U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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**Washington, DC 20548**

**Comptroller General**
**of the United States**

Accessible Version

May 28, 2024

The Honorable Xavier Becerra
Secretary
The Honorable Andrea Palm
Deputy 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 Secretary Becerra and Deputy Secretary Palm:

The purpose of this letter is to update you on the overall status of the U.S. Department of Health and Human Services' (HHS) implementation of GAO's recommendations and to call your continued personal attention to areas where open recommendations should be given high priority.[1] In November 2023, we reported that, on a government-wide basis, 75 percent of our recommendations made 4 years ago were implemented.[2] HHS's recommendation implementation rate was about 68 percent. As of April 2024, HHS had 417 open recommendations. Implementing these recommendations could significantly improve HHS's operations.

In our May 2023 letter, we designated 45 recommendations as priorities for HHS, and HHS has implemented seven of them.[3]

[1]Priority 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 operations, for example, by realizing large dollar savings; eliminating mismanagement, fraud, and abuse; or making progress toward addressing a high-risk or duplication issue.

[2]GAO, *Performance and Accountability Report: Fiscal Year 2023*, GAO-24-900483 (Washington, D.C.: Nov. 15, 2023).

[3]In addition to the seven priority recommendations that HHS implemented, we closed five recommendations as no longer valid and determined that three recommendations no longer warrant priority attention. We made three recommendations in February 2020 related to establishing plans and guidance for the Biodefense Coordination Team. However, in October 2022 the White House issued an updated National Biodefense Strategy and Implementation Plan, which made the Biodefense Coordination Team obsolete.

We made another recommendation in September 2020 related to collecting more complete data on COVID-19 cases and deaths in nursing homes retrospectively to January 1, 2020, and to clarifying the extent to which nursing homes reported data before May 8, 2020. As of October 2023, the recommendation remained unimplemented and we determined that, at that point in time, retrospectively collecting data prior to May 8, 2020, could prove burdensome for both nursing homes and HHS and detract from resources that could otherwise be used to support resident care.

- In October 2023 the Food and Drug Administration (FDA) posted a pesticide monitoring program annual report to its website that provided additional transparency about the scope of pesticide residue monitoring. This is consistent with our recommendation to better inform report users about the frequency and scope of pesticide tolerance violations.[4]

- In September 2023 HHS provided supporting documentation of enhancements made to its improper payment risk assessment process. These enhancements help ensure all programs and activities are assessed for susceptibility to significant improper payments at least once every 3 years, thereby contributing to more complete improper payment estimates.[5]

- In December 2023 HHS provided interagency agreements with federal partners ensuring such partners understood the capabilities that HHS may need from them during incident response. This helps HHS to be better prepared for large-scale disasters and emergencies.[6]

- In March 2023 HHS outlined several steps taken to use Defense Production Act authorities to help bolster domestic production of medical supplies and reduce U.S. dependence on foreign manufacturers of medical supplies.[7]

- Based on documents provided in April 2023, HHS incorporated expert feedback on COVID-19 data collection to support future public health emergency responses.[8]

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We made a fifth recommendation in January 2021 related to the development of a comprehensive national COVID-19 testing strategy. However, with the expiration of the COVID-19 public health emergency, the finding that COVID-19 is endemic, and the circulation of other infectious diseases, we determined that this recommendation is no longer valid.

The three recommendations we determined no longer warrant priority attention were related to the Centers for Medicare & Medicaid Services (CMS) improving its ability to identify self-referred advanced imaging services and address increases in these services. When we made these recommendations in 2012, these services were increasing. Since then, per capita use and per capita cost for these services have reportedly decreased. Additionally, CMS has finalized regulations that include new exceptions for physician self-referral as part of value-based arrangements. Because of these changes, we no longer believe these recommendations warrant priority attention. However, we continue to believe that these recommendations should be addressed. These recommendations will remain open until CMS modifies its claims form to allow it to better identify self-referred services; implements a payment reduction for self-referred services to recognize efficiencies when the same provider refers and performs a service; and implements an approach to ensure the appropriateness of self-referred services. GAO, *Medicare: Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions,* GAO-12-966 (Washington, D.C.: Sept. 28, 2012).

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

[5]GAO, *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).

[6]GAO, *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.: Sept. 20, 2019).

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

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

- FDA's drug manufacturing inspection planning documents for fiscal years 2023 and 2024 outlined plans for responding to the backlog of inspections. This allowed it to move toward exclusively risk-driven drug manufacturing inspections.[9]

- In July 2023 the Administration on Community Living launched an interagency coordinating committee, allowing it to sustain information sharing on all populations at risk of falls, including people with disabilities, veterans, and older adults.[10]

We ask your continued attention to the remaining 30 priority recommendations. We also are adding five new priority recommendations related to public health emergency preparedness; the Medicaid program; improper payments in Medicaid and Medicare; and infrastructure, health information technology, and cybersecurity. This brings the total number of priority recommendations to 35. (See the Enclosure for the list of recommendations.)

The 35 priority recommendations fall into the following seven areas.

**Public health emergency preparedness, including the COVID-19 response.** The COVID-19 pandemic has highlighted 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.[11] We have identified five priority recommendations in this area. These include a recommendation to develop an approach for managing risks associated with gaps between Strategic National Stockpile medical countermeasure inventory levels and recommended quantities. We also recommended that HHS develop a mechanism to routinely monitor, evaluate, and report on coordination efforts for infectious disease modeling across multiple agencies. If implemented, these recommendations will help improve HHS's preparedness for 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 five priority recommendations in this area. For example, we recommended that HHS assess the likelihood and impact of fraud risks to the Head Start program. We also recommended that HHS ensure it has key information to monitor trends in abuse in nursing homes. If implemented, these actions would strengthen oversight of public health and human services.

**Food and Drug Administration (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. Both areas are on our High-Risk List.[12] We have identified three priority recommendations in this area. For example, we recommended that FDA assess the effectiveness of the foreign offices' contributions to drug safety. If implemented,

[9]GAO-21-265.

[10]GAO, *Older Adults and Adults with Disabilities: Federal Programs Provide Support for Preventing Falls, but Program Reach is Limited,* GAO-22-105276 (Washington, D.C.: July 27, 2022).

[11]GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to be Maintained and Expanded to Fully Address All Areas*, GAO-23-106203 (Washington, D.C.: Apr. 20, 2023).

[12]GAO-23-106203.

these recommendations would help FDA ensure that medical products and food imported into the United States are safe.

**Medicaid program.** Medicaid is a critically important federal-state health care financing program. It served about 90 million low-income and medically needy individuals at an estimated cost of $587 billion to the federal government in fiscal year 2023. We have identified eight priority recommendations in this area. For example, we recommended that HHS collect complete data on beneficiary blood lead screenings, ensure greater transparency for certain Medicaid demonstration applications, and improve oversight of state-directed payments for managed care. If implemented, these recommendations would help HHS improve oversight of Medicaid funding and protect the health and welfare of Medicaid beneficiaries.

**Medicare program.** In 2023, the Medicare program spent an estimated $1.0 trillion to provide health care services for about 66 million elderly and disabled beneficiaries, with spending expected to increase significantly over the next 10 years. We have identified four priority recommendations in this area. These include a recommendation to fully validate Medicare Advantage (MA) encounter data and a recommendation to account for Medicaid payments that offset uncompensated care costs when making Medicare uncompensated care payments to individual hospitals. We also recommended that HHS improve 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. This would potentially improve the sustainability of the program by, for example, reducing billions of dollars in unnecessary expenditures.

**Improper payments in Medicaid and Medicare.** Estimates of improper payments in the Medicaid and Medicare programs continue to be unacceptably high and totaled about $101 billion in fiscal year 2023. Improper payments in the Medicare program and strengthening Medicaid program integrity are also areas on our High-Risk List.[13]

We have identified five priority recommendations in this area. For example, one recommendation is for the Centers for Medicare & Medicaid Services (CMS) to complete a comprehensive, national risk assessment and ensure that resources to oversee expenditures reported by states are adequate and allocated based on areas of highest risk. Another recommendation is for CMS to ensure that Medicare and Medicaid documentation requirements are necessary and effective at demonstrating compliance with coverage policies and addressing program risks. A third recommendation is for CMS to conduct a study to determine if it would be cost effective to require states to include payments to managed care organizations and their providers in states' recovery audit contractor programs. If implemented, these recommendations could reduce improper payments, such as by improving oversight of providers.

**Health care infrastructure, 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 five priority recommendations in this area. For example, we recommended that CMS revise its

[13]GAO-23-106203.

policies to maximize coordination with other federal agencies on the assessment of state agencies' cybersecurity.

In addition, as a co-sector risk management agency for the food and agriculture sector with the Department of Agriculture, we urge HHS to implement our priority recommendation related to critical infrastructure protection. We recommend HHS work within the food and agriculture sector to develop methods to determine the level and type of adoption of the National Institute of Standards and Technology's *Framework for Improving Critical Infrastructure Cybersecurity*. If implemented, these recommendations could help address current cybersecurity weaknesses.

Implementing our priority recommendations could help improve the efficiency and effectiveness of key federal health care programs and funding. Further, implementing our priority recommendations could be done in conjunction with efforts to address high-risk areas related to HHS. In April 2023, we issued our biennial update to our High-Risk List. This list identifies government operations with greater vulnerabilities to fraud, waste, abuse, and mismanagement. It also identifies the need for transformation to address economy, efficiency, or effectiveness challenges.[14]

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. Four 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; (3) enforcement of tax laws; and (4) improving federal management of programs that serve tribes and their members.

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, and (5) government-wide personnel security 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 (OMB), 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 these issues.[15]

We also recognize the key role Congress plays in providing oversight and maintaining focus on our recommendations to ensure they are implemented and produce their desired results. Legislation enacted in December 2022 includes a provision for GAO to identify any additional

[14]GAO-23-106203.

[15]GAO, *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).

congressional oversight actions that can help agencies implement priority recommendations and address any underlying issues relating to such implementation.[16]

Congress can use various strategies to help implement our recommendations, such as incorporating them into legislation. Congress can also use its budget, appropriations, and oversight processes to incentivize executive branch agencies to act on our recommendations and monitor their progress. For example, Congress can hold hearings focused on HHS's progress in implementing GAO's priority recommendations, withhold funds when appropriate, or take other actions to provide incentives for agencies to act. Moreover, Congress could follow up during the appropriations process and request periodic updates. Congress also plays a key role in addressing any underlying issues related to the implementation of these recommendations. For example, Congress could pass legislation providing an agency explicit authority to implement a recommendation or requiring an agency to take certain actions to implement a recommendation.

Copies of this report are being sent to the Director of OMB and the appropriate congressional committees. In addition, the report will be available on our website at Priority Open Recommendation Letters | U.S. GAO.

I appreciate HHS's continued 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 417 open recommendations as well as those additional recommendations in the high-risk areas for which HHS has a leading role. Thank you for your attention to these matters.

Sincerely,

Gene L. Dodaro
Comptroller General
of the United States

Enclosure

cc: Sean McCluskie, Chief of Staff, Department of Health and Human Services
Lisa Molyneux, Acting Assistant Secretary for Financial Resources
Miranda Lynch-Smith, Deputy Assistant Secretary for Human Services Policy, Performing the Delegable Duties of the Assistant Secretary for Planning and Evaluation

[16]James M. Inhofe National Defense Authorization Act for Fiscal Year 2023, Pub. L. No. 117-263, § 7211(a)(2), 136 Stat. 2395, 3668 (2022); see also H.R. Rep. No. 117-389 (2022) (accompanying Legislative Branch Appropriations Act, H.R. 8237, 117th Cong. (2022)).

Jeff Hild, Principal Deputy Assistant Secretary for the Administration for Children and Families
Dawn O'Connell, Assistant Secretary for Preparedness and Response
Mandy Cohen, 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
Roselyn Tso, 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**

**Public Health Emergency Preparedness, including the COVID-19 Response**

*Zoonotic Diseases: Federal Actions Needed to Improve Surveillance and Better Assess Human Health Risks Posed by Wildlife.* GAO-23-105238. Washington, D.C.: May 31, 2023.

**Year recommendation made:** 2023

**Recommendation:** The Director of the Centers for Disease Control and Prevention (CDC), in collaboration with other agencies, as appropriate, should comprehensively assess zoonotic disease risks related to imported wildlife to inform CDC's decisions about regulations. Such an assessment could include identifying high priority categories of wildlife and then conducting risk assessments for those particular categories.

**Actions needed:** The Department of Health and Human Services (HHS) disagreed with this recommendation. As of February 2024, CDC agreed that qualitative and quantitative public health risk assessments are valuable for informing policy decisions, but said that comprehensively assessing zoonotic disease risks was too broad. CDC also said the Smithsonian Institution's project to rank the risk of imported wildlife made GAO's recommendation duplicative.

GAO continues to believe that CDC could use a risk-based approach—for example, identifying high priority categories of wildlife for risk assessments—to use its resources efficiently. It could do so in collaboration with other agencies, such as the Smithsonian Institution, as appropriate. Conducting such an assessment could help prevent the introduction of zoonotic diseases into the United States.

**Directors:** Steve D. Morris, Natural Resources & Environment and Karen L. Howard, Science, Technology Assessment, and Analytics

**Contact information:** MorrisS@gao.gov, 202-512-3841 and HowardK@gao.gov, 202-512-6888

*Public Health Preparedness: HHS Should Address Strategic National Stockpile Requirements and Inventory Risks.* GAO-23-106210. Washington, D.C.: October 17, 2022.

**Year recommendation made:** 2023

**Recommendation:** The Assistant Secretary for Preparedness and Response should develop and document an approach for regularly managing the risks associated with the gaps between Strategic National Stockpile (SNS) medical countermeasure (MCM) inventory levels and recommended quantities. Such an approach, which could occur as part of the SNS reviews, should clearly prioritize risks, track progress made in addressing the risks, and estimate resources needed to address risks. This approach should involve communicating this information to key decision makers, including Congress.

**Actions needed:** HHS agreed with this recommendation. In February 2024, HHS described routine interagency meetings through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to assess threats, evaluate and prioritize risks, and assess gaps in SNS

inventory. In addition, HHS officials said they are continuing to draft procedures for managing risks associated with gaps in the SNS inventory, but they did not have a time frame for completion of such procedures.

To fully implement this recommendation, HHS needs to finalize procedures for managing risks and provide documentation of how the described risk-management activities are conducted in order for GAO to assess how risks, gaps, and priorities are determined from year to year. Doing so would provide assurance that HHS is effectively preparing for public health emergencies.

**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

*COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity.* GAO-21-551. Washington, D.C.: July 19, 2021.

**Year recommendation made:** 2021

**Recommendation:** To improve the nation's preparedness for a wide range of threats, including pandemics, the Office of the Assistant Secretary for Preparedness and Response (ASPR) should develop and document plans for restructuring the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).[1] These plans should describe how the Assistant Secretary will ensure a transparent and deliberative process that engages interagency partners in the full range of responsibilities for the PHEMCE outlined in the Pandemic and All-Hazards Preparedness and Innovation Act of 2019, including the annual Strategic National Stockpile (SNS) Threat-Based Reviews.[2] These plans should also incorporate GAO's leading practices to foster more effective collaboration, while ensuring that sensitive information is appropriately protected.

**Actions needed:** HHS agreed with this recommendation. HHS relaunched the PHEMCE in February 2022 and released the 2022 PHEMCE Strategy and Implementation Plan in October 2022. In February 2024, HHS reported that it developed plans related to the purpose and responsibility of the PHEMCE; however, some plans were not yet finalized. Further, HHS reported that it updated the process used to develop the 2022 SNS annual review, but has not documented a standardized process that will be followed for future reviews.

To fully implement this recommendation, HHS needs to finalize and provide documentation of the PHEMCE's operating structure and procedures; the process by which HHS ensures transparency in its engagement with interagency partners; and the extent to which HHS has made progress on the goals and objectives of the October 2022 strategy and implementation plan. Until HHS implements this recommendation, it risks being unable to fulfill its

[1]In July 2022, the Secretary of Health and Human Services removed ASPR from the HHS Office of the Secretary and created a new operating division in the department, known as the Administration for Strategic Preparedness and Response. In this letter, we refer to ASPR under the organizational name and structure in place at the time the recommendations were made.

[2]The annual Strategic National Stockpile Threat-Based Review is now known as the Medical Countermeasure Preparedness Review.

responsibilities in advancing national preparedness for a wide range of threats, including pandemics.

**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.

**Year recommendations made:** 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 February 2024, HHS reiterated the response it provided in 2021, 2022, and 2023—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. However, HHS has not yet identified steps taken to develop this process or when it expects to complete this work.

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 any duplication and overlap among agencies, which could help them to better plan for and respond to disease outbreaks.

**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. As of January 2023, CDC said it was updating its policies to better align them with the current data landscape, lessons learned, and federal guidance on ensuring access to federally funded research. In February 2024, CDC said it was making progress toward improving the speed, quality, and timeliness of its shared data. CDC additionally noted that it had implemented system efficiencies and process improvements to improve data clearance efficiency.

To fully implement this recommendation, CDC needs to finish updating and provide its policies and guidelines and modernize its information sharing processes. 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:** Karen L. Howard, Science, Technology Assessment, and Analytics

**Contact information:** HowardK@gao.gov, 202-512-6888

**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.

**Year recommendation made:** 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 the Department of Homeland Security (DHS) agreed with this recommendation. In coordination with HHS, DHS implemented the Unified Immigration Portal, which provides real-time data to help track unaccompanied children from the time of DHS apprehension to their referral and placement in HHS-funded facilities, including those who are apprehended with an adult. Additionally, HHS continues to implement its case management data system, which is integrated with the Unified Immigration Portal. This helps HHS officials retrieve information about a child's case more quickly and automates the process of referring children from DHS to HHS.

However, as of March 2024, the information gaps we highlighted in our report continue to exist. In particular, ORR officials stated they do not consistently receive information from DHS about the adults who arrived with unaccompanied children. This would help ORR make placement and release decisions. In the fall of 2023, DHS reported it was working with ORR on a new interagency agreement to govern information sharing. DHS stated it anticipates concluding work on the new agreement by August 2024.

To fully address this recommendation, DHS and HHS should finalize their information sharing agreement and ensure the agreement addresses information sharing gaps identified in our report. Doing so would help ensure that HHS's ORR receives information needed to make decisions for unaccompanied children, including those apprehended with an adult. Doing so would also enable ORR 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.

**Year recommendation made:** 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 2024, HHS told us its fraud risk assessment approach was still under development and that a timeline for completing this work had not been established.

To fully implement this recommendation, HHS needs to finalize its approach and complete a fraud risk assessment. Doing so could help OHS better identify and address the fraud risk vulnerabilities we identified.

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

**Contact information:** BagdoyanS@gao.gov, 202-512-6722

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

**Year recommendation made:** 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. In October 2022, CMS issued guidance that requires surveyors from state agencies to enter the abuse and perpetrator type into CMS's deficiencies database. Officials said the agency is monitoring trends in abuse deficiencies and reviewing the types of perpetrators. However, as of February 2024, CMS has not required that state surveyors submit abuse and perpetrator type in CMS's databases for complaint and facility-reported incident data. Taking the actions we recommended for all relevant databases will help ensure that CMS has key information needed to address the most prevalent types of abuse and perpetrators.

**High-risk areas:** Medicare Program & Improper Payments, Strengthening Medicaid Program Integrity

**Director**: John E. Dicken, Health Care

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

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

**Year recommendations made:** 2018

**Recommendations:**

- 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.

- 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 2024, it had not taken steps to implement them. Since 2019, HRSA has expressed concerns that, because guidance is not enforceable, it cannot implement these recommendations until the

agency has regulatory authority. HRSA has identified a proposed CMS rule that may allow the agency to issue enforceable guidance and is monitoring the outcome of this rule.

To fully implement these recommendations, HRSA needs to communicate to covered entities how they are to prevent duplicate discounts under Medicaid managed care and assess the potential for these duplicate discounts as part of its audits. Until our recommendations are fully implemented, HRSA will not have assurance that covered entities' efforts are effectively preventing noncompliance. As a result, manufacturers will continue to be at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions.

**Director:** Michelle B. Rosenberg, Health Care

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

**Food and Drug Administration Oversight**

*Laboratory Safety: FDA Should Strengthen Efforts to Provide Effective Oversight.* GAO-20-594. Washington, D.C.: September 8, 2020.

**Year recommendation made:** 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 its leadership and safety staff were reviewing and updating their staff manual guides related to FDA's safety program. In addition, as of January 2023, FDA stated its staff were developing documents outlining the roles and responsibilities of its components within FDA's safety program. Officials noted that such documents will inform the agency's update of the OLS strategic plan. In February 2024, FDA said it plans to complete these updates by the end of the year.

To fully implement this recommendation, FDA needs to clarify roles and responsibilities for the centers and offices in implementing laboratory safety reforms through updates to the OLS strategic plan, staff manual guides and other documents describing roles and responsibilities. Until it does so, FDA will continue to face challenges implementing the changes needed to ensure OLS can effectively oversee FDA's laboratory safety program.

**Director:** Mary Denigan-Macauley, Health Care

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

*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.

**Year recommendation made:** 2017

**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. In October 2023, FDA provided a draft of its drug safety focal area, including proposed indicators and measures within that area to track progress toward long-term goals. The draft indicated that the proposed measures were under discussion to ensure alignment between the foreign offices and FDA's product centers. As of February 2024, FDA indicated that this work was continuing.

To fully implement this recommendation, FDA needs to finalize 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

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

*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.

**Year recommendation made:** 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. In March 2020, FDA officials said that they cannot meet the number of foreign inspections required under FSMA due to capacity constraints. They further noted that FDA's strategy for the safety of imported food relies on a "cumulative oversight" approach involving 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. As of February 2024, FDA had not determined the annual number of foreign food inspections that is sufficient to ensure comparable safety of imported and domestic food, nor reported this information to Congress.

To fully implement this recommendation, FDA should complete all steps in its cumulative oversight approach and report to Congress on its data-driven assessment of the appropriate number or range of foreign inspections that would be sufficient to ensure the safety of the imported food supply. Doing so would better position FDA to determine whether to 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 D. Morris, Natural Resources & Environment

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**Medicaid Program**

*Medicaid Managed Care: Rapid Spending Growth in State Directed Payments Needs Enhanced Oversight and Transparency.* GAO-24-106202. Washington, D.C.: December 14, 2023.

**Year recommendation made:** 2024

**Recommendation:** The Administrator of CMS should enhance the agency's fiscal guardrails for approving state directed payments by establishing a definition of, and standards for, assessing whether directed payments result in payment rates that are reasonable and appropriate, and communicating those to states; determining whether additional limits are needed; and requiring states to submit data on actual spending amounts at renewal.

**Actions Needed:** HHS neither agreed nor disagreed with this recommendation. In the November 2023 comments on GAO's draft report, HHS said that, if finalized, provisions in CMS's May 2023 proposed rule should address the recommendation. For example, HHS noted provisions in the rule related to ensuring that state directed payments are reasonable and appropriate. As of February 2024, the proposed rule had not been finalized.

To fully implement this recommendation, CMS would, in addition to ensuring reasonable and appropriate payments, need to determine whether additional limits are needed and require states to submit data on actual spending amounts at renewal. Implementing this recommendation would help CMS develop fiscal guardrails and reduce the agency's risk of approving billions of dollars in federal funds for ineffective state directed payments.

**High-risk area:** Strengthening Medicaid Program Integrity

**Director:** Catina B. Latham, Health Care

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

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

**Year recommendation made:** 2021

**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. HHS acknowledged the need for additional state Medicaid financing and payment data to oversee the Medicaid program. Regarding supplemental payments, while states have begun reporting some information about these payments, in February 2024, CMS officials said that this reporting does not include information on states' sources of funding for the nonfederal share. Regarding state directed managed care payments, in February 2024, CMS officials said the agency has

developed the tools and process for collecting standardized information about these payments, including on the source of funding of the nonfederal share. However, the standardized information about source of funding for these payments is not always provider specific.

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:** Catina B. Latham, Health Care

**Contact information:** LathamC@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.

**Year recommendation made:** 2021

**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 managed care organizations 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. However, as of February 2024, CMS had taken some steps to enhance oversight, such as by issuing a technical assistance toolkit for states to use in overseeing managed long-term services and supports programs and updating its Managed Care Program Annual Report template.

To fully implement this recommendation, CMS needs to develop a strategy for resolving identified problems with state managed long-term services and supports programs. Implementing this recommendation 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:** Catina B. Latham, Health Care

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

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

**Year recommendation made:** 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. As of February 2024, CMS officials had added a lead screening measure to the Child Core Set of quality measures, which CMS uses to monitor state performance. States began reporting this measure in late 2023, and CMS officials expect data to be available in late 2024. CMS officials also said that the agency is planning to update blood lead screening guidance in 2024 and will emphasize the importance of complete and accurate data.

To fully implement this recommendation, CMS needs to finalize its guidance and ensure that it addresses limitations in blood lead screening data to help the agency better monitor compliance with its 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:** Michelle B. Rosenberg, Health Care

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*Medicaid Demonstrations: Approvals of Major Changes Need Increased Transparency*. GAO-19-315. Washington, D.C.: April 17, 2019.

**Year recommendation made:** 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. In November 2019, HHS 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 to new demonstrations. In December 2020, CMS said the agency planned to develop guidance reflecting criteria for determining whether an amendment application proposes a substantial change to an existing demonstration. However, as of February 2024, HHS officials had not taken any additional actions taken to implement this recommendation.

To fully implement this recommendation, CMS needs to issue the planned policy guidance. 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:** Catina B. Latham, 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.

**Year recommendation made:** 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 January 2023, CMS provided states with technical assistance on critical incident reporting, including providing training and an optional incident reporting template. CMS published a proposed rule in May 2023 that included provisions to standardize critical incident oversight, including data reporting requirements. As of February 2024, CMS officials said that comments on the proposed rule were under review.

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 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:** Catina B. Latham, Health Care

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

**Year recommendation made:** 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 with the recommendation. 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. However, as of February 2024, CMS had not issued written guidance to all states on this policy. Taking action to do so would better position CMS to help curtail the process of states making large supplemental payments in excess of costs.

**High-risk area:** Strengthening Medicaid Program Integrity

**Director:** Catina B. Latham, Health Care

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

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

**Year recommendation made:** 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.[3] HHS has taken some action to address the recommendation. 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. For example, one policy change that went into effect for demonstration renewals in 2021 required states' cost projections to be based on recent data. These changes addressed some, but not all, of the questionable methods we identified in our reports. As of February 2024, HHS had taken no further action to address the recommendation.

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, which threatens budget neutrality of demonstrations.

**High-risk area:** Strengthening Medicaid Program Integrity

**Director:** Catina B. Latham, Health Care

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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.

**Year recommendation made:** 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 agreed with this recommendation; however, in 2018, March 2021, January 2023, and February 2024, HHS indicated it was reconsidering whether to implement this recommendation because officials stated that it may not be appropriate to offset Medicare UC payments by Medicaid payments that help offset UC costs. We maintain that CMS should implement this recommendation because it would (1) ensure that Medicare UC payments are

[3]GAO, *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).

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.

**Potential financial benefit if implemented:** Billions

**High-risk area:** Medicare Program & Improper Payments

**Director:** Leslie V. Gordon, Health Care

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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.

**Year recommendation made:** 2014

**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 MA organizations with summary reports on CMS's findings, before using the data to risk adjust payments or for other intended purposes.

**Actions needed:** HHS agreed with this recommendation. As of February 2024, CMS made progress in examining the completeness and accuracy of MA encounter data. But CMS has not fully validated these data. For example, CMS has established some performance metrics for the completeness and accuracy of these data, but these metrics are not sufficiently detailed or comprehensive.

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. Without fully validating the completeness and accuracy of MA encounter data, the soundness of adjustments to payments to MA organizations remains unsubstantiated.

**High-risk area:** Medicare Program & Improper Payments

**Director:** Leslie V. Gordon, Health Care

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

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

**Year recommendation made:** 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 2024, CMS stated that the agency had obtained input on the LVPA and planned to revise the LVPA as part of the calendar year 2024 rulemaking process.

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 services.

**High-risk area:** Medicare Program & Improper Payments

**Director:** Leslie V. Gordon, Health Care

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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.

**Year recommendation made:** 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 agreed with this recommendation. CMS applied the statutory minimum adjustment to MA payments for calendar year 2023; however, as of February 2024, CMS had not provided any documentation of its analysis or the basis for its determination of the diagnostic coding adjustment. In recent years, 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 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 recalculate its adjustment using an updated methodology. Until CMS takes these steps, the agency is at continued risk of making excess payments to MA plans.

**Potential financial benefit if implemented:** Billions

**High-risk area:** Medicare Program & Improper Payments

**Director:** Leslie V. Gordon, Health Care

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**Improper Payments in Medicaid and Medicare**

*Medicaid: CMS Oversight and Guidance Could Improve Recovery Audit Contractor Program.* GAO-23-106025. Washington, D.C.: June 28, 2023.

**Year recommendation made:** 2023

**Recommendation:** The Administrator of CMS should conduct a study to determine whether it is cost effective to require states to include payments to managed care organizations and their providers as part of the Recovery Audit Contractor (RAC) program.

**Actions Needed:** HHS disagreed with this recommendation. In May 2023, CMS stated that states have many other ways to oversee managed care improper payments and that conducting a study regarding the cost-effectiveness of requiring all states to include managed care in their recovery audit contractor programs may not be the most efficient use of time and resources. In March 2024, CMS reiterated that the current regulatory flexibility allows states to review managed care encounters if they determine it to be appropriate.

GAO believes that while it is important that CMS use its resources efficiently, it is also essential that states use Medicaid funds effectively. CMS can determine whether including managed care payments in the recovery audit contractor programs would be cost effective for the overall program. As such, we maintain that conducting a study to determine if it is cost effective for the recovery audit contractors to include managed care claims is valid and could generate sufficient revenue to support a recovery audit contractor program.

**High-risk area:** Strengthening Medicaid Program Integrity

**Director:** M. Hannah Padilla, Financial Management and Assurance

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

**Year recommendation made:** 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. In February 2020, 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.

As of February 2024, CMS stated that the agency is reviewing and assessing how to best implement this recommendation. 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:** Leslie V. Gordon, Health Care

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

**Year recommendation made:** 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. Although CMS suspended implementation of the tool the agency developed in October 2019 to assess risk and staff capacity, the agency has taken steps to strengthen financial oversight. In November 2019, the agency reorganized 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.

In February 2024, agency officials told us that the reorganization had increased staff resources for financial reviews and allowed the agency to work toward reducing the backlog of financial management reviews. To fully implement this recommendation, CMS needs to complete a risk assessment. Such an assessment would help better target resources to areas of highest risk.

**High-risk area:** Strengthening Medicaid Program Integrity

**Director:** Michelle B. Rosenberg, 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.

**Year recommendation made:** 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, noting that CMS has other program integrity activities to prevent improper payments. As of February 2024, HHS had not taken steps to seek legislative authority to allow the RAs to conduct prepayment claim reviews. We maintain that CMS should seek legislative authority since prepayment reviews better protect agency funds compared with post-payment reviews. Until CMS seeks this authority, it will be missing an opportunity to help identify improper payments before they are made.

**High-risk area:** Medicare Program & Improper Payments

**Director:** Leslie V. Gordon, Health Care

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

*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.

**Year recommendation made:** 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. As of February 2024, HHS described steps CMS has taken to improve the timeliness of the RADV audit process. These include developing and testing the use of artificial intelligence technology to further automate the medical record intake process.

To fully implement this recommendation, CMS will need to complete steps such as these and demonstrate that the agency's actions have enhanced the timeliness of CMS's contract-level RADV process. Implementing this recommendation would potentially allow CMS to improve the timeliness of its recovery of 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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**Health Care Infrastructure, Information Technology, and Cybersecurity**

*Federal Real Property: Agencies Should Provide More Information about Increases in Deferred Maintenance and Repair.* GAO-24-105485. Washington, D.C.: November 16, 2023.

**Year recommendation made:** 2024

**Recommendation:** The Secretary of Health and Human Services should ensure that the department works with its component agencies to develop plans to address their deferred maintenance and repair (DM&R) backlogs and identify the funding and time frames needed to reduce them in congressional budget requests, related reports to decision-makers, or both.

**Actions Needed:** HHS agreed with this recommendation. In November 2023, HHS stated that it will work with partners in the Program Support Center offices to include guidance in preliminary budget submissions. This guidance will ask agencies to develop plans to address their DM&R

backlog and identify the funding and time frames needed to reduce the backlog identified in the congressional justifications. HHS stated it can also work to include the DM&R backlog considerations in budget decision meeting materials and discussions.

In its fiscal year 2025 budget justification, published in March 2024, HHS requested an additional $35 million in funding for fiscal year 2025 to help address its backlog. As part of the budget justification, HHS also stated that beginning in fiscal year 2026, the budget request would make funding for its facilities account mandatory, and would automatically grow to provide more than $1 billion in funding increases to address existing maintenance and improvement backlogs. However, the 2025 budget justification does not provide specific information, including funding and time frames, for how HHS intends to address its backlog of more than $5 billion in DM&R.

To fully implement this recommendation, HHS needs to develop a more specific plan for reducing the backlog and include it in congressional budget requests or related reports to decision-makers. Doing so could help HHS better inform decision-makers about how funding levels could affect backlog reduction and help the decision-makers evaluate budget requests.

**High-risk area:** Managing Federal Real Property

**Director:** Andrew Von Ah, Physical Infrastructure

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*Privacy: Dedicated Leadership Can Improve Programs and Address Challenges.* GAO-22-105065. Washington, D.C.: September 22, 2022.

**Year recommendation made:** 2022

**Recommendation:** The Secretary of Health and Human Services should fully define and document a process for ensuring that the senior agency official for privacy or other designated privacy official is involved in assessing and addressing the hiring, training, and professional development needs of the agency with respect to privacy.

**Actions needed:** HHS agreed with this recommendation. Specifically, HHS stated that it planned to more fully define and document the responsibility and process of the senior agency official for privacy in its next iteration of the HHS Policy for Information Security and Privacy Protection. As of February 2024, HHS stated that it was actively working to implement the recommendation. However, HHS did not provide further details or an estimated completion date. Implementing this recommendation would help ensure consistent focus on privacy among senior leadership, facilitate cross-agency coordination, and elevate the importance of privacy.

**High-risk area:** Ensuring the Cybersecurity of the Nation

**Directors:** Jennifer R. Franks and Marisol Cruz Cain, Information Technology and Cybersecurity

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*COVID-19: Pandemic Lessons Highlight Need for Public Health Situational Awareness Network.* GAO-22-104600. Washington, D.C.: June 23, 2022.

**Year recommendation made:** 2022

**Recommendation:** The Secretary of Health and Human Services should ensure that the lead operational division, in developing the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA) work plan, includes specific near-term and long-term actions that can be completed to show progress in developing the network.

**Actions needed:** HHS agreed with this recommendation. In April 2023, HHS stated that longer-term actions that can be completed beyond fiscal year 2023 will require the establishment of dedicated funding resources. HHS also stated that it had completed specific near-term actions to establish an electronic public health situational awareness network capability by transitioning the HHS Protect data system and program stewardship to CDC and approving a new governance structure. In March 2024, HHS stated that the fiscal year 2024 CDC Congressional Justification request will support the Response Ready Enterprise Data Platform (formerly HHS Protect). The Platform is to serve as the common operating picture and central hub to collect, integrate, and share public health data in near-real time across federal agencies and with state, local, territorial, and tribal partners.

To fully implement this recommendation, HHS should ensure that it develops a plan for specific long-term actions in addition to near-term actions to show progress in the network's development. For example, the plan should include PAHPAIA requirements regarding HHS' efforts to conduct a review of the data and information transmitted by the network and a discussion of any additional data sources and challenges in the incorporation of standardized data from various sources. Until HHS fully implements this recommendation, it may not be able to show that it is making significant progress in developing the network.

**High-risk area:** Improving the Management of IT Acquisitions and Operations

**Director:** Jennifer R. Franks, Information Technology and Cybersecurity

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

**Year recommendation made:** 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 2024, CMS stated that it would accept results of a recent, independent third-party assessment conducted for another federal agency. CMS also stated it would 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. In addition, CMS stated that the Office of Management and Budget would need to be involved in developing a standardized process for sharing independent security assessments performed by the states with other federal agencies.

To fully implement 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 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.

**Year recommendation made:** 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.[4]

**Actions needed:** HHS agreed with this recommendation. In April 2023, HHS, in collaboration with the Healthcare and Public Health Sector Coordinating Council, published an analysis that describes industry adoption of the National Institute of Standards and Technology cybersecurity framework based on results from a third-party survey sent to hospitals. HHS also evaluated the extent to which responding hospitals adopted the five core functions of the cybersecurity framework and its associated subcategories.

In addition, HHS coordinated with the Department of Agriculture in taking initial steps to determine framework adoption across the sector by distributing several requests for information to food and agriculture sector members. However, those efforts did not generate enough responses to be useful. For instance, the Department of Agriculture did not receive any responses from private sector members regarding plans to implement, adopt, and measure improvements resulting from use of the framework. The Department of Agriculture stated that it has collaborated with HHS and DHS to determine if there are alternative methods for collecting and assessing more substantive information. As of February 2024, HHS and the other agencies have not yet identified alternative approaches or completed other actions for determining framework adoption in the food and agriculture sector.

To fully implement this recommendation, HHS needs to implement actions that will allow the agency to better assess framework adoption among entities within the food and agriculture sector. 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

[4]For the framework, see National Institute of Standards and Technology (NIST), *The NIST Cybersecurity Framework (CSF) 2.0* (Gaithersburg, Md.: Feb. 26, 2024). HHS and the Department of Agriculture are co-risk management agencies for the food and agriculture sector; HHS is the sole risk management agency for the healthcare and public health sector.

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