-era-smarter-food-safety/new-era-smarter-food-safety-frequently-asked-questions>.
- ²⁷ OIG, *Challenges Remain in FDA's Inspections of Domestic Food Facilities*, OEI-02-14-00420, September 2017. Available at <https://www.oig.hhs.gov/oei/reports/oei-02-14-00420.asp>. See also 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.asp>.
- ²⁸ OIG, *Food and Drug Administration's Actions Regarding the Abbott Infant Formula Recall*. Available at <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000708.asp>.
- ²⁹ FDA, *Center for Tobacco Products Overview*. Available at <https://www.fda.gov/tobacco-products>.
- ³⁰ CDC, *Tobacco Product Use and Associated Factors Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021*. Available at https://www.cdc.gov/mmwr/volumes/71/ss/ss7105a1.htm?s_cid=ss7105a1_w.
- ³¹ *Ibid.*
- ³² OIG, *Audit of the Food and Drug Administration's Premarket Tobacco Product Application Process for Electronic Nicotine Delivery System Products*. Available at <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000632.asp>.
- ³³ OIG, *FDA's Tobacco Retailer Compliance Check Inspection Program*. Available at <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000441.asp>.
- ³⁴ SAMHSA, *2020 National Survey of Drug Use and Health (NSDUH) Releases*. Available at <https://www.samhsa.gov/data/release/2020-national-survey-drug-use-and-health-nsduh-releases>.
- ³⁵ KFF, *Mental Health and Substance Use State Fact Sheets*. Available at <https://www.kff.org/statedata/mental-health-and-substance-use-state-fact-sheets/>.

³⁶ *Ibid.*

³⁷ OIG has ongoing work on States' and Medicaid Managed Care Organizations' compliance with mental health parity requirements and the availability of behavioral health in Medicare fee-for-service, Medicare Advantage, and Medicaid Managed Care. See OIG, *Work Plan*. Available at <https://oig.hhs.gov/reports-and-publications/workplan/>.

³⁸ OIG, *Availability of Behavioral Health in Medicare Fee-For-Service, Medicare Advantage, and Medicaid Managed Care*. Available at <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000644.asp>.

³⁹ Congressional Research Service, *Mental Health Funding in the Bipartisan Safer Communities Act*. Available at <https://crsreports.congress.gov/product/pdf/IN/IN11970>.

⁴⁰ CDC, National Center for Vital Statistics, *Vital Statistics Rapid Release, Provisional Drug Overdose Death Counts*. Available at <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>.

⁴¹ *Ibid.*

⁴² HHS, *Overdose Prevention Strategy*. Available at <https://www.hhs.gov/overdose-prevention/>.

⁴³ Executive Office of the President, Office of National Drug Control Policy, *The Biden-Harris Administration's Statement of Drug Policy Priorities for Year One*. Available at <https://www.whitehouse.gov/wp-content/uploads/2021/03/BidenHarris-Statement-of-Drug-Policy-Priorities-April-1.pdf>.

⁴⁴ OIG, *Concerns Persist About Opioid Overdoses and Medicare Beneficiaries' Access to Treatment and Overdose-Reversal Drugs*, OEI-02-20-00401, August 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-02-20-00401.pdf>.

⁴⁵ FDA, *Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework, Guidance for Industry*. Available at <https://www.fda.gov/media/128150/download>. See also FDA, *Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap*. Available at <https://www.fda.gov/media/110587/download>.

⁴⁶ FDA, *Opioid Medications*. Available at <https://www.fda.gov/drugs/information-drug-class/opioid-medications>. FDA, *Information about Medication-Assisted Treatment (MAT)*. Available at <https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat>.

⁴⁷ OIG, *FDA's Risk Evaluation and Mitigation Strategies: Uncertain Effectiveness in Addressing the Opioid Crisis*, OEI-01-17-00510, September 2020. Available at <https://oig.hhs.gov/oei/reports/OEI-01-17-00510.asp>.

⁴⁸ See, e.g., Testimony of OIG Office of Investigations Special Agent in Charge Maureen Dixon, *Examining Efforts to Prevent Opioid Overutilization and Misuse in Medicare and Medicaid*, pp. 4–5. Available at <https://oig.hhs.gov/testimony/docs/2018/dixon-testimony052918.pdf>.

⁴⁹ OIG, *Opioids in Medicaid: Concerns About Opioid Use Among Beneficiaries in Six Appalachian States*, OEI-05-19-00410, December 2020. Available at <https://oig.hhs.gov/oei/reports/OEI-05-19-00410.asp>.

⁵⁰ OIG, *Opioid Treatment Programs Reported Challenges Encountered During the COVID-19 Pandemic and Actions Taken To Address Them*, A-09-20-01001, November 2020. Available at <https://www.oig.hhs.gov/oas/reports/region9/92001001.asp>.

⁵¹ OIG, *SAMHSA Is Missing Opportunities To Better Monitor Access to Medication Assisted Treatment Through the Buprenorphine Waiver Program*, OEI-BL-20-00260, June 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-BL-20-00260.asp>.

⁵² Federal Register, *Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder*. Available at <https://www.federalregister.gov/documents/2021/04/28/2021-08961/practice-guidelines-for-the-administration-of-buprenorphine-for-treating-opioid-use-disorder>.

⁵³ OIG, *Medicaid Claims for Opioid Treatment Program Services*. Available at <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000234.asp>.

⁵⁴ OIG, *Oklahoma's Oversight of Medicaid Outpatient Services for Opioid Use Disorder Was Generally Effective*, A-06-20-08000, August 2021. Available at <https://oig.hhs.gov/oas/reports/region6/62008000.asp>.

⁵⁵ OIG, *Louisiana Faced Compliance and Contracting Challenges in Implementing Opioid Response Grant Programs*, A-06-20-07003, April 2022. Available at <https://oig.hhs.gov/oas/reports/region6/62007003.asp>.

⁵⁶ USAspending.gov, *Agency Profile: Department of Health and Human Services*. Available at <https://www.usaspending.gov/agency/806>.

⁵⁷ HHS, TAGGS, *Grants By OPDIV*. Available at <https://taggs.hhs.gov/ReportsGrants/GrantsByOPDIV>.

⁵⁸ As of June 14, 2021, HHS had awarded \$74.6 billion for contractual services and supplies. See USAspending.gov, *Spending Explorer, Contractual services and supplies*. Available at https://www.usaspending.gov/explorer/object_class.

⁵⁹ CMS, *April 2022 Medicaid and CHIP Enrollment Snapshot*. Available at <https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/april-2022-medicaid-chip-enrollment-trend-snapshot.pdf>. See also, CMS, *2021 Annual Financial Report*, p. 12. CHIP represents an additional 10 million children who are projected by CMS to be enrolled for at least 1 month during the year. Available at <https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2021.pdf>.

⁶⁰ As of September 30, 2021, HHS had obligated \$236.4 billion in grants (excluding CMS). See USAspending.gov, *Spending Explorer, Department of Health and Human Services (HHS), Award Spending*. Available at <https://www.usaspending.gov/agency/departments-of-health-and-human-services?fy=2021>.

⁶¹ CMS, *Financial Report, fiscal year 2021*. See pp. 46-47, Note 10: Net Costs of Operations. Available at <https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2021.pdf>.

⁶² HHS, TAGGS, *Grants By OPDIV*. Available at <https://taggs.hhs.gov/ReportsGrants/GrantsByOPDIV>.

⁶³ Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds stated that the Federal Hospital Insurance Trust Fund is expected to be depleted in 2026. See CMS, *2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*. Available at <https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf>.

⁶⁴ GAO, *Financial Audit: FY 2019 and FY 2018 Consolidated Financial Statements of the U.S. Government*. Available at <https://www.gao.gov/products/GAO-20-315R>.

⁶⁵ CMS, *National Health Expenditure Data*. Available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical>.

⁶⁶ CMS, *Financial Report, fiscal year 2021*. Available at <https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2021.pdf>.

⁶⁷ KFF, *Key Facts About Medicare Part D Enrollment, Premiums, and Cost Sharing in 2021*. Available at <https://www.kff.org/medicare/issue-brief/key-facts-about-medicare-part-d-enrollment-premiums-and-cost-sharing-in-2021/>.

⁶⁸ Specifically at issue were inhalation drugs administered through DME and supplying fees for immunosuppressive drugs associated with organ transplant, oral anticancer chemotherapeutic drugs, and oral antiemetic drugs used as 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>.

⁶⁹ 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>.

⁷⁰ OIG, *Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use*, OEI-05-20-00480, March 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-05-20-00480.asp>.

⁷¹ OIG, *Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices*, OEI-12-17-00130, September 2019. Available at <https://oig.hhs.gov/oei/reports/oei-12-17-00130.asp>.

⁷² 31 USC § 3351(4).

⁷³ According to PaymentAccuracy.gov, the total estimated government improper payment amount for FY 2020 was \$206.4 billion. Available at <https://www.paymentaccuracy.gov/payment-accuracy-the-numbers/>. See also (for Medicare and Medicaid estimated improper payment rates) CMS, *2020 Estimated Improper Payment Rates for Centers for Medicare & Medicaid Services (CMS) Programs*. Available at <https://www.cms.gov/newsroom/fact-sheets/2020-estimated-improper-payment-rates-centers-medicare-medicaid-services-cms-programs>.

⁷⁴ HHS, *Agency Financial Report, fiscal year 2021*. Available at <https://www.hhs.gov/sites/default/files/fy-2021-hhs-agency-financial-report.pdf>.

⁷⁵ CMS, *Comprehensive Error Rate Testing (CERT)*. Available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Improper-Payment-Measurement-Programs/CERT>. See also HHS, *Agency Financial Report, fiscal year 2021*. Available at <https://www.hhs.gov/sites/default/files/fy-2021-hhs-agency-financial-report.pdf>.

⁷⁶ See endnote 69.

⁷⁷ OIG, *Trend Toward More Expensive Inpatient Hospital Stays in Medicare Emerged Before COVID-19 and Warrants Further Scrutiny*, OEI-02-18-00380, February 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-02-18-00380.asp>.

⁷⁸ OIG, *CMS Reported Collecting Just Over Half of the \$498 Million in Medicare Overpayments Identified by OIG Audits*, A-04-18-03085, July 2022. Available at <https://oig.hhs.gov/oas/reports/region4/41803085.asp>.

⁷⁹ CMS, *Financial Report, fiscal year 2021*. Available at <https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2021.pdf>.

⁸⁰ PaymentAccuracy.gov, *Annual Improper Payments Datasets*. Available at <https://www.paymentaccuracy.gov/payment-accuracy-the-numbers/>.

⁸¹ CMS, *2020 Estimated Improper Payment Rates for Centers for Medicare & Medicaid Services (CMS) Programs*. Available at <https://www.cms.gov/newsroom/fact-sheets/2020-estimated-improper-payment-rates-centers-medicare-medicaid-services-cms-programs>.

⁸² CMS, *Fiscal Year (FY) 2019 Medicare Fee-For-Service Improper Payment Rate is Lowest Since 2010 while data points to concerns with Medicaid eligibility*, press release, November 19, 2019. Available at <https://www.cms.gov/newsroom/press-releases/fiscal-year-fy-2019-medicare-fee-service-improper-payment-rate-lowest-2010-while-data-points>.

⁸³ OIG, *The Centers for Medicare & Medicaid Services Had Not Recovered More Than a Billion Dollars in Medicaid Overpayments Identified by OIG Audits*, A-05-17-00013, December 2018. Available at <https://oig.hhs.gov/oas/reports/region5/51700013.asp>.

⁸⁴ OIG, *Unaccompanied Children*, June 2022. Available at <https://oig.hhs.gov/reports-and-publications/featured-topics/uac/>.

⁸⁵ OIG, *The Office of Refugee Resettlement Did Not Award and Manage the Homestead Influx Care Facility Contracts in Accordance With Federal Requirements*, A-12-20-20001, December 2020. Available at <https://oig.hhs.gov/oas/reports/region12/122020001.asp>.

⁸⁶ 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>.

⁸⁷ 31 USC §§ 3351-3358.

⁸⁸ OIG, *Department of Health and Human Services Met Many Requirements, but It Did Not Fully Comply With the Payment Integrity Act of 2019 and Applicable Improper Payment Guidance for Fiscal Year 2021*, A-17-22-52000, May 2022. Available at <https://oig.hhs.gov/oas/reports/region17/172252000.pdf>.

⁸⁹ OIG, *The Food and Drug Administration Needs To Improve Its Contract Closeout Processes To Identify Contracts Eligible for Closeout and Close Contracts Timely*, A-03-20-03004, December 2021. Available at <https://oig.hhs.gov/oas/reports/region3/32003004.asp>.

⁹⁰ OIG, *The National Heart, Lung, and Blood Institute Did Not Fully Comply With Federal Requirements for Other Transactions*, A-04-20-04078, April 2021. Available at <https://www.oig.hhs.gov/oas/reports/region4/42004078.asp>.

⁹¹ USASpending.gov, *The Federal Response to COVID-19*. Available at <https://www.usaspending.gov/disaster/covid-19?publicLaw=all>.

⁹² HRSA, *COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured*. Available at <https://www.hrsa.gov/coviduninsuredclaim>.

⁹³ HRSA, *COVID-19 Coverage Assistance Fund*. Available at <https://www.hrsa.gov/covid19-coverage-assistance>.

⁹⁴ OIG, *HHS's and HRSA's Controls Related to Selected Provider Relief Fund Program Requirements Could Be Improved*, A-09-21-06001, September 2022. Available at <https://oig.hhs.gov/oas/reports/region9/92106001.asp>.

⁹⁵ OIG, *Active Work Plan Items*, including ongoing PRF-related reviews. Available at <https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp?search.search=PRF>.

⁹⁶ 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.

⁹⁷ 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 noncompetitive awards when appropriate or required by Federal statute.

⁹⁸ OIG, *HHS's Suspension and Debarment Program Helped Safeguard Federal Funding, But Opportunities for Improvement Exist*, OEI-04-19-00570, January 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-04-19-00570.asp>.

⁹⁹ 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>.

¹⁰⁰ OIG, *Problems Remain for Ensuring That All High Risk Medicaid Providers Undergo Criminal Background Checks*, OEI-05-00070, July 2019. Available at <https://oig.hhs.gov/oei/reports/oei-05-18-00070.asp>.

¹⁰¹ 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>.

¹⁰² HHS, *FY 2019 Agency Financial Report*. Available at <https://www.hhs.gov/sites/default/files/fy2019-hhs-agency-financial-report.pdf>.

¹⁰³ *Ibid*.

¹⁰⁴ CMS, *CMS Fast Facts*. Available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts>. See also CMS, *Financial Report, fiscal year 2021*, pp. 10–12. Available at <https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2021.pdf>.

¹⁰⁵ CMS, *Financial Report, fiscal year 2021*. Available at <https://www.cms.gov/files/document/cms-financial-report-fiscal-year-2021.pdf>. See pp. 46–47, Note 10: Net Costs of Operations.

¹⁰⁶ This TMC focuses on Medicare and Medicaid, the Department's largest health care programs. The Department funds other vital health services including those through IHS, HRSA, and SAMHSA that are addressed in other TMCs.

¹⁰⁷ CMS, *2020 Report to Congress, Center for Medicare and Medicaid Innovation*. Available at <https://innovation.cms.gov/data-and-reports/2021/rtc-2020>.

¹⁰⁸ CMS, *Meaningful Measures 2.0: Moving from Measure Reduction to Modernization*. Available at <https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization>.

¹⁰⁹ CMS, *Measuring and Improving Quality in Home and Community-Based Services (HCBS)*. Available at <https://www.medicare.gov/medicaid/quality-of-care/quality-improvement-initiatives/measuring-and-improving-quality-home-and-community-based-services-hcbs/index.html#:~:text=On%20July%2021st%2C%202022%2C%20CMS,measures%20for%20Medicaid%2Dfunded%20HCBS>.

¹¹⁰ CMS, *Report to Congress, Annual Update: Identification of Quality Measurement Priorities and Associated Funding for the Consensus-Based Entity (currently the National Quality Forum) and Other Entities*. Available at <https://www.cms.gov/files/document/2021-report-congress-identification-quality-measurement-priorities-strategic-plan-initiatives.pdf>.

-
- ¹¹¹ OIG, *Medicare Could Have Saved Approximately \$993 Million in 2017 and 2018 if It Had Implemented an Inpatient Rehabilitation Facility Transfer Payment Policy for Early Discharges to Home Health Agencies*, A-01-20-00501, December 2021. Available at <https://oig.hhs.gov/oas/reports/region1/12000501.asp>.
- ¹¹² OIG, *Medicare and Beneficiaries Pay More for Preadmission Services at Affiliated Hospitals Than at Wholly Owned Settings*, OEI-05-19-00380, December 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-05-19-00380.asp>.
- ¹¹³ OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018*, OEI-06-18-00400, May 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-06-18-00400.asp>.
- ¹¹⁴ CMS, *Synthesis of Evaluation Results across 21 Medicare Models, 2012–2020*. Available at <https://innovation.cms.gov/data-and-reports/2022/wp-eval-synthesis-21models>.
- ¹¹⁵ OIG, *Provider Shortages and Limited Availability of Behavioral Health Services in New Mexico’s Medicaid Managed Care*, OEI-02-17-00490, September 2019. Available at <https://oig.hhs.gov/oei/reports/oei-02-17-00490.asp>.
- ¹¹⁶ OIG, *COVID-19 Had a Devastating Impact on Medicare Beneficiaries in Nursing Homes During 2020*, OEI-02-20-00490, June 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-02-20-00490.asp>.
- ¹¹⁷ OIG, *Inaccuracies in Medicare’s Race and Ethnicity Data Hinder the Ability To Assess Health Disparities*, OEI-02-21-00100, June 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-02-21-00100.asp>.
- ¹¹⁸ CMS, *Medicaid Managed Care Enrollment and Program Characteristics, 2020*. Available at <https://www.medicaid.gov/medicaid/managed-care/downloads/2020-medicaid-managed-care-enrollment-report.pdf>.
- ¹¹⁹ OIG, *Medicare Advantage Compliance Audit of Diagnosis Codes That Humana, Inc., (Contract H1036) Submitted to CMS*, A-07-16-01165, April 2021. Available at <https://oig.hhs.gov/oas/reports/region7/71601165.asp>. See also OIG, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Anthem Community Insurance Company, Inc. (Contract H3655) Submitted to CMS*, A-07-19-01187, May 2021. Available at <https://oig.hhs.gov/oas/reports/region7/71901187.asp>. See also OIG, *Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross Blue Shield of Michigan (Contract H9572) Submitted to CMS*, A-02-18-01028, February 2021. Available at <https://oig.hhs.gov/oas/reports/region2/21801028.asp>.
- ¹²⁰ 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>.
- ¹²¹ 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>.
- ¹²² OIG, *Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care*, OEI-09-18-00260, April 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp>.
- ¹²³ OIG, *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials*, OEI-09-1600410, September 2018. Available at <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>.
- ¹²⁴ KFF, authored by Matthew Rae, et al., *How the American Rescue Plan Act Affects Subsidies for Marketplace Shoppers and People Who Are Uninsured*. Available at <https://www.kff.org/health-reform/issue-brief/how-the-american-rescue-plan-act-affects-subsidies-for-marketplace-shoppers-and-people-who-are-uninsured>. See also Congressional Budget Office, *Reconciliation Recommendations of the House Committee on Ways and Means*. Available at <https://www.cbo.gov/system/files/2021-02/hwaysandmeansreconciliation.pdf>.
- ¹²⁵ OIG, *CMS Authorized Hundreds of Millions of Dollars in Advanced Premium Tax Credits on Behalf of Enrollees Who Did Not Make Their Required Premium Payments*, A-02-19-02005, March 2021. Available at <https://oig.hhs.gov/oas/reports/region2/21902005.asp>.
- ¹²⁶ CMS, *May 2022 Medicaid and CHIP Enrollment Trends Snapshot*. Available at <https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/may-2022-medicaid-chip-enrollment-trend-snapshot.pdf>.
- ¹²⁷ KFF, *Medicaid and CHIP Eligibility and Enrollment Policies as of January 2022: Findings from a 50-State Survey*. Available at <https://www.kff.org/medicaid/report/medicaid-and-chip-eligibility-and-enrollment-policies-as-of-january-2022-findings-from-a-50-state-survey/>.

-
- ¹²⁸ Some CMS resources for States include: *Medicaid and CHIP Unwinding Planning Efforts*, April 2022, available at <https://www.medicaid.gov/resources-for-states/downloads/state-unwinding-best-practices.pdf>; *Updated Guidance*, addressed to State health officials, March 2022, available at <https://www.medicaid.gov/federal-policy-guidance/downloads/sho-21-002.pdf>; *Medicaid and Children's Health Insurance Program Return to Normal Operations, Eligibility and Enrollment Pending Actions Resolution Planning Tool – Version 2.0*, March 2022, available at <https://www.medicaid.gov/resources-for-states/downloads/medicaid-chip-covid19-health-emergency-eligibility-enrollment-pending-actions-resolution-planning-tool.docx>; *Top 10 Fundamental Actions to Prepare for Unwinding*, June 2022, available at <https://www.medicaid.gov/resources-for-states/downloads/top-10-fundamental-actions-to-prepare-for-unwinding-and-resources-to-support-state-efforts.pdf>.
- ¹²⁹ Mostly Medicaid, *Brooks-LaSure: ACA marketplace key to Medicaid redeterminations after COVID-19 PHE ends*. Available at <https://www.mostlymedicaid.com/brooks-lasure-aca-marketplace-key-to-medicaid-redeterminations-after-covid-19-phe-ends/>.
- ¹³⁰ OIG, *Certain Medicare Beneficiaries, Such as Urban and Hispanic Beneficiaries, Were More Likely Than Others To Use Telehealth During the First Year of the COVID-19 Pandemic*, OEI-02-20-00522, September 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-02-20-00522.asp>.
- ¹³¹ The White House, *Fact Sheet: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes*, February 2022. Available at <https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/>.
- ¹³² CMS, *Updated Guidance for Nursing Home Resident Health and Safety*, June 2022. Available at <https://www.cms.gov/newsroom/fact-sheets/updated-guidance-nursing-home-resident-health-and-safety>.
- ¹³³ OIG, *COVID-19 Had a Devastating Impact on Medicare Beneficiaries in Nursing Homes During 2020*, OEI-02-20-00490, June 2021. Available at <https://www.oig.hhs.gov/oei/reports/OEI-02-20-00490.asp>.
- ¹³⁴ OIG, *An Estimated 91 Percent of Nursing Home Staff Nationwide Received the Required COVID-19 Vaccine Doses, and an Estimated 56 Percent of Staff Nationwide Received a Booster Dose*, A-09-22-02003, June 2022. Available at <https://oig.hhs.gov/oas/reports/region9/92202003.asp>.
- ¹³⁵ CMS, *Centers for Medicare & Medicaid Services Staffing Study to Inform Minimum Staffing Requirements for Nursing Homes*, August 2022. Available at <https://www.cms.gov/blog/centers-medicare-medicare-services-staffing-study-inform-minimum-staffing-requirements-nursing-homes>.
- ¹³⁶ CMS, *Revised Long-Term Care Surveyor Guidance: Revisions to Surveyor Guidance for Phases 2 & 3, Arbitration Agreement Requirements, Investigating Complaints & Facility Reported Incidents, and the Psychosocial Outcome Severity Guide*, June 2022. Available at <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/revised-long-term-care-surveyor-guidance-revisions-surveyor-guidance-phases-2-3-arbitration>.
- ¹³⁷ OIG, *Audits of Nursing Home Life Safety and Emergency Preparedness in Eight States Identified Noncompliance With Federal Requirements and Opportunities for the Centers for Medicare & Medicaid Services to Improve Resident, Visitor, and Staff Safety*, OAS-02-21-01010, July 2022. Available at <https://oig.hhs.gov/oas/reports/region2/22101010.asp>.
- ¹³⁸ OIG, *Onsite Surveys of Nursing Homes During the COVID-19 Pandemic: March 23-May 30, 2020*, OEI-01-20-00430, December 2020. Available at <https://oig.hhs.gov/oei/reports/OEI-01-20-00430.asp>.
- ¹³⁹ OIG, *States' Backlogs of Standard Surveys of Nursing Homes Grew Substantially During the COVID-19 Pandemic*, OEI-01-20-00431, July 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-01-20-00431.asp>.
- ¹⁴⁰ OIG, *States Continued To Fall Short in Meeting Required Timeframes for Investigating Nursing Home Complaints: 2016-2018*, September 2020. Available at <https://oig.hhs.gov/oei/reports/OEI-01-19-00421.asp>.
- ¹⁴¹ OIG, *CMS Should Take Further Action To Address States With Poor Performance in Conducting Nursing Home Surveys*, OEI-06-19-00460, January 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-06-19-00460.asp>.
- ¹⁴² 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.asp>.
- ¹⁴³ 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_LL_C_Imperial_Gardens_Health_and_Rehabilitation_Vanguard_of_Manchester_%20LLC_Vanguard_Financial_Svcs_LLC_et al_01092019.asp.

¹⁴⁴ OIG, *CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes*, OEI-07-19-00490, May 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-07-19-00490.pdf>.

¹⁴⁵ OIG, *Facility-Initiated Discharges in Nursing Homes Require Further Attention*, OEI-01-18-00250, November 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-01-18-00250.pdf>.

¹⁴⁶ CMS, *Updated Guidance for Nursing Home Resident Health and Safety*, June 2022. Available at <https://www.cms.gov/newsroom/fact-sheets/updated-guidance-nursing-home-resident-health-and-safety>.

¹⁴⁷ 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.asp>.

¹⁴⁸ OIG, *2019: Vulnerabilities in Hospice Care*. Available at <https://oig.hhs.gov/newsroom/media-materials/2019/hospice/>.

¹⁴⁹ HHS, *Featured Priority: Vaccine Confidence*. Available at <https://www.hhs.gov/vaccines/featured-priorities/vaccine-confidence/index.html>.

¹⁵⁰ OIG, *Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018*, OEI-06-18-00400, May 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-06-18-00400.asp>. See also:

- 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.asp>;
- OIG, *Adverse Events in Rehabilitation Facilities: National Incidence Among Medicare Beneficiaries*, OEI-06-14-00110, July 2016. Available at <https://oig.hhs.gov/oei/reports/oei-06-14-00110.asp>; and
- OIG, *Adverse Events in Long-Term-Care Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-14-00530, November 2018. Available at <https://www.oig.hhs.gov/oei/reports/oei-06-14-00530.asp>.

¹⁵¹ 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>.

¹⁵² OIG, *Adverse Events In Hospitals: One Quarter of Medicare Patients Experienced Harm in October 2018*, OEI-06-18-00400, May 2022. Available at <https://oig.hhs.gov/oei/reports/oei-06-18-00400.asp>.

¹⁵³ 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.asp>. See also OIG, *Indian Health Service Hospitals: 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.asp>.

¹⁵⁴ IHS, *Quality at IHS*. Available at <https://www.ihs.gov/quality/>.

¹⁵⁵ 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.asp>.

¹⁵⁶ 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.asp>. See also 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.asp>. See also OIG, *Case Study: Indian Health Service Management of Rosebud Hospital Emergency Department Closure and Reopening*, OEI-06-17-00270, July 2019. Available at <https://oig.hhs.gov/oei/reports/oei-06-17-00270.asp>.

¹⁵⁷ ACF, Office of Head Start, *Head Start Services*. Available at <https://www.acf.hhs.gov/ohs/about/head-start>.

¹⁵⁸ ACF, Office of Child Care, *Characteristics of Families Served by the Child Care and Development Fund (CCDF) Based on Preliminary FY2019 Data*. Available at <https://www.acf.hhs.gov/occ/fact-sheet/characteristics-families-served-child-care-and-development-fund-ccdf-based>.

¹⁵⁹ HHS, *Fact Sheet: Unaccompanied Children (UC) Program*, August 2022. Available at <https://www.hhs.gov/sites/default/files/uac-program-fact-sheet.pdf>.

¹⁶⁰ HHS, *Latest UC Data—FY 2022*. Available at <https://www.hhs.gov/programs/social-services/unaccompanied-children/latest-uc-data-fy2022/index.html>.

¹⁶¹ 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.asp>.

¹⁶² OIG, *The Tornillo Influx Care Facility: Concerns About Staff Background Checks and Number of Clinicians on Staff*, A-12-19-20000, November 2018. Available at <https://oig.hhs.gov/oas/reports/region12/121920000.asp>.

¹⁶³ 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.asp>.

¹⁶⁴ 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.asp>.

¹⁶⁵ OIG, *HHS Should Improve Internal Coordination Regarding Unaccompanied Children*, OEI-BL-20-00670, May 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-BL-20-00670.asp>.

¹⁶⁶ OIG, *Operational Challenges Within ORR and the ORR Emergency Intake Site at Fort Bliss Hindered Case Management for Children*, September 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-07-21-00251.asp>.

¹⁶⁷ The United States Attorney's Office, District of Montana, *White House Announces Presidential Task Force on Protecting Native American Children in the Indian Health Service System*, press release, March 26, 2019. Available at <https://www.justice.gov/usao-mt/pr/white-house-announces-presidential-task-force-protecting-native-american-children-indian>.

¹⁶⁷ OIG, *Unaccompanied Alien Children Care Provider Facilities Generally Conducted Required Background Checks but Faces Challenges in Hiring, Screening, and Retaining Employees*, A-12-19-20001, September 2019. Available at <https://oig.hhs.gov/oas/reports/region12/121920001.asp>.

¹⁶⁸ DOJ, *Presidential Task Force on Protecting Native American Children in the Indian Health Service System Presents Findings to First Lady Melania Trump*, press release, July 24, 2020. Available at <https://www.justice.gov/usao-ndok/pr/presidential-task-force-protecting-native-american-children-indian-health-service>.

¹⁶⁹ OIG, *The Tornillo Influx Care Facility: Concerns About Staff Background Checks and Number of Clinicians on Staff*, A-12-19-20000, November 2018. Available at <https://oig.hhs.gov/oas/reports/region12/121920000.asp>.

¹⁷⁰ OIG, *Work Plan, Office of Refugee Resettlement Influx Care Facilities and Emergency Intake Sites: Employee/Staff Background Screening*, W-00-21-59459. Report scheduled for release in 2023. Available at <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000590.asp>.

¹⁷¹ 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>. See also:

- OIG, *Colorado's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 18 of 30 Providers Reviewed*, A-07-19-06084, April 2021. Available at <https://oig.hhs.gov/oas/reports/region7/71906084.asp>;
- OIG, *Virginia's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 8 of 30 Providers Reviewed*, A-03-19-00253, February 2021. Available at <https://oig.hhs.gov/oas/reports/region3/31900253.asp>;
- OIG, *Indiana's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 17 of 30 Providers Reviewed*, A-05-19-00012, August 2020. Available at <https://oig.hhs.gov/oas/reports/region5/51900012.asp>;
- OIG, *Rhode Island's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 18 of 30 Providers Reviewed*, A-01-18-02505, August 2020. Available at <https://oig.hhs.gov/oas/reports/region1/11802505.asp>;
- OIG, *New Jersey's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 9 of 30 Providers Reviewed*, A-02-19-02004, July 2020. Available at <https://oig.hhs.gov/oas/reports/region2/21902004.asp>;

- OIG, *Illinois' Monitoring Did Not Ensure Childcare Provider Compliance With State Criminal Background Check Requirements at 12 of 30 Providers Reviewed*, A-05-19-00016, April 2020. Available at <https://oig.hhs.gov/oas/reports/region5/51900016.asp>; and
- OIG, *New Hampshire's Monitoring Did Not Ensure Childcare Provider Compliance With State Criminal Background Check Requirements at 21 of 30 Providers Reviewed*, A-01-18-02504, April 2020. Available at <https://oig.hhs.gov/oas/reports/region1/11802504.asp>.

¹⁷² 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>.

¹⁷³ OIG, *National Background Check Program for Long-Term-Care Providers: An Interim Assessment*, OEI-07-20-00181, May 2022. Available at <https://oig.hhs.gov/oei/reports/oei-07-20-00181.asp>.

¹⁷⁴ Federal Register, *HHS-ACF final rule for Child Care and Development Fund Program*, September 30, 2016. Available at <https://www.govinfo.gov/content/pkg/FR-2016-09-30/pdf/2016-22986.pdf>.

¹⁷⁵ OIG, et al., *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.asp>.

¹⁷⁶ CMS, *CMCS Informational Bulletin: Health and Welfare of Home and Community Based Services (HCBS) Waiver Recipients*. Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/cib062818.pdf>.

¹⁷⁷ See Medicaid.gov, *Home & Community Based Services Training Series*. Available at <https://www.medicaid.gov/medicaid/home-community-based-services/home-community-based-services-training-series/index.html#health>. See also CMS, *Home and Community-Based Services Quality Measure Set*, letter to State Medicaid directors, July 2022. Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/smd22003.pdf>.

¹⁷⁸ CMS, *CMS Fast Facts*. Available at <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/cms-fast-facts/index.html>.

¹⁷⁹ 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.asp>.

¹⁸⁰ CMS, *Updated Guidance for Nursing Home Resident Health and Safety*. Available at <https://www.cms.gov/newsroom/fact-sheets/updated-guidance-nursing-home-resident-health-and-safety>.

¹⁸¹ OIG, *Safeguards Must Be Strengthened To Protect Medicare Hospice Beneficiaries From Harm*, OEI-02-17-00021, July 2019. Available at <https://oig.hhs.gov/oei/reports/oei-02-17-00021.asp>.

¹⁸² 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.asp>.

¹⁸³ OIG, *In Five States There Was No Evidence That Many Children in Foster Care Had a Screening for Sex Trafficking When They Returned After Going Missing*, OEI-07-19-00371, July 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-07-19-00371.asp>.

¹⁸⁴ 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.

¹⁸⁵ 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.asp>.

¹⁸⁶ *Foundations for Evidence-Based Policymaking Act of 2018*, P.L. 111-435 (January 14, 2019). Enterprise data governance is one of the four areas 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. The plan includes Action 2: Constitute a Diverse Data Governance Body. Available at <https://strategy.data.gov/action-plan/#action-2-constitute-a-diverse-data-governance-body>. The HHS Data Governance Board serves as the principal data governance forum and decision-making body for managing HHS's data as a strategic asset and

supporting HHS in meeting its mission and agency priorities, including implementation of the *Evidence Act*. See <https://beta.healthdata.gov/dataset/HHS-Data-Governance-Board-Membership/w3i2-jayx/data>.

¹⁸⁷ HHS, Office of the Chief Technology Officer, *The State of Data Sharing at the U.S. Department of Health and Human Services*. Available at https://www.hhs.gov/sites/default/files/HHS_StateofDataSharing_0915.pdf.

¹⁸⁸ CDC, *CDC Moving Forward*, August 2022. Available at <https://www.cdc.gov/about/organization/cdc-moving-forward.html>. CDC, *Data Modernization Initiative*, May 2022. Available at <https://www.cdc.gov/surveillance/data-modernization/index.html>.

¹⁸⁹ GAO, *Agencies Need to Develop Modernization Plans for Critical Legacy Systems*, GAO-19-471, June 2019. Available at <https://www.gao.gov/assets/gao-19-471.pdf>.

¹⁹⁰ OIG, *Operational Challenges Within ORR and the ORR Emergency Intake Site at Fort Bliss Hindered Case Management for Children*, OEI-07-21-00251, September 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-07-21-00251.asp>.

¹⁹¹ OIG, *Communication and Management Challenges Impeded HHS's Response to the Zero-Tolerance Policy*, OEI-BL-18-00510, March 2020. Available at <https://oig.hhs.gov/oei/reports/oei-BL-18-00510.asp>.

¹⁹² HHS, 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.

¹⁹³ 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. See CMS, letter to State health officials, SHO #18-008, August 10, 2018. Available at <https://www.medicaid.gov/federal-policy-guidance/downloads/sho18008.pdf>.

¹⁹⁴ CMS, *Fact Sheet: Medicaid & CHIP and the COVID-19 Public Health Emergency*, May 2021. Available at <https://www.cms.gov/newsroom/fact-sheets/fact-sheet-medicaid-chip-and-covid-19-public-health-emergency>.

¹⁹⁵ OIG, *Data on Medicaid Managed Care Payments to Providers Are Incomplete and Inaccurate*, OEI-02-19-00180, March 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-02-19-00180.asp>.

¹⁹⁶ HHS, *HHS Information Technology Strategic Plan*. Available at <https://www.hhs.gov/sites/default/files/hhs-it-strategic-plan-final-fy2021-2023.pdf>.

¹⁹⁷ As of 2019, 65 percent of physicians electronically exchanged health information through some mechanism (sending, receiving, or querying), and of those physicians more than 75 percent experienced improvements in their practice quality, care coordination, patient safety and efficiency. Office of the National Coordinator for Health Information Technology, *Interoperability Among Office-Based Physicians in 2019*, July 2022. Available at https://www.healthit.gov/sites/default/files/2022-07/Interoperability_Among_Office-Based_Physicians_in_2019.pdf. See also, 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.asp>.

¹⁹⁸ National Cybersecurity Center of Excellence and National Institute of Standards and Technology, *Implementing a Zero Trust Architecture*, October 2020. Available at <https://www.nccoe.nist.gov/sites/default/files/legacy-files/zta-project-description-final.pdf>. A zero-trust cybersecurity approach removes the assumption of trust typically given to devices, subjects, and networks. It focuses on accessing resources in a secure manner, regardless of network location, subject, and asset, and enforcing risk-based access controls while continually inspecting, monitoring, and logging interactions.

¹⁹⁹ GAO, *NIH Needs to Take Further Actions to Resolve Control Deficiencies and Improve Its Program*, GAO-22-104467, December 2021. Available at <https://www.gao.gov/assets/gao-22-104467.pdf>.

²⁰⁰ OIG, *The IHS Telehealth System Was Deployed Without Some Required Cybersecurity Controls*, A-18-21-03100, September 2022. Available at <https://oig.hhs.gov/oas/reports/region18/182103100.asp>. 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.asp>.

²⁰¹ Fierce Healthcare, *Healthcare data breaches hit all-time high in 2021, impacting 45M people*, February 1, 2022. Available at <https://www.fiercehealthcare.com/health-tech/healthcare-data-breaches-hit-all-time-high-2021-impacting-45m-people>.

²⁰² Healthcare IT News, *Healthcare breach costs hit record high*, July 27, 2022. Available at <https://www.healthcareitnews.com/news/healthcare-breach-costs-hit-record-high#:~:text=The%20average%20total%20cost%20of,identify%20and%20contain%20a%20breach>.

²⁰³ American Hospital Association reposted an FBI report, *Unpatched and Outdated Medical Devices Provide Cyber Attack Opportunities*, September 2022. Available at <https://www.aha.org/cybersecurity-government-intelligence-reports/2022-09-12-fbi-pin-tlp-white-unpatched-and-outdated>.

²⁰⁴ HHS, FDA, *Justification of Estimates for Appropriations Committees*. Available at <https://www.fda.gov/media/157192/download>.

²⁰⁵ 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.asp>. See also 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.asp>.

²⁰⁶ OIG, *Medicare Lacks Consistent Oversight of Cybersecurity for Networked Medical Devices in Hospitals*, OEI-01-20-00220, June 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-01-20-00220.asp>.

²⁰⁷ ACF, HHS Task Force to Prevent and End Human Trafficking, *Fact Sheet*. Available at <https://www.acf.hhs.gov/archive/otip/fact-sheet/hhs-task-force-prevent-and-end-human-trafficking>.

²⁰⁸ HHS, *HHS Announces \$3 Billion in American Rescue Plan Funding for SAMHSA Block Grants to Address Addiction, Mental Health Crisis*, May 2021, Available at <https://www.hhs.gov/about/news/2021/05/18/hhs-announces-3-billion-in-american-rescue-plan-funding-for-samhsa-block-grants.html>.

²⁰⁹ ASPE, *U.S. Department of Health and Human Services Overdose Prevention Strategy*. Available at <https://aspe.hhs.gov/sites/default/files/documents/101936da95b69acb8446a4bad9179cc0/overdose-prevention-strategy.pdf>.

²¹⁰ Executive Office of the President, Office of Management and Budget, memorandum, *Promoting Accountability through Cooperation among Agencies and Inspectors General*, December 3, 2021. Available at <https://www.whitehouse.gov/wp-content/uploads/2021/12/M-22-04-IG-Cooperation.pdf>.

²¹¹ Executive Office of the President, Office of Management and Budget, memorandum, *Advancing Effective Stewardship of Taxpayer Resources and Outcomes in the Implementation of the Infrastructure Investment and Jobs Act*. Available at <https://www.whitehouse.gov/wp-content/uploads/2022/04/M-22-12.pdf>.

²¹² HHS, *IEA Mission Statement: Functions of the Office of Intergovernmental and External Affairs (IEA)*. Available at <https://www.hhs.gov/about/agencies/iea/about/index.html>.

²¹³ CDC, *Opioid Rapid Response Program (ORRP)*. Available at <https://www.cdc.gov/opioids/opioid-rapid-response-program.html>.

²¹⁴ FDA, *FDA Developing New Framework for Continued, Expanded Access to Infant Formula Options for U.S. Parents and Caregivers*. Available at <https://www.fda.gov/news-events/press-announcements/fda-developing-new-framework-continued-expanded-access-infant-formula-options-us-parents-and>.

²¹⁵ ASPR, *Public Health Supply Chain and Industrial Base One-Year Report*. Available at <https://aspr.hhs.gov/MCM/IBx/2022Report/Pages/default.aspx>.

²¹⁶ HHS, *U.S. Transition to 988 Suicide & Crisis Lifeline Begins Saturday*, July 15, 2022. Available at <https://www.hhs.gov/about/news/2022/07/15/us-transition-988-suicide-crisis-lifeline-begins-saturday.html>.

²¹⁷ GAO, *High Risk List*. Available at <https://www.gao.gov/high-risk-list?source=email>. See also <https://files.gao.gov/reports/GAO-22-105291/index.html#appendix18>.

²¹⁸ ASPR, *Introducing the Administration for Strategic Preparedness and Response*, July 2022. Available at <https://aspr.hhs.gov/ASPRBlog/Pages/BlogDetailView.aspx?ItemID=439>.

²¹⁹ ASPR, *ASPR's Response to the Monkeypox Outbreak*, August 2021. Available at <https://aspr.hhs.gov/monkeypox/Pages/default.aspx>.

-
- ²²⁰ CDC, *Moving Forward*, August 2022. Available at <https://www.cdc.gov/about/organization/cdc-moving-forward.html>.
- ²²¹ OIG, *OIG Resources for Emergency Preparedness and Response*. Available at <https://www.oig.hhs.gov/reports-and-publications/featured-topics/response/index.asp>.
- ²²² OIG, *Office of Refugee Resettlement's Influx Care Facility and Emergency Intake Sites Did Not Adequately Safeguard Unaccompanied Children From COVID-19*, A-06-21-07002, June 2022. Available at <https://www.oig.hhs.gov/oas/reports/region6/62107002.asp>.
- ²²³ 114th Congress (2021-2022), *S.1397 - Tribal Health Data Improvement Act of 2021*. Available at <https://www.congress.gov/bill/117th-congress/senate-bill/1397/text>.
- ²²⁴ GAO, *Tribal Epidemiology Centers: HHS Actions Needed to Enhance Data Access*, GAO-22-104698, March 2022. Available at <https://www.gao.gov/products/gao-22-104698>.
- ²²⁵ OIG, *CDC Found Ways To Use Data To Understand and Address COVID-19 Health Disparities, Despite Challenges With Existing Data*, OEI-05-20-00540, July 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-05-20-00540.asp>.
- ²²⁶ CDC, *CDC data show disproportionate COVID-19 impact in American Indian/Alaska Native populations*, press release, August 19, 2020. Available at <https://www.cdc.gov/media/releases/2020/p0819-covid-19-impact-american-indian-alaska-native.html>. See also CDC, *Morbidity and Mortality Weekly Report (MMWR), COVID-19 Among American Indian and Alaska Native Persons—23 States, January 31–July 3, 2020*, August 2020. Available at https://www.cdc.gov/mmwr/volumes/69/wr/mm6934e1.htm?s_cid=mm6934e1_w.
- ²²⁷ CDC, *Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity*, September 2022. Available at <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html>.
- ²²⁸ CDC, *What is Health Equity?* Available at <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html>.
- ²²⁹ 117th Congress (2021–2022), *H.R.3684 – Infrastructure Investment and Jobs Act*. Available at <https://www.congress.gov/bill/117th-congress/house-bill/3684>.
- ²³⁰ OIG, *In Five States, There Was No Evidence That Many Children in Foster Care Had a Screening for Sex Trafficking When They Returned After Going Missing*, OEI-07-19-00371, July 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-07-19-00371.asp>.
- ²³¹ OIG, *National Snapshot of State Agency Approaches To Reporting and Locating Children Missing From Foster Care*, A-07-20-06095, May 2022. Available at <https://oig.hhs.gov/oas/reports/region7/72006095.asp>.
- ²³² OIG, *Case Study: Missouri's Efforts To Protect Children Missing From Foster Care*, OEI-07-19-00372, September 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-07-19-00372.asp>.
- ²³³ OIG, *Communication and Management Challenges Impeded HHS's Response to the Zero-Tolerance Policy*, OEI-BL-18-00510, March 2020. Available at <https://oig.hhs.gov/oei/reports/oei-BL-18-00510.asp>.
- ²³⁴ OIG, *HHS Should Improve Internal Coordination Regarding Unaccompanied Children*, OEI-BL-20-00670, May 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-BL-20-00670.asp>.
- ²³⁵ OIG, *CMS Should Take Further Action To Address States With Poor Performance in Conducting Nursing Home Surveys*, OEI-06-19-00460, January 2022. Available at <https://oig.hhs.gov/oei/reports/OEI-06-19-00460.asp>.
- ²³⁶ OIG, *More Than One-Third of Medicaid-Enrolled Children in Five States Did Not Receive Required Blood Lead Screening Tests*, OEI-07-18-00371, October 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-07-18-00371.asp>.
- ²³⁷ OIG, *Many Medicare Beneficiaries Are Not Receiving Medication to Treat Their Opioid Use Disorder*, OEI-02-20-00390, December 2021. Available at <https://oig.hhs.gov/oei/reports/OEI-02-20-00390.asp>.