U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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Comptroller General
of the United States

May 7, 2025

The Honorable Robert F. Kennedy, Jr.
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 Kennedy:

Congratulations on your appointment. The purpose of this letter is to call your personal attention to three areas based on GAO's past work and 35 open priority recommendations, which are enclosed.[1] Additionally, there are 417 other GAO open recommendations that we will continue to work with your staff to address.

We are highlighting the following areas that warrant your timely and focused attention. Specifically:

Improve leadership over public health emergency preparedness and response. Deficiencies in the nation's preparedness for public health emergencies have hindered the nation's response to the COVID-19 pandemic, the 2022 mpox outbreak, and a variety of other past emergencies. HHS's leadership and coordination of public health emergencies remains critical to address emerging and concurrent threats that could affect the nation's health and security, such as avian influenza with pandemic potential, and was added to our High-Risk List in 2022.

For example, the Strategic National Stockpile is a multibillion-dollar inventory of drugs, vaccines, supplies, and other medical countermeasures that can be used in emergencies. To prepare for public health emergencies, we recommended that HHS develop an approach for regularly managing the risks associated between gaps in the stockpile's inventory levels and recommended quantities. To ensure transparency and effective collaboration, we also recommended that HHS develop and document plans for restructuring the Public Health Emergency Medical Countermeasures Enterprise, the interagency group of experts that advises on prioritizing, developing, procuring, deploying, and effectively using medical supplies and other countermeasures for the Strategic National Stockpile.

Ensure effective 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. This extends to products and food that are manufactured both domestically and internationally. Given that strengthening the food

[1]GAO considers a recommendation to be a priority if when implemented, it 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.

safety oversight system is critical to protecting Americans, improving federal oversight of food safety has been on GAO's High Risk List since 2007. In addition, protecting public health through enhanced oversight of medical products has been on GAO's High Risk List since 2009.

For example, FDA is responsible for overseeing the safety and effectiveness of all drugs marketed in the U.S., including those manufactured overseas. To help do this, FDA began opening overseas offices in 2008 to obtain better information on products coming into the U.S. and perform inspections. While FDA has taken some steps to assess the effectiveness of its overseas offices, FDA has not yet demonstrated that it can systematically measure whether the offices' activities contribute to drug safety-related outcomes as we recommended. With such information, FDA could better assess how overseas offices' contributions help ensure imported drugs are safe.

Additionally, FDA faces vacancies in its drug inspection workforce. Investigator attrition has generally outpaced hiring since 2021, which has hindered FDA's ability to conduct inspections at rates comparable to the rate prior to the COVID-19 pandemic. To address investigator vacancies and help increase the number of inspections, we recommended that FDA develop and implement plans to address the causes of investigator attrition.

Regarding food safety, FDA is responsible for ensuring the safety and proper labeling of nearly 80 percent of the food produced in the U.S. and imported from other countries. As we recommended, FDA completed an analysis to determine the target number of annual overseas food inspections sufficient to ensure comparable safety of imported and domestic food. However, FDA has not taken additional necessary steps, such as communicating to Congress the workforce and other resources required to meet the annual target or using updated information and assumptions to identify a new annual target. As a result, FDA is unable to measure the performance of its overall foreign inspection efforts or assess whether such efforts are achieving the intended result to protect U.S. consumers.

Prevent and reduce improper payments in Medicaid and Medicare. Estimates of improper payments in the Medicaid and Medicare programs totaled about $85 billion in fiscal year 2024. As such, it is important that CMS continue taking actions to address strengthening Medicaid program integrity as well as the Medicare program and improper payments, which have been on the High Risk List since 2003 and 1990, respectively.

For example, CMS has a state-based program to identify and recoup Medicaid overpayments. We found that states that elect to use this program for managed care payments have reported collecting overpayments, including one state that reported collecting more than $177 million in overpayments in 1 year. However, CMS has not studied the cost-effectiveness of expanding the state-based program to include managed care. If CMS were to conduct a study to do so, as we recommended, the federal government may identify additional opportunities to recover Medicaid overpayments.

Please see Enclosure 1 for additional details about the status and actions needed to fully implement all 35 open priority recommendations out of the 452 total recommendations that remain open. This includes priority recommendations on public health and human services program oversight; Medicaid program oversight; Medicare payment accuracy and appropriateness; and health care infrastructure, information technology, and cybersecurity improvements.

I understand that the Department recently announced plans for a major structural reorganization, including changes to some of the operating divisions to whom we have made

past recommendations. As the Department embarks on these efforts, I would note that GAO has identified leading practices for successful agency reform efforts. These leading practices indicate that agencies can successfully change if they have (1) clear goals, (2) follow a process to develop proposed reforms, (3) allocate implementation resources, and (4) consider workforce needs during and after the reform. In addition, I firmly believe the recommendations we have identified in this letter will provide valuable insights as the Department works through this transition.

We also provide in Enclosure 2 additional information on HHS's recommendation implementation rate and implemented, closed, and new priority recommendations since our May 2024 letter to Secretary Becerra and Deputy Secretary Palm, and relevant management challenges from our high-risk list that apply to HHS. In response to legislation enacted in December 2022, this enclosure also includes information on any additional congressional oversight actions that can help agencies implement priority recommendations and address any underlying issues relating to such implementation.

Copies of this letter are being sent to the appropriate congressional committees. The letter will be available on the GAO website at Priority Recommendations | U.S. GAO. We also plan to send separate letters specifically focused on open recommendations and key issues related to financial management and information technology. These letters will be sent to your Chief Financial Officer and Chief Information Officer, respectively.

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. 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 addressing these priority recommendations and the remaining 417 open recommendations. I appreciate HHS's continued commitment and thank you for your attention to these matters.

Sincerely,

//SIGNED//

Gene L. Dodaro
Comptroller General
of the United States

Enclosures--2

cc: Heather Flick Melanson, Chief of Staff, Department of Health and Human Services
Andrew Gradison, Acting Assistant Secretary for the Administration for Children and Families
Susan Monarez, Acting Director, Centers for Disease Control and Prevention
Mehmet Oz, Administrator, Centers for Medicare & Medicaid Services
Marty Makary, Commissioner, Food and Drug Administration
Thomas J. Engels, Administrator, Health Resources and Services Administration

Enclosure 1

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

Improve Leadership over Public Health Emergency Preparedness and Response

Public Health Preparedness: Mpox Response Highlights Need for HHS to Address Recurring Challenges. GAO-24-106276. Washington, D.C.: April 18, 2024.

Year recommendations made: 2024

Recommendations:

- The Secretary of Health and Human Services should develop and implement a coordinated, department-wide after-action program that encourages collaboration between HHS's component agencies, including integrating the existing public health emergency after-action programs of these component agencies.

- The Secretary of Health and Human Services should develop and implement a coordinated, department-wide after-action program that includes relevant external stakeholders involved in each public health emergency response—such as other federal agencies, jurisdictions, and nongovernmental partners—when identifying challenges and associated solutions.

Actions needed: HHS agreed with these recommendations. As of January 2025, HHS had developed a standard operating procedure to establish a coordinated, department-wide after-action program that includes relevant external stakeholders.

To fully implement these recommendations, HHS needs to apply the standard operating procedure to its response to a public health emergency. Doing so would demonstrate HHS's preparedness for threats to public health. We will review HHS's use of the standard operating procedure in response to a public health emergency to determine the extent to which the procedure fully satisfies our recommendations.

High-risk area: HHS Leadership and Coordination of Public Health Emergencies

Director: Mary Denigan-Macauley, Health Care
Contact information: DeniganMacauleyM@gao.gov

Public Health Preparedness: HHS Emergency Agency Needs to Strengthen Workforce Planning. GAO-24-106108. Washington, D.C.: January 16, 2024.

Year recommendation made: 2024

Recommendation: The Assistant Secretary for Preparedness and Response should establish specific goals and related performance measures to use for its new in-house hiring office once it is fully operational. This could include goals and performance measures to help address areas of concern the new office was intended to address, including time-to-hire, service quality, and unique workforce needs.

Actions needed: HHS neither agreed nor disagreed with this recommendation. In July 2024, the Administration for Strategic Preparedness and Response (ASPR) officials reported that they are working to establish performance measures for the new in-house hiring office and that these measures will be tied to ASPR's goals for the new office. However, the agency lacks other goals and related performance measures, including for three areas of concern ASPR identified: time-to-hire; the quality of hiring services; and the agency's unique workforce needs. As of February 2025, HHS had not provided additional information on the status of their efforts.

To fully implement this recommendation, HHS needs to establish specific goals and related performance measures, including for the three areas of concern. Doing so would better position ASPR and its stakeholders to ensure clear goals for this new office and identify necessary adjustments if goals are not met.

High-risk area: HHS Leadership and Coordination of Public Health Emergencies, Strategic Human Capital Management

Director: Mary Denigan-Macauley, Health Care
Contact information: DeniganMacauleyM@gao.gov

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: HHS disagreed with this recommendation. In August 2024, CDC officials reported establishing an agency workgroup to systemically review the CDC zoonotic disease risk assessment process. The workgroup created a risk assessment model for estimating the zoonotic risk a species poses to the U.S population and tested it on three species CDC regulates. CDC officials said they plan to build upon this risk assessment model and use it to review additional species CDC regulates, in addition to other species that post a threat to public health. CDC officials also said they were awaiting the publication of a Smithsonian Institution study to help determine what, if any, public health risk assessments of wildlife may be needed. In January 2025, CDC released a National One Health Framework that includes an objective to support the development of risk-prediction tools for zoonotic diseases, in line with this recommendation. As of February 2025, CDC had not taken further action to address this recommendation.

While CDC has taken positive steps, we continue to believe that CDC's assessment of zoonotic disease risks related to imported wildlife should be comprehensive to fully address this recommendation. 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.

High-risk area: HHS Leadership and Coordination of Public Health Emergencies

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

Contact information: MorrisS@gao.gov and HowardK@gao.gov

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 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. As of February 2025, HHS reported it was continuing to take steps to address this recommendation.

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 Leadership and Coordination of Public Health Emergencies

Director: Mary Denigan-Macauley, Health Care
Contact information: DeniganMacauleyM@gao.gov

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 should develop and document plans for restructuring the 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 SNS

[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.

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.[3]

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 it has not documented a standardized process that will be followed for future reviews. As of February 2025, HHS reported it was continuing to take steps to address this recommendation.

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; the extent to which HHS has made progress on the goals and objectives of the October 2022 PHEMCE Strategy and Implementation plan; and whether HHS has finalized PHEMCE standard operating procedures. Until HHS implements this recommendation, it risks being unable to fulfill its responsibilities in advancing national preparedness for a wide range of threats, including pandemics.

High-risk area: HHS Leadership and Coordination of Public Health Emergencies

Director: Mary Denigan-Macauley, Health Care
Contact information: DeniganMacauleyM@gao.gov

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 2025, HHS reiterated the response it provided since 2021—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 did not share when it expects to complete this work.

To fully implement this recommendation, HHS needs to finalize this process, and provide relevant documentation, while ensuring that the process routinely monitors, evaluates, and reports on coordination of infectious disease modeling efforts across multiple agencies.

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

[3]This report was released in 2021 and was based on GAO's leading practices available at that time. In 2023, we validated and updated these leading practices; see GAO, *Government Performance Management: Leading Practices to Enhance Interagency Collaboration and Address Crosscutting Challenges,* GAO-23-105520 (Washington, D.C.: May 24, 2023).

Successful completion of this effort could help HHS better identify any duplication and overlap among agencies, which could help them to better plan for and respond to disease outbreaks.

High-risk area: HHS Leadership and Coordination of Public Health Emergencies

Director: Karen L. Howard, Science, Technology Assessment, and Analytics
Contact information: HowardK@gao.gov

Ensure Effective Food and Drug Administration Oversight

Drug Safety: FDA Should Implement Strategies to Retain Its Inspection Workforce. GAO-25-106775. Washington, D.C.: November 13, 2024.

Year recommendation made: 2025

Recommendation: The Commissioner of the Food and Drug Administration (FDA) should ensure that FDA develops and implements action plans that address attrition caused by issues with investigator travel, workload, and work-life balance. In doing so, the Office of Regulatory Affairs, Center for Drug Evaluation and Research, and other relevant stakeholders should collaborate to identify strategies that balance current inspectional needs against the need to retain an experienced workforce and identify any necessary actions, resources, or new authorities.[4]

Actions needed: HHS agreed with this recommendation. In its comments on the draft report, HHS said that FDA plans to establish a committee that includes representatives from all affected departments to comprehensively address issues related to attrition. This committee will be responsible for developing a detailed action plan with defined timelines and deliverables. This committee will also collaborate with the existing Inspections Oversight Board to consolidate efforts related to attrition and create a holistic strategy. As of January 2025, GAO was awaiting HHS's first update on actions to address this recommendation.

High-risk area: Protecting Public Health Through Enhanced Oversight of Medical Products

Director: Mary Denigan-Macauley, Health Care
Contact information: DeniganMacauleyM@gao.gov

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.

[4] In October 2024, FDA implemented a restructuring of its field operations and changed the name of ORA to the Office of Inspections and Investigations. In this letter, we refer to ORA under the organizational name and structure in place at the time the recommendation was made.

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. As of February 2025, FDA officials said these updates were in progress.

While FDA has taken steps to implement this recommendation, to fully implement it 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

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 January 2025, FDA stated that it finalized its strategic plan and proposed goals at the end of fiscal year 2024 and plans to finalize a system to track offices' contributions toward goals by June 2025.

To fully implement this recommendation, FDA needs to finalize the system and demonstrate that it can systematically track information to measure offices' contributions to drug-safety related outcomes. Doing so 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

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 FDA Food Safety Modernization Act, FDA should report the results to Congress and recommend appropriate legislative changes.

Actions needed: HHS agreed with this recommendation. As of February 2025, FDA has taken some steps to address this recommendation. In May 2023, FDA conducted an analysis that determined 4,695 annual foreign inspections represented an optimal target for ensuring the safety of imported food when combined with other FDA programs and oversight activities. FDA's analysis used a risk-based approach to prioritize certain foreign facilities for inspections while excluding others for varied reasons, such as facilities other countries are routinely inspecting. However, the analysis states that FDA does not have the resources to meet the identified target. Further, in August 2024, FDA officials told us they do not use the annual target when planning FDA's foreign inspection efforts. FDA officials told us the agency does not intend to take further action to implement the risk-based approach for prioritizing facilities. According to officials, the agency does not intend to report the results of the 2023 analysis to Congress or take steps to recommend legislative changes in support of FDA's foreign inspection efforts.[5]

To address the intent of this recommendation, FDA could use the target it identified and communicate to Congress regarding the resources FDA requires to meet it. FDA could instead revisit its May 2023 analysis and use updated information and assumptions to identify a new annual target, and then communicate this new target to Congress. By not pursuing either option, FDA is unable to measure the performance of its overall foreign inspection efforts or assess whether such efforts are sufficiently protecting U.S. consumers.

High-risk area: Improving Federal Oversight of Food Safety

Director: Steve D. Morris, Natural Resources & Environment
Contact information: MorrisS@gao.gov

Prevent and Reduce 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

[5] In 2025, we found that between 2018 and 2023, FDA conducted at most 1,727 inspections of foreign facilities—about 9 percent of its annual target under the FDA Food Safety Modernization Act. As FDA has not fully addressed this recommendation from 2015, we asked Congress to consider directing FDA to conduct an analysis to determine the annual number of foreign food facility inspections sufficient to ensure the safety of imported food, and communicate this number and FDA's underlying analysis to Congress. We also asked Congress to consider, upon receiving the relevant information and analysis from FDA, updating the annual target number of foreign facility food inspections FDA should conduct to ensure the safety of imported food. For more information, see GAO, *Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply*, GAO-25-107571 (Washington, D.C.: Jan. 8, 2025).

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 program.

Actions needed: HHS disagreed with this recommendation. 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. As of February 2025, CMS did not indicate any change in its position.

We believe 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 the validity of conducting a study to determine if it is cost effective for the recovery audit contractors to include managed care claims 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
Contact information: PadillaH@gao.gov

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.

In March 2025, CMS noted that it had implemented a process to identify and mitigate program integrity vulnerabilities. This process involves identifying and implementing effective program integrity approaches and lessons learned across Medicare and Medicaid. However, the agency did not describe how this process had been used to assess documentation requirements and 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
Contact information: GordonLV@gao.gov

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.

As of February 2025, agency officials had told us that the reorganization had increased staff resources for financial reviews and allowed the agency to reduce the backlog of its financial management reviews. While CMS has taken steps to address this recommendation, 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.

Potential financial benefit if implemented: Hundreds of millions

High-risk area: Strengthening Medicaid Program Integrity

Director: Michelle B. Rosenberg, Health Care
Contact information: RosenbergM@gao.gov

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 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 2025, HHS had not taken steps to seek legislative authority to allow the recovery auditors 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

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. In 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. In November 2024, CMS initiated contract-level RADV audits for payment year 2018. As of February 2025, these audits were ongoing and CMS reported that it expects to begin issuing findings in 2026.

To fully implement this recommendation, CMS will need to 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
Contact information: GordonLV@gao.gov

Ensure 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 the Department of Homeland Security (DHS), 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, including those apprehended with an adult.

Actions needed: HHS and 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. 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, ORR officials have told us that they do not consistently receive information from DHS about the adults who arrived with unaccompanied children. Consistently receiving information 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. As of February 2025, DHS and HHS have not finalized the new agreement, but DHS officials stated they expect to finalize it in spring 2025.

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

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 2025, HHS told us its fraud risk assessment approach was 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

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 the Center for Medicare and Medicaid Services (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. While the agency has taken steps to address this recommendation, as of February 2025, 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

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. In February 2025, HHS reported that CMS had recently finalized new regulations which included policies that impact 340B covered entities and the prevention of duplicate discounts in Medicaid managed care. It also noted that in the absence of explicit statutory authority for HRSA itself to issue regulations on this topic, HRSA plans to use this rule to strengthen efforts to prevent duplicate discounts.

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

Strengthen Medicaid Program Oversight

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 May 2024, CMS finalized a proposed rule that included activities to enhance the agency's fiscal guardrails for state directed payments. The final rule also requires states to submit data to CMS on the total dollars expended by each managed care organization for state directed payments paid to providers. CMS officials said they will revise review procedures to reflect the need to consider available spending data when the agency approves a renewal of a state directed payments. Officials also said they plan to issue technical guidance to states that will include additional information on standards for assessing whether proposed state directed payments are reasonable and appropriate. As of February 2025, we continued to monitor progress toward these actions.

The provisions CMS included in the agency's final rule partially address our recommendation. To fully implement this recommendation, CMS needs to take additional steps, such as finalizing its review procedures for renewal applications and issuing the planned technical guidance on payment rate standards. 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: Michelle B. Rosenberg, Health Care
Contact information: RosenbergM@gao.gov

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, states have begun reporting some information about these payments, which CMS was working to validate as of February 2025. However, 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, 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: Michelle B. Rosenberg, Health Care
Contact information: RosenbergM@gao.gov

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. As of February 2024, however, 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. As of March 2025, CMS officials reported that, instead of toolkits, the agency is working on improving states' managed care program annual reports and related analytics to better support monitoring and oversight.

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: Michelle B. Rosenberg, Health Care
Contact information: RosenbergM@gao.gov

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. In addition, CMS 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. As of February 2025, CMS officials said that the agency is planning to update blood lead screening guidance in 2025 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
Contact information: RosenbergM@gao.gov

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 planned 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. As of February 2025, CMS officials planned to develop this criteria. However, the agency did not have a timeline for doing so.

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: Michelle B. Rosenberg, Health Care
Contact information: RosenbergM@gao.gov

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 final rule in the Federal Register in May 2024 that included provisions to standardize critical incident oversight, including data reporting requirements. As of January 2025, CMS officials said that the agency was developing guidance on the reporting requirements.

To fully implement this recommendation, CMS needs to ensure reporting requirements for critical incidents include the type of residential facilities, including assisted living facilities, where critical incidents occurred. 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: Michelle B. Rosenberg, Health Care
Contact information: RosenbergM@gao.gov

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 2025, 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: Michelle B. Rosenberg, Health Care
Contact information: RosenbergM@gao.gov

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.[6] HHS has taken some action to address the recommendation. For example, in 2021, CMS began implementing changes in the agency's methods for setting spending limits when demonstrations are renewed that better assure budget neutrality. These changes were consistent with our recommendation. However, these changes did not address all of the questionable methods we identified. As of February 2025, 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: Michelle B. Rosenberg, Health Care
Contact information: RosenbergM@gao.gov

Enhance the Accuracy and Appropriateness of Medicare Payments

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

[6]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).

costs when determining hospital uncompensated care costs for the purposes of making Medicare uncompensated care payments to individual hospitals.

Actions needed: HHS agreed with this recommendation; however, as of February 2025, executive action has not been taken. In 2018, 2021, 2023, and each year since, HHS indicated it was reconsidering whether to implement this recommendation because officials stated that it may not be appropriate to offset Medicare uncompensated care payments by Medicaid payments that help offset hospital uncompensated care costs. We maintain that CMS should implement this recommendation because it would (1) ensure that Medicare uncompensated care payments are based on accurate levels of hospital uncompensated care costs, and (2) result in CMS better targeting billions of dollars in Medicare uncompensated care payments to hospitals with the most uncompensated care costs.

High-risk area: Medicare Program & Improper Payments

Director: Leslie V. Gordon, Health Care
Contact information: GordonLV@gao.gov

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 Medicare Advantage (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 2025, CMS has 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 an additional step 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 in a timely manner. 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

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 2025, 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 implement an adjustment based on analysis using an updated methodology. Until CMS takes these steps, payments to MA plans may not accurately account for differences in diagnostic coding between these plans and traditional Medicare providers.

Potential financial benefit if implemented: Tens of billions

High-risk area: Medicare Program & Improper Payments

Director: Leslie V. Gordon, Health Care
Contact information: GordonLV@gao.gov

Improve 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, HHS requested additional funding for fiscal year 2025 and proposed additional funding for fiscal years 2026 and 2027 to address its backlog. However, the 2025 budget justification does not provide a specific plan, including funding and

time frames, for how HHS intends to address its backlog. As of February 2025, HHS had not provided further information about actions taken to address this recommendation

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
Contact information: Vonaha@gao.gov

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 2025, 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
Contact information: FranksJ@gao.gov and CruzCainM@gao.gov

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 it had completed specific near-term actions to establish an electronic public health situational awareness network 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. In February 2025, HHS stated that it was working on an action plan to address this recommendation. However, the department did not identify when the action plan would be finalized and shared with us.

To fully implement this recommendation, HHS should ensure that the action plan includes 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 IT Acquisitions and Management, HHS Leadership and Coordination of Public Health Emergencies

Director: Jennifer R. Franks, Information Technology and Cybersecurity
Contact information: FranksJ@gao.gov

Enclosure 2

Key Information About the Status of GAO Recommendations and Improving Agency Operations

HHS's Recommendation Implementation Rate

In November 2024, we reported that, on a government-wide basis, 70 percent of our recommendations made 4 years ago were implemented.[1] HHS's recommendation implementation rate was about 62 percent as of March 2025. As of April 2025, HHS had 452 open recommendations.

Implemented, Closed, and New Priority Recommendations

Our May 2024 letter to the Secretary and others identified 35 priority recommendations.[2] Since then, four recommendations were implemented, and we added four new priority recommendations.

Implemented recommendations:

- In September 2024, the Centers for Disease Control and Prevention (CDC) provided information on efforts to share science and data with the public, including Open CDC, an open technology platform to share public health data sets, code repositories, and rules that enable software applications to exchange data.[3] As of February 2025, CDC made such information available through a public data-sharing platform. These actions addressed our May 2020 recommendation and will help ensure full reproducibility of CDC's research.

- In February 2025, CMS provided its security assessment policy, which identifies multiple options for meeting the requirements of an independent assessment to maximize coordination with other federal agencies to the greatest extent practicable. This action addressed our May 2020 recommendation and may help CMS reduce unnecessary burdens on state officials' time and resources, by, for example, avoiding the need for officials to respond to duplicative requests and inquiries.[4]

- In January 2025, the U.S. Department of Agriculture and HHS took steps to consult with sector partners and develop methods for obtaining information. These actions addressed

[1]GAO, *Performance and Accountability Report: Fiscal Year 2024*, (Washington, D.C.: Nov. 15, 2024).

[2]GAO, *Priority Open Recommendations: Department of Health and Human Services*, GAO-24-107257 (Washington, D.C.: May 28, 2024).

[3]GAO, *Infectious Disease Modeling: Opportunities to Improve Coordination and Ensure Reproducibility*, GAO-20-372 (Washington, D.C.: May 13, 2020).

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

our February 2018 recommendation and increased the agencies' awareness of the data limitations they have about the sector's cybersecurity posture.[5]

- In November 2024, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that changed the low-volume payment adjustment treatment threshold for end-stage renal disease to a tiered adjustment. This action addressed our March 2013 recommendation and diminished the incentive for dialysis facilities to limit service provision.[6]

New priority recommendations: The four new priority recommendations fall into the public health emergency preparedness and response and Food and Drug Administration (FDA) oversight areas. (See Enclosure 1.)

High-Risk List

In February 2025, we issued our biennial update to our High-Risk List.[7] 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. Four of our high-risk areas—(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—directly center on HHS. Additionally, the improving federal oversight of food safety high-risk area centers on HHS and the U.S. Department of Agriculture (USDA), the agencies with primary responsibility for food safety.

Several other government-wide, high-risk areas also have direct implications for HHS and its operations. These include improving IT acquisitions and management, improving strategic human capital management and the government-wide personnel security clearance process, improving federal management of programs that serve tribes and their members, national efforts to prevent, respond to, and recover from drug misuse, managing federal real property, and ensuring the cybersecurity of the nation.

In addition to HHS's high-risk areas, we urge your continued attention to the other government-wide, high-risk issues as they relate to HHS. 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 high-risk issues.[8]

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

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

[7] GAO, *High-Risk Series*: *Heightened Attention Could Save Billions More and Improve Government Efficiency and Effectiveness*, GAO-25-107743 (Washington, D.C.: Feb. 25, 2025).

[8]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).

Congress's Role on GAO Recommendations

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 congressional oversight actions that can help agencies implement priority recommendations and address any underlying issues relating to such implementation.[9]

Congress can use various strategies to address 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 can 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 can pass legislation providing an agency explicit authority to implement a recommendation or requiring an agency to take certain actions to implement a recommendation.

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