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Comptroller General
of the United States

Accessible Version

May 26, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, D.C. 20201

Priority Open Recommendations: Department of Health and Human Services

Dear Mr. Secretary:

The purpose of this letter is to provide an update on the overall status of the U.S. Department of Health and Human Services' (HHS) implementation of GAO's recommendations and call your continued personal attention to areas where recommendations should be given high priority.¹ In November 2021, we reported that on a government-wide basis, 76 percent of our recommendations made 4 years ago were implemented.² As of April 2022, HHS had 452 open recommendations with an implementation rate of 65 percent. Implementing all open recommendations could significantly improve HHS's operations.

In our May 2021 letter to the department, we designated 61 recommendations as priorities for HHS, and HHS has since implemented nine of them.³ In doing so, HHS has taken steps to

- revise its processes for conducting improper payment risk assessments for its programs, including the Head Start program;⁴

¹Priority recommendations are those that GAO believes warrant priority attention from heads of key departments or agencies. They are highlighted because, upon implementation, they may significantly improve government operation, for example, by realizing large dollar savings; eliminating mismanagement, fraud, and abuse; or making progress toward addressing a high-risk or duplication issue.

²GAO, *Performance and Accountability Report: Fiscal Year 2021*, [GAO-22-4SP](#) (Washington, D.C.: Nov. 15, 2021).

³In addition to the nine priority recommendations HHS implemented, we closed one recommendation made in September 2020 related to establishing a time frame for documenting and sharing a national plan for distributing and administering COVID-19 vaccines. Over the course of the pandemic, HHS, including CDC, and the White House issued vaccine planning documents; however, these documents did not provide details—such as specific roles of non-federal entities—to fully implement this recommendation. Given the widespread distribution and administration of COVID-19 vaccines, we closed this recommendation because the effective timeframe for its implementation has passed.

⁴GAO, *Improper Payments: Selected Agencies Need Improvements in Their Assessments to Better Determine and Document Risk Susceptibility*, [GAO-19-112](#) (Washington, D.C.: Jan. 10, 2019).

- conduct additional studies measuring the long-term health outcomes of persons with COVID-19;⁵
- evaluate and continue programs for prior authorization of health care items and services in the Medicare program;⁶
- document roles and responsibilities for making enterprise-wide decisions related to biodefense;⁷
- improve cybersecurity risk management at the department for two of our recommendations;⁸
- protect infants exposed to opioids in utero;⁹ and
- help ensure that the Office of Refugee Resettlement systematically reviews licensing status of, past disciplinary actions against, and previous performance for grantees applying to care for unaccompanied children for two of our recommendations.¹⁰

We ask your continued attention to the remaining 51 priority recommendations we identified in our 2021 letter. We also are adding five new priority recommendations related to the response to, and recovery from, the COVID-19 pandemic and other public health emergency preparedness issues; Food and Drug Administration (FDA) oversight; health information technology and cybersecurity; and the Medicaid program. With these additions, the total number of priority recommendations is 56. (See enclosure for a more comprehensive description of all 56 recommendations and actions needed to implement them.)

The 56 priority recommendations fall into the following eight areas.

COVID-19 response and other public health emergency preparedness.

The COVID-19 pandemic continues to highlight the critical need for an effective national response to public health emergencies—an area for which HHS’s leadership and coordination has been placed on GAO’s [High-Risk List](#). We have identified 15 priority recommendations in this area, such as documenting roles and responsibilities for supply chain management and developing plans to mitigate remaining medical supply gaps for the remainder of the pandemic. If implemented, these recommendations will help improve HHS’s preparedness to address the

⁵GAO, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions*, [GAO-20-701](#) (Washington, D.C.: Sept. 21, 2020).

⁶GAO, *Medicare: CMS Should Take Actions to Continue Prior Authorization Efforts to Reduce Spending*, [GAO-18-341](#) (Washington, D.C.: Apr. 20, 2018).

⁷GAO, *National Biodefense Strategy: Additional Efforts Would Enhance Likelihood of Effective Implementation*, [GAO-20-273](#) (Washington, D.C.: Feb. 19, 2020).

⁸GAO, *Cybersecurity: Agencies Need to Fully Establish Risk Management Programs and Address Challenges*, [GAO-19-384](#) (Washington, D.C.: July 25, 2019).

⁹GAO, *Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome*, [GAO-18-32](#) (Washington, D.C.: Oct. 4, 2017).

¹⁰GAO, *Unaccompanied Children: Actions Needed to Improve Grant Application Reviews and Oversight of Care Facilities*, [GAO-20-609](#) (Washington, D.C.: Sept. 15, 2020).

ongoing and evolving challenges of the COVID-19 pandemic—as well as any future public health emergencies.

Public health and human services program oversight.

Public health and human services programs serve to enhance health and well-being; however, we have found weaknesses in a variety of such programs that have left them vulnerable to inefficiency, ineffectiveness, fraud, or improper payments. We have identified eight priority recommendations that, if implemented, would strengthen oversight of public health and human services, such as the HHS program that provides care to noncitizen children who have no lawful immigration status and no parents or guardians in the United States, known as unaccompanied children, and state survey agencies' oversight of nursing homes.

FDA oversight.

FDA has a critical role in ensuring the safety, efficacy, and security of the millions of medical products used by Americans each day, as well as the safety of our nation's food supply. We have identified seven priority recommendations in this area, such as ensuring that FDA's future drug manufacturing inspection plans account for its backlog and assessing its foreign offices' contributions to ensuring the safety of imported products. If implemented, these recommendations would help FDA ensure the safety of medical products and food imported into the United States.

Improper payments in Medicaid and Medicare.

Estimates of improper payments in the Medicaid and Medicare programs continue to be unacceptably high and totaled about \$148 billion in fiscal year 2021. We have identified six priority recommendations that, if implemented, could reduce improper payments by assessing documentation requirements, minimizing program risks, and conducting prepayment claim reviews, among other things.

Medicaid program.

Medicaid is a critically important federal-state health care financing program that served about 83 million low-income and medically needy individuals at an estimated cost of \$455 billion to the federal government in fiscal year 2021. By fully implementing the nine priority recommendations in this area—such as collecting complete data on provider-specific Medicaid payments and beneficiary blood lead screenings—HHS could improve oversight of Medicaid funding and protect the health and welfare of Medicaid beneficiaries.

Medicare program.

In fiscal year 2021, the Medicare program spent an estimated \$712 billion to provide health care services for about 64 million elderly and disabled beneficiaries, with spending expected to increase significantly over the next 10 years. We have identified eight priority recommendations in this area, such as validating Medicare Advantage (MA) encounter data before using it for risk adjustment, and improving the accuracy of the adjustment to MA payments to account for differences in diagnostic coding practices between MA and Medicare fee-for-service. If implemented, these recommendations would help HHS improve the Medicare program's payment policy and design, potentially improving the sustainability of the program by, for example, reducing unnecessary expenditures.

Health information technology and cybersecurity.

The federal government exchanges a large variety of sensitive information with states to implement key federal and state programs. Recent high profile cyberattacks targeting the public and private sectors highlight the urgent need to address cybersecurity weaknesses. We have identified two priority recommendations in this area that call for working with sector partners to determine cybersecurity framework adoption and revising assessment policies to maximize coordination. If implemented, these recommendations would improve HHS's ability to address cyber-related risks.

Health insurance premium tax credit payment integrity.

The Patient Protection and Affordable Care Act (PPACA) established health insurance marketplaces where consumers can select private health insurance plans. For individuals who meet certain requirements, PPACA provides subsidies, including a premium tax credit (PTC), to help cover costs. With those subsidies and other costs, PPACA represents a significant, long-term fiscal commitment for the federal government. We identified one priority recommendation that would help ensure the integrity of PTC payments by annually reporting improper payment estimates and error rates for the advance PTC program.

Implementing our priority recommendations could help improve the efficiency and effectiveness of key federal health care programs and funding, including those relevant to the nation's ongoing response to COVID-19. Further, implementing our priority recommendations could be done in conjunction with efforts to address high-risk areas related to HHS. In March 2021, we issued our biennial update to our [High-Risk List](#), which identifies government operations with greater vulnerabilities to fraud, waste, abuse, and mismanagement or the need for transformation to address economy, efficiency, or effectiveness challenges.¹¹ We also designated HHS's leadership and coordination of public health emergencies as a new high-risk area in January 2022.¹²

The following four high-risk areas center directly on HHS: (1) [protecting public health through enhanced oversight of medical products](#), (2) [strengthening Medicaid program integrity](#), (3) [Medicare program and improper payments](#), and (4) [HHS's leadership and coordination of public health emergencies](#). Three additional high-risk areas are shared among HHS and other agencies: (1) [improving federal oversight of food safety](#); (2) [national efforts to prevent, respond to, and recover from drug misuse](#); and (3) [enforcement of tax laws](#).

Several other government-wide high-risk areas also have direct implications for HHS and its operations. These include (1) [improving the management of IT acquisitions and operations](#), (2) [improving strategic human capital management](#), (3) [managing federal real property](#), (4) [ensuring the cybersecurity of the nation](#),¹³ and (5) [government-wide personnel security](#)

¹¹GAO, *High-Risk Series: Dedicated Leadership Needed to Address Limited Progress in Most High-Risk Areas*, [GAO-21-119SP](#) (Washington, D.C.: Mar. 2, 2021).

¹²GAO, *COVID-19: Significant Improvements Are Needed for Overseeing Relief Funds and Leading Responses to Public Health Emergencies*, [GAO-22-105291](#) (Washington, D.C.: Jan. 27, 2022).

¹³With regard to cybersecurity, we also urge you to use foundational information and communications technology supply chain risk management practices set forth in our December 2020 report: GAO, *Information Technology*:

[clearance process](#). We urge your attention to the HHS-specific, shared, and government-wide high-risk issues. Progress on high-risk issues has been possible through the concerted actions and efforts of Congress, the Office of Management and Budget, and the leadership and staff in agencies, including within HHS. In March 2022 we issued a report on key practices to successfully address high-risk areas, which can be a helpful resource as your agency continues to make progress to address high-risk issues.¹⁴

Copies of this report are being sent to the Director of the Office of Management and Budget and appropriate congressional committees including the Committees on Appropriations; Budget; Finance; Health, Education, Labor, and Pensions; and Homeland Security and Governmental Affairs, United States Senate; and the Committees on Appropriations; Budget; Energy and Commerce; Oversight and Reform; and Ways and Means, House of Representatives. In addition, the report will be available on the GAO website at <http://www.gao.gov>.

I appreciate HHS's commitment to these important issues. If you have any questions or would like to discuss any of the issues outlined in this letter, please do not hesitate to contact me or Jessica Farb, Managing Director, Health Care at FarbJ@gao.gov or 202-512-7114. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Our teams will continue to coordinate with your staff on all 452 open recommendations. Thank you for your attention to these matters.

Sincerely yours,

A handwritten signature in black ink that reads "Gene L. Dodaro". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Gene L. Dodaro
Comptroller General
of the United States

Enclosure – 1

cc: Sean McCluskie, Chief of Staff, Department of Health and Human Services
January Contreras, Assistant Secretary, Administration for Children and Families
Norris Cochran, Acting Assistant Secretary for Financial Resources
Rebecca Haffajee, Acting Assistant Secretary for Planning and Evaluation
Dawn O'Connell, Assistant Secretary for Preparedness and Response
Rochelle Walensky, Director, Centers for Disease Control and Prevention
Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services
Robert Califf, Commissioner, Food and Drug Administration
Carole Johnson, Administrator, Health Resources and Services Administration

Federal Agencies Need to Take Urgent Action to Manage Supply Chain Risks, [GAO-21-171](#) (Washington, D.C.: Dec. 15, 2020).

¹⁴GAO, *High-Risk Series: Key Practices to Successfully Address High-Risk Areas and Remove Them from the List*, [GAO-22-105184](#) (Washington, D.C.: Mar. 3, 2022).

Elizabeth Fowler, Acting Director, Indian Health Service
The Honorable Shalanda Young, Director, Office of Management and Budget

Enclosure - Priority Open Recommendations to the Department of Health and Human Services (HHS) –

COVID-19 Response and Other Public Health Emergency Preparedness

COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention. [GAO-21-265](#). Washington, D.C.: January 28, 2021.

Recommendation: The Secretary of Health and Human Services should develop and make publicly available a comprehensive national COVID-19 testing strategy that incorporates all six characteristics of an effective national strategy.¹ Such a strategy could build upon existing strategy documents that HHS has produced for the public and Congress to allow for a more coordinated pandemic testing approach.

Actions needed: HHS partially agreed with this recommendation. In January 2021, HHS agreed that the department should take steps to more directly incorporate some elements of an effective national strategy, but expressed concern that producing such a strategy at this time could be overly burdensome on the federal, state, and local entities that are responding to the pandemic, and that a plan would be outdated by the time it was finalized or potentially rendered obsolete by the rate of technological advancement. In March 2022, the White House updated its general COVID-19 strategy, which provided new strategic elements related to testing but did not contain all of the elements of an effective national strategy, such as clearly defined performance metrics and benchmarks.

We maintain that a comprehensive and public national strategy is an important and worthwhile investment in resources so that all participants have the necessary information to support an informed and coordinated testing response to accomplish shared goals. We also maintain that this can be done efficiently and flexibly, without imposing unnecessary burden, by building upon existing strategy documentation. Such a strategy could also be a living document, allowing for changes to be made publicly and transparently as new information is gained.

Recommendation: To improve the federal government's response to COVID-19 and preparedness for future pandemics, the Secretary of Health and Human Services should immediately establish an expert committee or use an existing one to systematically review and inform the alignment of ongoing data collection and reporting standards for key health indicators. This committee should include a broad representation of knowledgeable health care professionals from the public and private sectors, academia, and nonprofits.

Actions needed: HHS partially agreed with this recommendation. In July 2021, HHS stated that an existing workgroup established as part of HHS's COVID-19 response has

¹The six characteristics of an effective national strategy are the following: (1) clear purpose, scope, and methodology; (2) problem definition and risk assessment; (3) goals, subordinate objectives, activities, and performance measures; (4) resources, investments, and risk management; (5) organizational roles, responsibilities, and coordination; and (6) integration and implementation. Each characteristic has several sub-elements. See GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, [GAO-04-408T](#) (Washington, D.C.: Feb. 3, 2004).

helped to align COVID-19 data collection and reporting efforts. HHS said it plans to consider ways to establish more permanent workgroups to incorporate best practices for ongoing interagency data needs. However, as of February 2022, HHS had not established an expert committee that includes knowledgeable health care professionals outside the federal government. We maintain that including knowledgeable health care professionals from the public and private sectors, academia, and nonprofits is important to help inform the federal government's response to COVID-19 and its preparedness for future pandemics.

High-risk area: [HHS's Leadership and Coordination of Public Health Emergencies](#)

Directors: Jessica Farb and Mary Denigan-Macauley, Health Care

Contact information: FarbJ@gao.gov, DeniganMacauleyM@gao.gov, 202-512-7114

Defense Production Act: Opportunities Exist to Increase Transparency and Identify Future Actions to Mitigate Medical Supply Chain Issues. [GAO-21-108](#). Washington, D.C.: November 19, 2020.

Recommendation: The HHS Assistant Secretary for Preparedness and Response should identify how the Defense Production Act (DPA) and similar actions will be used to increase domestic production of medical supplies going forward. This could be included in HHS's 180-day effort to identify and mitigate vulnerabilities for essential medicines, medical countermeasures, and critical inputs that is required to support Executive Order 13944, which is aimed at reducing reliance on foreign manufacturers of medical supplies.

Actions needed: HHS agreed with this recommendation. As of February 2022, no specific action had been taken by HHS, although agency officials stated that they are evaluating the potential use of DPA authorities to respond to future pandemics and national emergencies. We maintain that identifying further use of the DPA and similar actions can help inform efforts to reduce reliance on foreign manufacturers and increase domestic production of essential medical items.

High-risk area: [HHS's Leadership and Coordination of Public Health Emergencies](#)

Director: W. William Russell, Contracting and National Security Acquisitions

Contact information: RussellW@gao.gov, 202-512-4841

COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions. [GAO-20-701](#). Washington, D.C.: September 21, 2020.

Recommendation: The Secretary of Health and Human Services in coordination with the Administrator of the Federal Emergency Management Agency (FEMA)—who head agencies leading the COVID-19 response through the Unified Coordination Group—should immediately document roles and responsibilities for supply chain management functions that are transitioning to HHS, including continued support from other federal partners, to ensure sufficient resources exist to sustain and make the necessary progress in stabilizing the supply chain, and address emergent supply issues for the duration of the COVID-19 pandemic.

Actions needed: HHS disagreed with this recommendation and, as of February 2022, noted, among other things, the work that the department had done to manage the medical supply chain and increase supply availability. We acknowledge those efforts, but as supply chain efforts continue—and HHS continues to work closely with, and rely on, federal partners—we maintain that this recommendation is warranted to sustain the progress made, especially as the pandemic continues. Fully implementing this recommendation would reduce the likelihood of further disruptions to the supply chain and may help inform a longer-term national supply chain strategy, which could in turn better position stakeholders for future pandemics or other chemical, biological, nuclear, or radiological events.

Recommendation: The Secretary of Health and Human Services in coordination with the Administrator of FEMA—who head agencies leading the COVID-19 response through the Unified Coordination Group—should further develop and communicate to stakeholders plans outlining specific actions the federal government will take to help mitigate remaining medical supply gaps necessary to respond to the remainder of the pandemic, including through the use of DPA authorities.

Actions needed: HHS disagreed with this recommendation and, as of February 2022, noted, among other things, the work that the department had done to manage the medical supply chain and increase supply availability. We acknowledge those efforts, but maintain that HHS should outline specific actions to mitigate remaining COVID-19 supply gaps to ensure that the federal response will align with the needs of stakeholders, such as state, local, tribal, and territorial governments. Further, such plans would provide needed clarity to federal partners and nonfederal entities on priority needs and ongoing efforts to address those needs.

Recommendation: The Secretary of Health and Human Services—who heads one of the agencies leading the COVID-19 response through the Unified Coordination Group—consistent with their roles and responsibilities, should work with relevant federal, state, territorial, and tribal stakeholders to devise interim solutions, such as systems and guidance and dissemination of best practices, to help states enhance their ability to track the status of supply requests and plan for supply needs for the remainder of the COVID-19 pandemic response.

Actions needed: HHS disagreed with this recommendation and noted, among other things, the work that the department had done to manage the medical supply chain and increase supply availability. As of February 2022, HHS had not demonstrated action to devise interim solutions that would systematically help states, territories, and tribes effectively track, manage, and plan for supplies to carry out the COVID-19 pandemic response when they do not have the logistics capabilities to track critical supplies required for a response of this scale. Until HHS fully implements this recommendation, those on the front lines of the national COVID-19 response may continue to face challenges that hamper their effectiveness.

Recommendation: The Secretary of Health and Human Services, in consultation with the Centers for Medicare & Medicaid Services (CMS) and CDC, should develop a strategy to capture more complete data on confirmed COVID-19 cases and deaths in nursing homes retroactively back to January 1, 2020, and to clarify the extent to which nursing homes have reported data before May 8, 2020. To the extent feasible, this

strategy to capture more complete data should incorporate information nursing homes previously reported to CDC or to state or local public health offices.

Actions needed: HHS partially agreed with this recommendation. As of February 2022, no specific action had been taken by HHS, although agency officials stated that they continue to consider how to implement this recommendation. We maintain that collecting data on COVID-19 cases and deaths from nursing homes retroactively would better inform the government's continued response and recovery, and we maintain that HHS could ease the burden by incorporating data previously reported to CDC or to state or local public health offices.

High-risk area: [HHS's Leadership and Coordination of Public Health Emergencies](#)

Directors: John E. Dicken, Alyssa Hundrup, and Mary Denigan-Macauley, Health Care

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Public Health Preparedness: HHS Should Take Actions to Ensure It Has an Adequate Number of Effectively Trained Emergency Responders. [GAO-20-525](#). Washington, D.C.: June 18, 2020.

Recommendation: The Assistant Secretary for Preparedness and Response should develop a National Disaster Medical System (NDMS) responder workforce target that accounts for the critical skills and competencies that are needed to meet current and future programmatic results, such as a workforce target that considers (1) a nationwide event or multiple concurrent events, (2) the needs of at-risk individuals, and (3) the availability of other medical responders.

Actions needed: HHS agreed with this recommendation. Officials with the Office of the Assistant Secretary for Preparedness and Response (ASPR) stated that they will work to develop a strategic documented workforce target that considers (1) a nationwide event or multiple concurrent events, (2) the needs of at-risk individuals, and (3) the availability of other medical responders. They also stated that ASPR's ability to realize this workforce target will be subject to the availability of funding. As of February 2022, ASPR officials said they continue to work on implementing this recommendation.

To fully implement this recommendation, ASPR needs to develop an NDMS responder workforce target that accounts for the critical skills and competencies needed to meet current and future programmatic events. Until it does so, HHS cannot be sure its target, if achieved, will provide an adequate number of responders with the skill sets needed to effectively respond to an event.

High-risk area: [HHS's Leadership and Coordination of Public Health Emergencies](#)

Director: Mary Denigan-Macauley, Health Care

Contact information: DeniganMacauleyM@gao.gov, 202-512-7114

Infectious Disease Modeling: Opportunities to Improve Coordination and Ensure Reproducibility. GAO-20-372. Washington, D.C.: May 13, 2020.

Recommendation: The Secretary of Health and Human Services should develop a mechanism to routinely monitor, evaluate, and report on coordination efforts for infectious disease modeling across multiple agencies.

Actions needed: HHS agreed with this recommendation. As of March 2022, HHS stated that it is developing a process to coordinate its efforts in infectious disease modeling across its components, including efforts to monitor, evaluate, and report on that coordination. To fully implement this recommendation, HHS needs to finalize a process that includes efforts to monitor, evaluate, and report on coordination across multiple agencies. Until it does so, HHS will be limited in its ability to identify areas for improvement.

Recommendation: The Secretary of Health and Human Services should direct CDC to establish guidelines that ensure full reproducibility of CDC's research by sharing with the public all permissible and appropriate information needed to reproduce research results, including, but not limited to, model code.

Actions needed: HHS agreed with this recommendation. In February 2022, CDC said it had established a center to serve as a hub for infectious disease modeling innovation and research. However, CDC has not taken steps to update its guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated to the public. Such guideline modifications could include language relating to model reproducibility, such as model code. To fully implement this recommendation, CDC needs to provide evidence of updated guidelines for sharing with the public all permissible, appropriate information to ensure the full reproducibility of its research. Without sharing code and other important information, CDC cannot ensure that its models are reproducible, a key characteristic of reliable, high-quality scientific research.

High-risk area: [HHS's Leadership and Coordination of Public Health Emergencies](#)

Director: Timothy M. Persons, Chief Scientist

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National Biodefense Strategy: Additional Efforts Would Enhance Likelihood of Effective Implementation. GAO-20-273. Washington, D.C.: February 19, 2020.

Recommendation: The Secretary of Health and Human Services should direct the Biodefense Coordination Team to establish a plan that includes change management practices—such as strategies for feedback, communication, and education—to reinforce collaborative behaviors and enterprise-wide approaches and to help prevent early implementation challenges from becoming institutionalized.

Actions needed: HHS agreed with this recommendation. As of February 2022, HHS described actions it has taken to implement it, but did not provide supporting documentation that would allow GAO to assess the extent to which these actions respond to the report findings and the recommendation.

To fully implement the recommendation, HHS needs to provide evidence of the plan it created to enhance change management, including a strategy for communication, and evidence of the feedback mechanisms it is using, such as tools used to conduct annual after action reviews of the data collection process, in the context of managing the change from a mission stovepipe orientation to an enterprise wide homeland and national security focus on biodefense preparedness. Doing so would help all the federal agencies in the biodefense enterprise reinforce collaborative behaviors and enterprise-wide risk management approaches to building national biodefense capabilities.

Recommendation: The Secretary of Health and Human Services should direct the Biodefense Coordination Team to clearly document guidance and methods for analyzing the data collected from the agencies, including ensuring that nonfederal resources and capabilities are accounted for in the analysis.

Actions needed: HHS agreed with this recommendation. As of February 2022, HHS described actions it has taken to implement it. For example, HHS described that standard operating procedures are in development to further codify the annual assessment process. However, HHS did not provide supporting documentation that would allow GAO to assess the extent to which these actions respond to the report findings and meet the intent of the recommendation.

To fully implement this recommendation, HHS needs to document standard operating procedures, and the procedures must outline how the Biodefense Coordination Team plans to account for nonfederal capabilities in its annual assessment. HHS also needs to provide other guidance documents established for the annual assessment that clearly articulate the methods to be used. Until HHS fully implements this recommendation, the federal agencies that support national biodefense capabilities will be limited in their ability to effectively use established processes to support an enterprise-wide risk management approach.

Recommendation: The Secretary of Health and Human Services should direct the Biodefense Coordination Team to establish a resource plan to staff, support, and sustain its ongoing efforts.

Actions needed: HHS agreed with this recommendation. As of February 2022, HHS described actions it has taken to implement it. For example, HHS submitted a budget request for \$5 million to support implementation of the National Biodefense Strategy. However, HHS did not provide supporting documentation that would allow GAO to assess the extent to which these actions respond to the report findings and meet the intent of the recommendation.

To fully implement this recommendation, HHS needs to provide a detailed plan on how such budget requests will be used to staff, support, and sustain ongoing implementation efforts. This is particularly important because the Biodefense Coordination Team comprises over a dozen member departments and agencies, and the budget request made by HHS does not detail specific resources that may be required of other member departments.

High-risk area: [HHS's Leadership and Coordination of Public Health Emergencies](#)

Directors: Chris P. Currie, Homeland Security and Justice and Mary Denigan-Macauley, Health Care

Contact information: CurrieC@gao.gov, 404-679-1875 and DeniganMacauleyM@gao.gov, 202-512-7114

**Disaster Response: HHS Should Address Deficiencies Highlighted by Recent Hurricanes in the U.S. Virgin Islands and Puerto Rico. [GAO-19-592](#).
Washington, D.C.: September 20, 2019.**

Recommendation: ASPR should work with support agencies to develop and finalize memorandums of agreement that include information on the capabilities and limitations of these agencies to meet emergency support function (ESF) #8 core capabilities.²

Actions needed: HHS disagreed with this recommendation. As of January 2022, HHS stated that the National Response Framework articulates how ESFs operate during incident response, and that further agreements are not needed to outline functions and responsibilities. In addition, HHS stated that it does not plan to develop a list of capabilities because capabilities can change, and due to the structure of the National Response Framework, all agency partners can quickly come together during a response to collaborate and coordinate resources.

We agree that HHS and all of its partners may be able to come together quickly to collaborate and coordinate resources during a response; however, as evidenced by the capabilities misalignment identified in our report, this was not enough during the response to Hurricanes Irma and Maria in the U.S. Virgin Islands and Puerto Rico, respectively. Further, as we reported, ASPR officials acknowledged that more needs to be done to better understand the resources available from its support agencies. We maintain that it is essential for ASPR to take steps to ensure it has a sufficient understanding of each ESF #8 support agency's potential capabilities and limitations.

Recommendation: ASPR should develop a response personnel strategy to ensure, at a minimum, a lead ASPR liaison officer is consistently at the local emergency operations center(s) during an ESF #8 response and another liaison, if not more, is at strategic location(s) in the area.

Actions needed: HHS agreed with this recommendation. As of February 2022, ASPR officials stated that their incident response framework includes a long-term goal of creating an incident response team that will establish an initial ESF #8 presence at local emergency operations centers and manage resources and capabilities. If implemented, this strategy may allow ASPR to provide more liaisons on the ground during a response and address the staffing deficiency we identified in our report. To fully implement this recommendation, ASPR officials need to provide us with evidence that this team has been established to ensure at least one liaison is consistently stationed at emergency operations centers. Until HHS fully implements this recommendation, it risks having inadequate liaison officer presence to effectively lead a response on the ground.

High-risk area: [HHS's Leadership and Coordination of Public Health Emergencies](#)

²The National Response Framework establishes an all-hazards response structure to coordinate federal resources during hurricanes and other emergencies and disasters, and is divided into 14 ESFs, which are functional areas that are most frequently needed during a national response. ESF #8 relates to the public health and medical services response.

Director: Mary Denigan-Macauley, Health Care

Contact information: DeniganMacauleyM@gao.gov, 202-512-7114

Public Health and Human Services Program Oversight

Southwest Border: Actions Needed to Improve DHS Processing of Families and Coordination between DHS and HHS. [GAO-20-245](#). Washington, D.C.: February 19, 2020.

Recommendation: The Secretary of Health and Human Services, jointly with the Secretary of Homeland Security, should collaborate to address information sharing gaps identified in this report to ensure that Office of Refugee Resettlement (ORR) receives information needed to make decisions for unaccompanied alien children (UAC), including those apprehended with an adult.

Actions needed: HHS and Department of Homeland Security (DHS) agreed with this recommendation. As of February 2022, HHS was continuing to develop a new data system that would be integrated with a portal being developed by DHS to track unaccompanied children from apprehension to placement in HHS-funded shelters and automatically share their biographic information. By connecting this data system to DHS's portal, HHS officials stated that its new data system will be able to retrieve data regarding a child's status in a more automated manner. DHS and HHS indicated that they expect to complete these actions by June 2022.

To fully address the recommendation, DHS and HHS need to collaborate to address information sharing gaps identified in our report to ensure that HHS's ORR receives information needed to make decisions for unaccompanied children, including those apprehended with adults, thereby enabling HHS to make more informed and timely decisions for unaccompanied children, including those separated from adults with whom they were apprehended.

Director: Rebecca Gambler, Homeland Security and Justice

Contact information: GamblerR@gao.gov, 202-512-8777

Head Start: Action Needed to Enhance Program Oversight and Mitigate Significant Fraud and Improper Payment Risks. [GAO-19-519](#). Washington, D.C.: September 13, 2019.

Recommendation: The Director of the Office of Head Start (OHS) should perform a fraud risk assessment for the Head Start program, to include assessing the likelihood and impact of fraud risks it faces.

Actions needed: HHS agreed with this recommendation. As of February 2022, HHS told us that its fraud risk assessment approach is still under development and that a timeline for completing this work had not been established. Completing a fraud risk assessment could help OHS better identify and address the fraud risk vulnerabilities we identified.

Director: Seto J. Bagdoyan, Forensic Audits and Investigative Service

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Nursing Homes: Improved Oversight Needed to Better Protect Residents from Abuse. [GAO-19-433](#). Washington, D.C.: June 13, 2019.

Recommendation: The Administrator of CMS should require that abuse and perpetrator type be submitted by state survey agencies in CMS's databases for deficiency, complaint, and facility-reported incident data, and that CMS systematically assess trends in these data.

Actions needed: HHS agreed with this recommendation. As of February 2022, CMS had not yet developed the ability to survey trends related to alleged perpetrator and alleged abuse types. We maintain that CMS should systematically collect and monitor specific abuse and perpetrator data to ensure that it will have key information needed to address the most prevalent types of abuse and perpetrators.

Recommendation: The Administrator of CMS should require state survey agencies to immediately refer complaints and surveys to law enforcement (and, when applicable, to Medicaid Fraud Control Units) if they have a reasonable suspicion that a crime against a resident has occurred when the complaint is received.

Actions needed: HHS agreed with this recommendation. In March 2021, HHS said CMS will require state survey agencies to immediately refer complaints and surveys to law enforcement (and, when applicable, to Medicaid Fraud Control Units) if they have a reasonable suspicion that a crime against a resident has occurred; however, as of February 2022, CMS had not yet implemented this requirement. We maintain that CMS should implement this recommendation to help address gaps in CMS's oversight of nursing homes and better protect residents from abuse.

Director: John E. Dicken, Health Care

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Improper Payments: Selected Agencies Need Improvements in Their Assessments to Better Determine and Document Risk Susceptibility. [GAO-19-112](#). Washington, D.C.: January 10, 2019.

Recommendation: The Secretary of Health and Human Services should revise HHS's procedures for conducting improper payment risk assessments to help ensure that all programs and activities are assessed for susceptibility to significant improper payments at least once every 3 years, as required by the Improper Payments Information Act of 2002, as amended.³

Actions needed: HHS agreed with this recommendation. In February 2022, HHS indicated that it is reviewing its current approach to risk assessments and is determining how its coverage can be expanded in a cost-effective manner to meet the Payment

³On March 2, 2020, the Payment Integrity Information Act of 2019 (PIIA) repealed the Improper Payments Information Act of 2002, the Improper Payments Elimination and Recovery Act of 2010, and the Improper Payments Elimination and Recovery Improvement Act of 2012. Although PIIA repealed the legal provisions underlying this recommendation, it also enacted substantially similar requirements in 31 U.S.C. § 3352(a). We therefore have not altered the status of this recommendation.

Integrity Information Act of 2019 requirements without having a negative impact on program operations or efficiency. HHS anticipates providing further updates in summer 2022. To fully implement this recommendation, HHS needs to finalize its procedures to allow for performing improper payment risk assessments of all programs and activities with annual outlays exceeding \$10 million at least once every 3 years. Until it has properly designed risk assessments in place, HHS's efforts to reduce improper payments may be hindered.

Director: M. Hannah Padilla, Financial Management and Assurance

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Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. [GAO-18-480](#). Washington, D.C.: June 21, 2018.

Recommendation: The Administrator of the Health Resources and Services Administration (HRSA) should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs.

Recommendation: The Administrator of HRSA should incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been issued and ensure that identified violations are rectified by the entities.

Actions needed: HHS agreed with these recommendations; however, as of February 2022, it had not taken steps to implement them. To fully implement these recommendations, HHS needs to issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care. After this guidance has been issued, HHS should also incorporate into its audit process an assessment of covered entities' compliance with the prohibition on duplicate discounts. Until HHS develops guidance and includes an assessment of the potential for duplicate discounts in Medicaid managed care as part of its audits, the agency does not have assurance that covered entities' efforts are effectively preventing noncompliance. As a result, manufacturers are at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions.

Director: Michelle B. Rosenberg, Health Care

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Unaccompanied Alien Children: Actions Needed to Ensure Children Receive Required Care in DHS Custody. [GAO-15-521](#). Washington, D.C.: July 14, 2015.

Recommendation: To increase the efficiency and improve the accuracy of the interagency UAC referral and placement process, the Secretaries of Homeland Security and Health and Human Services should jointly develop and implement a documented interagency process with clearly defined roles and responsibilities, as well as procedures to disseminate placement decisions, for all agencies involved in the referral and placement of UAC in HHS shelters.

Actions needed: HHS and DHS agreed with this recommendation. As of February 2022, HHS was continuing to develop a new data system that would be integrated with a portal being developed by DHS to track unaccompanied children from apprehension to placement in HHS-funded shelters and automatically share their biographic information. By connecting this data system to DHS's portal, HHS officials stated that its new data system will be able to retrieve data regarding a child's status in a more automated manner. DHS and HHS indicated that they expect to complete these actions by June 2022.

To fully implement this recommendation, DHS and HHS need to ensure that they have implemented procedures aimed at improving the efficiency and accuracy of the interagency referral and placement process for unaccompanied children. Doing so could prevent miscommunication between DHS and HHS in the referral process, and ensure HHS is making informed and timely placement decisions.

Director: Rebecca Gambler, Homeland Security and Justice

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Food and Drug Administration Oversight

COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention. [GAO-21-265](#). Washington, D.C.: January 28, 2021.

Recommendation: The Commissioner of the Food and Drug Administration (FDA) should, as inspection plans for future fiscal years are developed, ensure that such plans identify, analyze, and respond to the issues presented by the backlog of inspections that could jeopardize the goal of risk-driven inspections.

Actions needed: HHS agreed with this recommendation and, as of February 2022, had taken some steps to implement it, such as by publishing a plan to resume prioritized foreign inspections. To fully implement this recommendation, FDA needs to provide documentation that its inspection plans account for, and respond to, the backlog of drug manufacturing inspections. Until it does so, FDA's backlog of inspections may jeopardize its strategic goal of shifting toward exclusively risk-driven inspections.

High-risk area: [Protecting Public Health through Enhanced Oversight of Medical Products](#)

Director: Mary Denigan-Macauley, Health Care

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Laboratory Safety: FDA Should Strengthen Efforts to Provide Effective Oversight. [GAO-20-594](#). Washington, D.C.: September 8, 2020.

Recommendation: The Commissioner of FDA should, as part of the agency's efforts to update the Office of Laboratory Safety's (OLS) strategic plan for overseeing agency-wide laboratory safety, resolve agency-wide disagreements on the roles and responsibilities for the centers and OLS in implementing laboratory safety reforms.

Actions needed: HHS agreed with this recommendation. As of February 2022, FDA stated that its leadership and safety staff were reviewing and updating their staff manual guides related to FDA's safety program. As part of this update, FDA stated that it planned to further clarify laboratory safety roles and responsibilities across its centers and offices. To fully implement this recommendation, FDA needs to update its staff manual guides and the OLS strategic plan to clarify roles and responsibilities for the centers and offices in implementing laboratory safety reforms. Until it does so, FDA will continue to struggle to bring about the changes needed to ensure OLS can effectively oversee FDA's laboratory safety program.

High-risk area: [Improving Federal Oversight of Food Safety](#)

Director: Mary Denigan-Macauley, Health Care

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Food Safety: FDA and USDA Could Strengthen Existing Efforts to Prepare for Oversight of Cell-Cultured Meat. [GAO-20-325](#). Washington, D.C.: April 7, 2020.

Recommendation: As the three cell-cultured meat working groups move forward, the Commissioner of the Food and Drug Administration, in coordination with the Secretary of Agriculture, should more fully incorporate the seven leading practices for effective collaboration, such as identifying specific outcomes and a way to monitor and evaluate progress toward outcomes.⁴

Actions needed: HHS agreed with this recommendation to improve the working groups that FDA and the U.S. Department of Agriculture (USDA) created to implement the terms of their interagency agreement on oversight of cell-cultured meat. As of March 2022, these three groups were working on developing the process for FDA's pre-market reviews, joint principles for product labeling, and procedures for transferring inspection between agencies. To fully implement this recommendation, FDA and USDA must demonstrate how the working groups will assess what their needed resources are and opportunities to leverage resources across agencies. Doing so would better position FDA and USDA to sustain and enhance their collaborative efforts, and proactively minimize potential fragmentation and overlap in their oversight of cell-cultured meat.

Director: Steve Morris, Natural Resources & Environment

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Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues. [GAO-17-443](#). Washington, D.C.: September 15, 2017.

Recommendation: The Commissioner of FDA should coordinate and communicate with USDA's Food Safety and Inspection Service (FSIS) in developing drug residue testing methods and corresponding maximum residue levels for imported seafood that may also be applicable to imported catfish.

⁴For more information on the seven leading practices for interagency collaboration, see GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

Actions needed: HHS agreed with this recommendation. In February 2022, FDA stated that both agencies were using the same method for measuring and confirming residue levels of two unapproved drugs and convening quarterly meetings to discuss the establishment of drug residue limits in seafood. However, the agencies continue to use different testing methods, which FDA stated is efficient and appropriate, despite that it results in the agencies using different maximum residue levels for some drugs.

To fully implement this recommendation, FDA needs to coordinate with FSIS on (1) the development of testing methods that both agencies can use on imported seafood, including catfish, and (2) the establishment of maximum residue levels that would allow the agencies to consistently apply similar standards. Without the coordination we recommended, the agencies do not have reasonable assurance that they are consistently protecting consumers from unsafe drug residues.

High-risk area: [Improving Federal Oversight of Food Safety](#)

Director: Steve Morris, Natural Resources & Environment

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Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices. [GAO-17-143](#). Washington, D.C.: December 16, 2016.

Recommendation: To help ensure that FDA's foreign offices are able to fully meet their mission of helping to ensure the safety of imported products, as the agency continues to test performance measures and evaluate its Office of International Program's strategic workforce plan, the Commissioner of FDA should assess the effectiveness of the foreign offices' contributions to drug safety by systematically tracking information to measure whether the offices' activities specifically contribute to drug safety-related outcomes, such as inspections, import alerts, and warning letters.

Actions needed: HHS agreed with this recommendation. As of February 2022, FDA said it had drafted and was reviewing indicators of progress and desired outcomes. In June 2021, FDA also described related efforts to track information related to inspections, import alerts, and warning letters on a quarterly basis. To fully implement this recommendation, FDA needs to finalize and systematically track indicators of progress and desired drug safety-related outcomes to assess the effectiveness of the foreign offices' contributions to drug safety. Having performance measures that demonstrate results-oriented outcomes will better enable FDA to meaningfully assess the foreign offices' contributions to ensuring drug safety.

High-risk area: [Protecting Public Health through Enhanced Oversight of Medical Products](#)

Director: Mary Denigan-Macauley, Health Care

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Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food. [GAO-15-183](#). Washington, D.C.: January 30, 2015.

Recommendation: To help ensure the safety of food imported into the United States, the Commissioner of FDA should complete an analysis to determine the annual number of foreign food inspections that is sufficient to ensure comparable safety of imported and domestic food. If the inspection numbers from that evaluation are different from the inspection targets mandated in the Food Safety Modernization Act (FSMA), FDA should report the results to Congress and recommend appropriate legislative changes.

Actions needed: HHS agreed with this recommendation. As of February 2022, FDA officials said that they cannot meet the number of foreign inspections required under FSMA due to capacity constraints, and FDA's current strategy for the safety of imported food relies on multiple programs—in addition to foreign inspections—that could take a number of years to be fully implemented. As these new FSMA programs initiate and mature over time, FDA officials said they will comprehensively weigh outcomes and oversight from these programs and produce a data-driven assessment on the appropriate number or range of foreign inspections that provide appropriate oversight of the safety of the imported food supply.

To fully implement this recommendation, FDA should report this information to Congress and GAO. Implementing this recommendation would better position FDA to identify how many foreign inspections are sufficient and, if appropriate, request a change in the mandate regarding the number of foreign inspections to be conducted.

High-risk area: [Improving Federal Oversight of Food Safety](#)

Director: Steve Morris, Natural Resources & Environment

Contact information: MorrisS@gao.gov, 202-512-3841

Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations. [GAO-15-38](#). Washington, D.C.: October 7, 2014.

Recommendation: To better inform users of the annual monitoring report about the frequency and scope of pesticide tolerance violations, the Secretary of Health and Human Services should direct the Commissioner of FDA to disclose in the agency's annual pesticide monitoring program report which pesticides with Environmental Protection Agency (EPA)-established tolerances the agency did not test for in its pesticide monitoring program and the potential effect of not testing for those pesticides.

Actions needed: HHS agreed with this recommendation. As of February 2022, FDA acknowledged that some pesticides with EPA-established tolerances were not part of FDA's testing scope in its October 2021 annual pesticide residue monitoring report. In addition, FDA does not know the extent to which exposure to these pesticides may occur in the foods that FDA regulates. FDA included in this report an appendix listing all pesticides analyzed by FDA pesticide methods in that fiscal year. To fully implement this recommendation, FDA must disclose in its annual pesticide residue monitoring report which pesticides with EPA-established tolerances the agency did not test for in its pesticide monitoring program. Implementing this recommendation could provide users of

FDA's annual report with more accurate information and reduce potential misinterpretation of its results.

High-risk area: [Improving Federal Oversight of Food Safety](#)

Director: Steve Morris, Natural Resources & Environment

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Improper Payments in Medicaid and Medicare

Medicare and Medicaid: CMS Should Assess Documentation Necessary to Identify Improper Payments. [GAO-19-277](#). Washington, D.C.: March 27, 2019.

Recommendation: The Administrator of CMS should institute a process to routinely assess, and take steps to ensure, as appropriate, that Medicare and Medicaid documentation requirements are necessary and effective at demonstrating compliance with coverage policies while appropriately addressing program risks.

Actions needed: HHS agreed with this recommendation. As of February 2022, CMS noted that the agency had clarified and amended several Medicare documentation requirements as part of an agency initiative to assess such requirements. CMS further stated that Medicaid documentation requirements are generally established at the state level and that the agency has taken steps to identify best practices for documentation requirements and share them with states. To fully implement this recommendation, CMS needs to assess documentation requirements in both programs to better understand how the variation in the programs' requirements affects estimated improper payment rates. Until it does so, CMS may not have the information it needs to ensure that the programs' documentation requirements are effective and appropriately address program risks.

High-risk areas: [Medicare Program & Improper Payments](#); [Strengthening Medicaid Program Integrity](#)

Director: Carolyn L. Yocom, Health Care

Contact information: YocomC@gao.gov, 202-512-7114

Medicaid: CMS Needs to Better Target Risks to Improve Oversight of Expenditures. [GAO-18-564](#). Washington, D.C.: August 6, 2018.

Recommendation: The Administrator of CMS should complete a comprehensive, national risk assessment and take steps, as needed, to assure that resources to oversee expenditures reported by states are adequate and allocated based on areas of highest risk.

Actions needed: HHS agreed with this recommendation; however, CMS has suspended steps to conduct a comprehensive national risk assessment. CMS developed a standard tool to assess risk and staff capacity in October 2019, but the implementation of this tool was suspended in November 2019 when the agency initiated a reorganization of its regional office functions, including financial oversight. According to CMS, the reorganization is intended to improve coordination between central and regional offices

so that financial operations are consistent across the nation. As of February 2022, the tool remained suspended, and HHS officials have not informed us of any additional actions taken to implement this recommendation. We maintain that a risk assessment is still necessary to ensure that resources are allocated based on identified risks.

High-risk area: [Strengthening Medicaid Program Integrity](#)

Director: Carolyn L. Yocom, Health Care

Contact information: YocomC@gao.gov, 202-512-7114

Medicaid Managed Care: Improvements Needed to Better Oversee Payment Risks. GAO-18-528. Washington, D.C.: July 26, 2018.

Recommendation: The Administrator of CMS should eliminate impediments to collaborative audits in managed care conducted by audit contractors and states, by ensuring that managed care audits are conducted regardless of which entity—the state or the managed care organization (MCO)—recoups any identified overpayments.

Actions needed: HHS agreed with this recommendation. As of February 2022, HHS had highlighted for states and audit contractors the importance of conducting collaborative audits. In addition, CMS stated in September 2019 that it was evaluating several process improvements as a result of feedback and recommendations received through a meeting with states and audit contractors. However, it is unclear whether CMS's actions have removed impediments to audits of Medicaid MCOs or will cause the number of audits to increase. To fully implement this recommendation, CMS needs to provide evidence that the agency has removed impediments to audits of Medicaid MCOs by ensuring that they are conducted regardless of whether the state or the MCO recoups identified overpayments. Implementing this recommendation would help CMS develop more robust program integrity safeguards to mitigate payment integrity risks in managed care.

High-risk area: [Strengthening Medicaid Program Integrity](#)

Director: Carolyn L. Yocom, Health Care

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Medicaid: CMS Should Take Steps to Mitigate Program Risks in Managed Care. GAO-18-291. Washington, D.C.: May 7, 2018.

Recommendation: The Administrator of CMS should consider and take steps to mitigate the program risks that are not measured in the Payment Error Rate Measurement (PERM), such as overpayments and unallowable costs; such an effort could include actions such as revising the PERM methodology or focusing additional audit resources on managed care.

Actions needed: HHS agreed with this recommendation. As of February 2022, CMS stated that it was in the process of developing a strategy to reduce risk in Medicaid managed care. To fully implement this recommendation, CMS would need to implement its strategy to mitigate the managed care program risks not measured in the PERM. To the extent that overpayments and unallowable costs are unidentified and not removed

from the cost data used to set capitation rates, they may lead to inflated Medicaid managed care payments and minimize the appearance of program risks in Medicaid managed care.

High-risk area: [Strengthening Medicaid Program Integrity](#)

Director: Carolyn L. Yocom, Health Care

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Medicare: Claim Review Programs Could Be Improved with Additional Prepayment Reviews and Better Data. [GAO-16-394](#). Washington, D.C.: April 13, 2016.

Recommendation: In order to better ensure proper Medicare payments and protect Medicare funds, CMS should seek legislative authority to allow the recovery auditors (RA) to conduct prepayment claim reviews.

Actions needed: HHS disagreed with this recommendation and, as of February 2022, had not taken steps to seek legislative authority to allow the RAs to conduct prepayment claim reviews. We maintain that prepayment reviews protect agency funds better than postpayment reviews, and we believe that seeking this authority is consistent with CMS's strategy to pay claims properly the first time.

High-risk area: [Medicare Program & Improper Payments](#)

Director: Leslie V. Gordon, Health Care

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Medicare Advantage: Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments. [GAO-16-76](#). Washington, D.C.: April 8, 2016.

Recommendation: As CMS continues to implement and refine the contract-level risk adjustment data validation (RADV) audit process to improve the efficiency and effectiveness of reducing and recovering improper payments, the Administrator should enhance the timeliness of CMS's contract-level RADV process by taking actions such as the following: (1) closely aligning the time frames in CMS's contract-level RADV audits with those of the national RADV audits the agency uses to estimate the Medicare Advantage (MA) improper payment rate; (2) reducing the time between notifying MA organizations of contract audit selection and notifying them about the beneficiaries and diagnoses that will be audited; (3) improving the reliability and performance of the agency's process for transferring medical records from MA organizations, including assessing the feasibility of updating Electronic Submission of Medical Documentation for use in transferring medical records in contract-level RADV audits; and (4) requiring that CMS contract-level RADV auditors complete their medical record reviews within a specific number of days comparable to other medical record review time frames in the Medicare program.

Actions needed: HHS agreed with this recommendation. HHS stated that, as of February 2022, CMS had taken steps to improve the timeliness of the contract-level

RADV audit process, such as aligning the time frames in CMS's contract-level RADV audits with those of the national RADV audits. To fully implement this recommendation, CMS will need to provide evidence that it has completed steps such as these and that the agency's actions have enhanced the timeliness of CMS's contract-level RADV process. Implementing this recommendation would potentially allow CMS to recover hundreds of millions of dollars in improper payments each year.

High-risk area: [Medicare Program & Improper Payments](#)

Director: Leslie V. Gordon, Health Care

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Medicaid Program

Medicaid: CMS Needs More Information on States' Financing and Payment Arrangements to Improve Oversight. [GAO-21-98](#). Washington, D.C.: December 7, 2020.

Recommendation: The Administrator of CMS should collect and document complete and consistent provider-specific information about Medicaid payments to providers, including new state-directed managed care payments, and states' sources of funding for the nonfederal share of these payments.

Actions needed: HHS neither agreed nor disagreed with this recommendation but acknowledged the need for additional state Medicaid financing and payment data to oversee the Medicaid program. In December 2021, CMS issued guidance on supplemental payment reporting requirements for payments made in or after October 2021. In February 2022, CMS officials said states have begun making submissions through a revised form for collecting information on state-directed managed care payments.

To fully implement this recommendation, HHS needs to demonstrate how its ongoing and planned actions in this area will ensure complete, consistent, and sufficiently documented information about sources of funding for the nonfederal share and payments to providers. Implementing this recommendation would better position CMS to effectively oversee states' Medicaid programs and identify potentially impermissible financing and payment arrangements for additional review.

High-risk area: [Strengthening Medicaid Program Integrity](#)

Director: Carolyn L. Yocom, Health Care

Contact information: YocomC@gao.gov, 202-512-7114

Medicaid Long-Term Services and Supports: Access and Quality Problems in Managed Care Demand Improved Oversight. [GAO-21-49](#). Washington, D.C.: November 16, 2020.

Recommendation: The Administrator of CMS should develop and implement a national strategy for monitoring managed long-term services and supports programs and ensuring that states and MCOs resolve identified problems. Among other things, this

strategy should address state implementation of beneficiary protection and monitoring requirements.

Actions needed: HHS disagreed with this recommendation and did not report taking any actions to implement it as of March 2022. We maintain that having a national oversight strategy specifically for managed long-term services and supports could provide direction to the agency's broader efforts and ensure that it can detect and address quality and access problems experienced by beneficiaries.

High-risk area: [Strengthening Medicaid Program Integrity](#)

Director: Carolyn L. Yocom, Health Care

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Medicaid Providers: CMS Oversight Should Ensure State Implementation of Screening and Enrollment Requirements. [GAO-20-8](#). Washington, D.C.: October 10, 2019.

Recommendation: The Administrator of CMS should expand its review of states' implementation of the provider screening and enrollment requirements to include states that have not made use of CMS's optional consultations. Similar to CMS's contractor site visits, such reviews should include any necessary steps to address areas of noncompliance for all types of enrolled providers, including those under contract with managed care organizations.

Actions needed: HHS agreed with this recommendation. In June 2021, CMS issued an informational bulletin to introduce a series of tools for states and CMS to enhance monitoring and oversight of managed care, including new guidance for completing an annual managed care program report. According to this guidance, in 2022, states will submit information on managed care indicators related to some provider screening and enrollment requirements, such as federal database checks and disclosures. Further, in February 2022, CMS officials said that the agency continues to provide targeted assistance to states—through technical assistance and ongoing monthly calls and e-mails to assess states' compliance—that have not made use of CMS's optional consultations.

To fully implement this recommendation, CMS needs to review all states' implementation of the provider screening and enrollment requirements, including states that have not made use of CMS's optional consultations. Without taking such steps, CMS lacks assurance that only eligible providers are participating in the Medicaid program.

High-risk area: [Strengthening Medicaid Program Integrity](#)

Director: Carolyn L. Yocom, Health Care

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Medicaid: Additional CMS Data and Oversight Needed to Help Ensure Children Receive Recommended Screenings. [GAO-19-481](#). Washington, D.C.: August 16, 2019.

Recommendation: The Administrator of CMS should work with states and relevant federal agencies to collect accurate and complete data on blood lead screening for Medicaid beneficiaries in order to ensure that CMS is able to monitor state compliance with its blood lead screening policy and to assist states with planning improvements to address states' compliance as needed.

Actions needed: HHS agreed with this recommendation. In January 2021, CMS provided states with the option to use a new data system—as states meet certain data quality and completeness benchmarks—to generate the report that includes states' blood lead screening data. CMS stated that this will improve the agency's and states' ability to assess gaps in blood lead screening data. In February 2022, CMS officials said that the agency is planning to update 2016 lead screening guidance by the end of fiscal year 2022 and will emphasize the importance of complete and accurate data. To fully implement this recommendation, CMS needs to address limitations in blood lead screening data to better monitor compliance with the agency's blood lead screening policy. Until it does so, CMS will be unable to determine how many eligible beneficiaries have received, or not received, blood lead screenings.

High-risk area: [Strengthening Medicaid Program Integrity](#)

Director: Carolyn L. Yocom, Health Care

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Medicaid Demonstrations: Approvals of Major Changes Need Increased Transparency. [GAO-19-315](#). Washington, D.C.: April 17, 2019.

Recommendation: The Administrator of CMS should develop and communicate a policy whereby applications for section 1115 demonstration amendments that may have significant impact are subject to transparency requirements comparable to those for new demonstrations and extensions.

Actions needed: HHS agreed with this recommendation. HHS had stated that it plans to implement a policy applying state public input processes and application criteria to amendments proposing significant or substantial changes in the same manner as for new demonstrations. In December 2020, CMS said the agency planned to develop criteria for determining whether an amendment application proposes a substantial change to an existing demonstration and to include this in guidance; however, as of February 2022, HHS officials have not informed us of any additional actions taken to implement this recommendation. To fully implement this recommendation, CMS needs to issue the policy guidance as it previously indicated was planned. Until it does so, CMS and the public may lack key information to fully understand the potential impact of changes being proposed, including on beneficiaries and costs.

High-risk area: [Strengthening Medicaid Program Integrity](#)

Director: Carolyn L. Yocom, Health Care

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Medicaid Assisted Living Services: Improved Federal Oversight of Beneficiary Health and Welfare Is Needed. [GAO-18-179](#). Washington, D.C.: January 5, 2018.

Recommendation: The Administrator of CMS should establish standard Medicaid reporting requirements for all states to annually report key information on critical incidents, considering, at a minimum, the type of critical incidents involving Medicaid beneficiaries and the type of residential facilities, including assisted living facilities, where critical incidents occurred.

Actions needed: HHS neither agreed nor disagreed with this recommendation. As of February 2022, CMS completed a three part national training course for state officials on incident reporting. During this training, CMS reported on the wide variation among state systems, including the types of incidents identified as critical. CMS developed a proposed incident reporting template, but converted it to an optional incident reporting tool that the agency may share with states in providing technical assistance. To fully implement this recommendation, CMS needs to establish standard Medicaid reporting requirements for all states to report critical incidents annually. Implementing this recommendation would provide evidence that an effective system is in place, provide information on the extent beneficiaries are subject to actual or potential harm, and allow for tracking trends over time.

High-risk area: [Strengthening Medicaid Program Integrity](#)

Director: Carolyn L. Yocom, Health Care

Contact information: YocomC@gao.gov, 202-512-7114

Medicaid: Federal Guidance Needed to Address Concerns about Distribution of Supplemental Payments. [GAO-16-108](#). Washington, D.C.: February 5, 2016.

Recommendation: To promote consistency in the distribution of supplemental payments among states and with CMS policy, the Administrator of CMS should issue written guidance clarifying its policy that payments should not be made contingent on the availability of local funding.

Actions needed: HHS initially stated it was considering options to address this recommendation, and as of March 2021, the agency agreed. CMS noted that, per its existing policy, the receipt of payments under a Medicaid state plan cannot be contingent on the availability of local funding, but as of February 2022, CMS had not issued written guidance on this policy. We maintain that written guidance to all states could help curtail the process of states making large supplemental payments in excess of costs.

High-risk area: [Strengthening Medicaid Program Integrity](#)

Director: Carolyn L. Yocom, Health Care

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Medicaid: CMS Oversight of Provider Payments Is Hampered by Limited Data and Unclear Policy. [GAO-15-322](#). Washington, D.C.: April 10, 2015.

Recommendation: To improve CMS’s oversight of Medicaid payments, the Administrator of CMS should develop a policy establishing criteria for when such payments at the provider level are economical and efficient.

Actions needed: HHS agreed with this recommendation. In December 2020, Congress passed, and the President signed into law, requirements for additional state reporting on Medicaid supplemental payments, including for states to describe how these payments are economical and efficient. In December 2021, CMS issued guidance on these new supplemental payment reporting requirements, beginning with payments made in or after October 2021, but in January 2022, CMS officials said that neither the law nor the guidance establish criteria for economy and efficiency at the provider level. We maintain that criteria for determining the economy and efficiency of payments to individual providers will improve the agency’s ability to identify excessive payments.

High-risk area: [Strengthening Medicaid Program Integrity](#)

Director: Carolyn L. Yocom, Health Care

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Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns. [GAO-02-817](#). Washington, D.C.: July 12, 2002.

Recommendation: To meet its fiduciary responsibility of ensuring that section 1115 waivers are budget neutral, the Secretary of Health and Human Services should better ensure that valid methods are used to demonstrate budget neutrality, by developing and implementing consistent criteria for consideration of section 1115 demonstration waiver proposals.

Actions needed: HHS disagreed with this recommendation. However, we reiterated the need for increased attention to fiscal responsibility in the approval of the section 1115 Medicaid demonstrations in subsequent 2008 and 2013 reports.⁵ Despite disagreeing with this recommendation, as of February 2022, HHS had taken some action to address it. In August 2018, HHS issued written guidance through a State Medicaid Directors Letter documenting four key changes it made in 2016 to its budget neutrality policy. These changes addressed some, but not all, of the questionable methods we identified in our reports.

To fully implement this recommendation, HHS needs to also address the other questionable methods, such as setting demonstration spending limits based on hypothetical costs—what the state could have paid—rather than payments actually made by the state. We have found that the use of hypothetical costs has the potential to inflate spending limits and thus threatens budget neutrality of demonstrations.

⁵GAO, *Medicaid Demonstration Waivers: Recent HHS Approvals Continue to Raise Cost and Oversight Concerns*, [GAO-08-87](#) (Washington, D.C.: Jan. 31, 2008) and *Medicaid Demonstration Waivers: Approval Process Raises Cost Concerns and Lacks Transparency*, [GAO-13-384](#) (Washington, D.C.: June 25, 2013).

High-risk area: [Strengthening Medicaid Program Integrity](#)

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Medicare Program

Hospital Uncompensated Care: Federal Action Needed to Better Align Payments with Costs. [GAO-16-568](#). Washington, D.C.: June 30, 2016.

Recommendation: To ensure efficient use of federal resources, the Administrator of CMS should account for Medicaid payments a hospital has received that offset uncompensated care (UC) costs when determining hospital UC costs for the purposes of making Medicare UC payments to individual hospitals.

Actions needed: HHS initially agreed with this recommendation; however, in 2018 and again in March 2021, HHS indicated it was reconsidering whether to implement this recommendation because officials stated that it may not be appropriate to account for Medicaid payments that offset UC costs when determining the amount of Medicare UC payments a hospital should receive. As of February 2022, CMS had not taken any action to implement this recommendation. We maintain that CMS should implement this recommendation because it would (1) ensure that Medicare UC payments are based on accurate levels of UC costs, (2) result in CMS better targeting billions of dollars in Medicare UC payments to hospitals with the most UC costs, and (3) avoid Medicare UC payments to hospitals with little or no UC costs.

High-risk area: [Medicare Program & Improper Payments](#)

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Medicare Advantage: CMS Should Fully Develop Plans for Encounter Data and Assess Data Quality before Use. [GAO-14-571](#). Washington, D.C.: July 31, 2014.

Recommendation: To ensure that MA encounter data are of sufficient quality for their intended purposes, the Administrator of CMS should establish specific plans and time frames for using the data for all intended purposes in addition to risk adjusting payments to Medicare Advantage organizations (MAO).

Actions needed: HHS generally agreed with this recommendation. As of February 2022, CMS had finalized its time frame for using MA encounter data for risk adjustment. CMS had also begun using MA encounter data for purposes other than risk adjustment, such as quality measurement and program integrity, but the agency had not established specific plans and time frames for all uses. Although CMS continues to develop additional uses for MA encounter data, the agency's plans for using the data for comprehensive oversight purposes remain limited.

To fully implement this recommendation, CMS needs to establish specific plans and time frames for using MA encounter data for all intended purposes in addition to risk adjusting payments to MAOs. Doing so would improve CMS's ability to determine whether it is

gathering the proper amount and types of information for oversight and payment purposes and better establish management priorities.

Recommendation: To ensure that MA encounter data are of sufficient quality for their intended purposes, the Administrator of CMS should complete all the steps necessary to validate the data, including performing statistical analyses, reviewing medical records, and providing MAOs with summary reports on CMS's findings, before using the data to risk adjust payments or for other intended purposes.

Actions needed: HHS generally agreed with this recommendation but did not commit to completing data validation before using MA encounter data for risk adjustment. As of February 2022, CMS made additional progress in examining the completeness and accuracy of MA encounter data, but more work remains to fully validate these data. To fully implement this recommendation, CMS needs to complete all necessary steps to validate MA encounter data, including verifying the data by reviewing medical records, before using the data for risk adjustment payments or other intended purposes. Without fully validating the completeness and accuracy of MA encounter data, CMS would be unable to confidently use these data for risk adjustment or other program management or policy purposes.

High-risk area: [Medicare Program & Improper Payments](#)

Director: Leslie V. Gordon, Health Care

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End-Stage Renal Disease: CMS Should Improve Design and Strengthen Monitoring of Low-Volume Adjustment. [GAO-13-287](#). Washington, D.C.: March 1, 2013.

Recommendation: To reduce the incentive for dialysis facilities to restrict their service provision to avoid reaching the low-volume payment adjustment (LVPA) treatment threshold, the Administrator of CMS should consider revisions such as changing the LVPA to a tiered adjustment.

Actions needed: HHS agreed with this recommendation. In February 2022, CMS said that the agency had taken several steps to re-examine the current LVPA methodology. For example, CMS held a technical expert panel in December 2020, which included a review of alternatives to the LVPA. CMS also stated that the agency was analyzing the design of the LVPA as part of its evaluation of the end-stage renal disease prospective payment system. To fully implement this recommendation, CMS needs to finalize its decision on how, if at all, to revise the LVPA to reduce the incentive for facilities to restrict their service provision to avoid reaching the LVPA treatment threshold. Reducing the incentive for facilities to restrict service provision may improve beneficiary access to access to services.

High-risk area: [Medicare Program & Improper Payments](#)

Director: Leslie V. Gordon, Health Care

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Medicare: Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions. [GAO-12-966](#). Washington, D.C.: September 28, 2012.

Recommendation: In order to improve CMS's ability to identify self-referred advanced imaging services and help CMS address the increases in these services, the Administrator of CMS should insert a self-referral flag on its Medicare Part B claims form and require providers to indicate whether the advanced imaging services for which a provider bills Medicare are self-referred or not.

Actions needed: HHS disagreed with this recommendation and, as of February 2022, had no plans to take further action. CMS believes that a new checkbox on the claim form identifying self-referral would be complex to administer and that providers may not characterize referrals accurately. We maintain that such a flag on Part B claims would likely be the easiest and most cost-effective way for CMS to identify self-referred advanced imaging services and monitor the behavior of those providers who self-refer these services.

Recommendation: In order to improve CMS's ability to identify self-referred advanced imaging services and help CMS address the increases in these services, the Administrator of CMS should determine and implement a payment reduction for self-referred advanced imaging services to recognize efficiencies when the same provider refers and performs a service.

Actions needed: HHS disagreed with this recommendation and, as of February 2022, had no plans to take further action. CMS does not believe that a payment reduction would address overutilization that occurs as a result of self-referral and that the agency's multiple procedure payment reduction policy for advanced imaging already captures efficiencies inherent in providing multiple advanced imaging services by the same physician. Further, CMS does not think a payment reduction for self-referred services would be effective. We maintain that CMS should determine and implement a payment reduction to recognize efficiencies for advanced imaging services referred and performed by the same provider.

Recommendation: In order to improve CMS's ability to identify self-referred advanced imaging services and help CMS address the increases in these services, the Administrator of CMS should determine and implement an approach to ensure the appropriateness of advanced imaging services referred by self-referring providers.

Actions needed: HHS initially stated that it would consider this recommendation, but as of February 2022, the agency disagreed and had no plans to take further action. However, we maintain that this recommendation is valid, in part because we found that providers who began to self-refer advanced imaging services substantially increased their referral of such services relative to other providers in 2010. To the extent that these additional referrals are unnecessary, they pose an unacceptable risk for beneficiaries, particularly in the case of computerized tomography services, which involve the use of ionizing radiation. We maintain that this recommendation is warranted to help protect beneficiaries.

High-risk area: [Medicare Program & Improper Payments](#)

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Medicare Advantage: CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practices. [GAO-12-51](#). Washington, D.C.: January 12, 2012.

Recommendation: To help ensure appropriate payments to MA plans, the Administrator of CMS should take steps to improve the accuracy of the adjustment made for differences in diagnostic coding practices between MA and Medicare fee-for-service. Such steps could include, for example, accounting for additional beneficiary characteristics, including the most current data available, identifying and accounting for all years of coding differences that could affect the payment year for which an adjustment is made, and incorporating the trend of the impact of coding differences on risk scores.

Actions needed: HHS initially did not comment on this recommendation, but as of February 2022, the agency agreed. CMS applied the statutory minimum adjustment to MA payments for calendar year 2021. CMS made other changes to its methodology for calculating the diagnostic coding adjustment (i.e., excluding diagnosis codes that were differentially reported in Medicare fee-for-service and MA), which likely have improved accuracy of the adjustment. However, a modified methodology that, for example, incorporates more recent data and accounts for all relevant years of coding differences would better ensure an accurate adjustment in future years. To fully implement this recommendation, CMS needs to provide evidence of the sufficiency of its coding adjustment or re-calculate its adjustment using an updated methodology. Until CMS takes these steps, the agency is at continued risk of making excess payments to MA plans.

High-risk area: [Medicare Program & Improper Payments](#)

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Health Information Technology and Cybersecurity

Cybersecurity: Selected Federal Agencies Need to Coordinate on Requirements and Assessments of States. [GAO-20-123](#). Washington, D.C.: May 27, 2020.

Recommendation: The Administrator of CMS should revise its assessment policies to maximize coordination with other federal agencies to the greatest extent practicable.

Actions needed: HHS agreed with this recommendation. As of February 2022, CMS stated that it would accept results of a recent, independent third-party assessment conducted for another federal agency. CMS also stated it would also work to revise its assessment policies to maximize coordination with other federal agencies to the greatest extent possible, but has not yet set a time frame for doing so. To fully address this recommendation, CMS needs to determine what changes it can make to its assessment policies and implement those changes. Maximizing coordination with other federal

agencies would help provide reasonable assurance that CMS is leveraging compatible assessments with other agencies and may help to reduce federal resources associated with their implementation.

High-risk area: [Ensuring the Cybersecurity of the Nation](#)

Director: David B. Hinchman, Information Technology and Cybersecurity

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Critical Infrastructure Protection: Additional Actions Are Essential for Assessing Cybersecurity Framework Adoption. [GAO-18-211](#). Washington, D.C.: February 15, 2018.

Recommendation: The Secretary of Health and Human Services, in cooperation with the Secretary of Agriculture, should take steps to consult with respective sector partner(s), such as the sector coordinating council, DHS, and National Institute of Standards and Technology, as appropriate, to develop methods for determining the level and type of framework adoption by entities across their respective sector.⁶

Actions needed: HHS agreed with this recommendation. As of February 2022, ASPR officials stated that they planned to form a task group to discuss how to obtain an understanding of framework use across the sector, pending resource availability. HHS officials also stated that they will review actions of other sector risk management agencies to better assess framework adoption. We maintain that implementing this recommendation to gain a more comprehensive understanding of the framework's use by critical infrastructure sectors is essential to the success of protection efforts. Until sector risk management agencies have a more comprehensive understanding of the use of the cyber framework by the critical sectors, they will be limited in their ability to evaluate the success of protection efforts or to determine where to focus limited resources for cyber risk mitigation.

High-risk area: [Ensuring the Cybersecurity of the Nation](#)

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Health Insurance Premium Tax Credit (PTC) Payment Integrity

Improper Payments: Improvements Needed in CMS and IRS Controls over Health Insurance Premium Tax Credit. [GAO-17-467](#). Washington, D.C.: July 13, 2017.

Recommendation: To improve annual reporting on PTC improper payments, control activities related to eligibility determinations, and calculations of advance PTC, the Secretary of Health and Human Services should direct the Administrator of CMS to

⁶For the framework, see National Institute of Standards and Technology, *Framework for Improving Critical Infrastructure Cybersecurity, Version 1.1* (Gaithersburg, Md.: Apr. 16, 2018).

annually report improper payment estimates and error rates for the advance PTC program.

Actions needed: HHS agreed with this recommendation. In February 2022, HHS said that it intends to publish an advance PTC improper payment rate in CMS's fiscal year 2022 agency financial report for payments made by the federally facilitated exchange during benefit year 2020. CMS said that developing an advance PTC improper payment rate for payments made by state-based exchanges will be a multi-year process. To fully implement this recommendation, HHS needs to finalize and implement its methodology for producing advance PTC improper payment rate estimates and publicly report these estimates in its annual financial report. Until it does so, Congress and other external stakeholders will continue to lack key payment integrity information for monitoring improper payments.

High-risk area: [Enforcement of Tax Laws](#)

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