U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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Comptroller General
of the United States

May 10, 2023

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

Priority Open Recommendations: Department of Health and Human Services

Dear Mr. Secretary:

The purpose of this letter is to update you on the overall status of the U.S. Department of Health and Human Services' (HHS) implementation of our recommendations and call your continued personal attention to areas where recommendations should be given high priority.[1] In November 2022, we reported that, government-wide, 77 percent of our recommendations made 4 years ago were implemented.[2] HHS's recommendation implementation rate was 90 percent.[3] As of April 2023, HHS had not implemented 491 recommendations. Implementing all of our recommendations could significantly improve HHS's operations.

In our May 2022 letter to the department, we designated 56 recommendations as priorities for HHS, and HHS has since implemented 12 of them.[4] In doing so, HHS has taken steps to

[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 2022*, GAO-23-900398 (Washington, D.C.: Nov. 15, 2022).

[3]HHS's implementation rate increased in each of the past 4 years, from 61 percent for fiscal year 2019 to 90 percent for fiscal year 2022.

[4]We also determined that three recommendations no longer warrant priority attention. The first was for HHS to work with stakeholders to help states track supply requests and plan for supply for the remainder of the COVID-19 pandemic response. The global medical supply chain was severely constrained at the time the recommendation was made; however, it has since recovered from initial shortages. While we no longer believe this recommendation warrants priority attention, we believe it still needs to be addressed. GAO, *COVID-19: Federal Efforts Could Be Strengthened by Timely and Concerted Actions,* GAO-20-701 (Washington, D.C.: Sept. 21, 2020).

The second recommendation was for the Centers for Medicare & Medicaid Services (CMS) to expand its review of states' screening and enrollment requirements for providers. CMS has taken some actions to address the recommendation, such as by introducing a series of tools to enhance monitoring and oversight. In addition, during the pandemic, CMS used additional authorities available in certain emergency circumstances to waive Medicaid requirements to help ensure the availability of care. Thus, states have used federal flexibilities to waive certain provider screening and enrollment requirements to help respond to the COVID-19 pandemic. Based on the actions CMS has taken and states' use of flexibilities, we no longer believe this recommendation warrants priority attention,

- implement two recommendations to stabilize the supply chain and mitigate medical supply gaps in response to the COVID-19 pandemic;[5]

- adequately staff liaisons to support local emergency operations centers during disasters and emergencies;[6]

- help ensure their emergency responder workforce hiring target, once achieved, will be sufficient to provide an effective medical response to a nationwide event or multiple concurrent events, including the health needs of at-risk individuals;[7]

- promote timely referral to law enforcement when a crime against a nursing home resident is suspected;[8]

- improve oversight of Medicaid managed care program integrity by implementing two recommendations to focus additional audit resources in this area and remove impediments to audits;[9]

- demonstrate how the agency has used Medicare Advantage encounter data for various purposes other than risk adjustment—including monitoring Medicare Advantage program integrity—which can help the agency ensure that the amount and types of data being collected are sufficient for such purposes;[10]

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although we believe it still needs to be fully addressed. GAO, *Medicaid Providers: CMS Oversight Should Ensure State Implementation of Screening and Enrollment Requirements,* GAO-20-8 (Washington, D.C.: Oct. 10, 2019).

The third recommendation was for CMS to develop a policy establishing criteria for when Medicaid payments at the provider level are economical and efficient. Congress and CMS have taken some actions to address this recommendation. In December 2020, legislation was enacted requiring additional state reporting on Medicaid supplemental payments, including requiring states to describe how these payments are consistent with economy and efficiency. Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, div. CC, tit. II, § 202, 134 Stat. 1182, 2977 (2020). In December 2021, CMS issued guidance on these new requirements; however, officials said neither the law nor the guidance establish criteria for economy and efficiency for Medicaid supplemental payments at the provider level. Based on the actions taken, we no longer believe this recommendation warrants priority attention, although we believe additional action is still needed. GAO, *Medicaid: CMS Oversight of Provider Payments Is Hampered by Limited Data and Unclear Policy,* GAO-15-322 (Washington, D.C.: Apr. 10, 2015).

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

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

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

[9]GAO, *Medicaid: CMS Should Take Steps to Mitigate Program Risks in Managed Care,* GAO-18-291 (Washington, D.C.: May 7, 2018) and GAO, *Medicaid Managed Care: Improvements Needed to Better Oversee Payment Risks,* GAO-18-528 (Washington, D.C.: July 26, 2018).

[10]GAO, *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).

- annually report improper payment estimates and error rates for the advance premium tax credit program;[11]
- increase the efficiency and accuracy of the interagency process for referring noncitizen children who have no lawful immigration status and no parents or guardians in the United States—known as unaccompanied children—from the Department of Homeland Security for placement in HHS-funded shelters;[12]
- enhance coordination with the U.S. Department of Agriculture in developing testing methodology and standards for imported seafood;[13] and
- enhance collaboration with the U.S. Department of Agriculture for oversight of cell-cultured meat.[14]

We ask your continued attention to the remaining 41 priority recommendations we identified in our 2022 letter. We also are adding four new priority recommendations related to public health emergency preparedness; public health and human services program oversight; and health information technology and cybersecurity. With these additions, the total number of priority recommendations is 45. (See enclosure for the list of recommendations.)

The 45 priority recommendations fall into the following seven areas.

COVID-19 response and other public health emergency preparedness. 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. We have identified 11 priority recommendations in this area, such as identifying how the Defense Production Act and similar actions will be used to increase domestic production of medical supplies going forward and developing 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 capacity to address the recovery from the COVID-19 pandemic, and its 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 seven priority recommendations that, if implemented, would strengthen oversight of public health and human services by, for example, assessing the

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

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

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

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

likelihood and impact of fraud risks to the Head Start program and ensuring that HHS has key information to monitor trends in abuse in nursing homes.

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. We have identified five priority recommendations in this area, such as ensuring that FDA resolves disagreements regarding roles and responsibilities for overseeing laboratory safety; assessing the effectiveness of the foreign offices' contributions to drug safety; and that the agency's future drug manufacturing inspection plans account for its backlog of inspections. If implemented, 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 that served about 82 million low-income and medically needy individuals at an estimated cost of $516 billion to the federal government in fiscal year 2022. By implementing the seven priority recommendations in this area—such as collecting complete data on beneficiary blood lead screenings and ensuring greater transparency for certain Medicaid demonstration applications—HHS could improve oversight of Medicaid funding and protect the health and welfare of Medicaid beneficiaries.

Medicare program. In fiscal year 2022, the Medicare program spent an estimated $768 billion to provide health care services for about 65 million elderly and disabled beneficiaries, with spending expected to increase significantly over the next 10 years. We have identified seven priority recommendations in this area, such as fully validating Medicare Advantage (MA) encounter data and improving the accuracy of the adjustment to MA payments to account for differences in diagnostic coding practices between MA and Medicare fee-for-service. If implemented, these recommendations would help HHS improve the Medicare program's payment policy and design, potentially improving the sustainability of the program by, for example, reducing 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 $127 billion in fiscal year 2022. We have identified four priority recommendations that, if implemented, could reduce improper payments, such as by improving oversight of providers. For example, one recommendation is for the Centers for Medicare & Medicaid Services (CMS) to complete a comprehensive, national risk assessment and assure 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 demonstrate compliance with coverage policies and effectively address program risks.

Health information technology and cybersecurity. The federal government exchanges a large variety of sensitive information with states to implement key federal and state programs. Recent high-profile cyberattacks targeting the public and private sectors highlight the urgent need to address cybersecurity weaknesses. We have identified four priority recommendations in this area that, for example, call for CMS to revise its policies to maximize coordination with other federal agencies on the assessment of state agencies' cybersecurity. In addition, we urge HHS, as a risk management agency for the (1) food and agriculture and (2) healthcare and public health sectors, to implement our priority recommendation related to critical infrastructure protection by working with its sector partners 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* within these sectors.

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.[15] We designated HHS's leadership and coordination of public health emergencies as a new high-risk area in January 2022.[16]

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,[17] 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, 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.[18]

In addition to your continued attention to these issues, Congress plays a key role in providing oversight and maintaining focus on our recommendations to ensure they are implemented and produce their desired results. Legislation enacted in December 2022 included a provision for GAO to identify any additional congressional oversight actions that can help agencies

[15]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).

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

[17]With regard to cybersecurity, we also urge you to use foundational information and communications technology supply chain risk management practices set forth in our December 2020 report: GAO, *Information Technology: Federal Agencies Need to Take Urgent Action to Manage Supply Chain Risks,* GAO-21-171 (Washington, D.C.: Dec. 15, 2020).

[18]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).

implement priority recommendations and address any underlying issues relating to such implementation.[19]

There are various strategies Congress can use in addressing 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 the Office of Management and Budget and the appropriate congressional committees. In addition, the report will be available on our website at www.gao.gov.

I appreciate HHS's commitment to these important issues. If you have any questions or would like to discuss any of the issues outlined in this letter, please do not hesitate to contact me or Jessica Farb, Managing Director, Health Care at FarbJ@gao.gov or 202-512-7114. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Our teams will continue to coordinate with your staff on all 491 open recommendations. Thank you for your attention to these matters.

Sincerely yours,

Gene L. Dodaro
Comptroller General
of the United States

Enclosure – 1

cc: Sean McCluskie, Chief of Staff, Department of Health and Human Services
January Contreras, Assistant Secretary, Administration for Children and Families
Robert Gordon, Assistant Secretary for Financial Resources
Benjamin Sommers, Senior Official Performing the Duties of the Assistant Secretary for Planning and Evaluation

[19]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)).

Dawn O'Connell, Assistant Secretary for Preparedness and Response
Rochelle Walensky, Director, Centers for Disease Control and Prevention
Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services
Robert Califf, Commissioner, Food and Drug Administration
Carole Johnson, Administrator, Health Resources and Services Administration
Roselyn Tso, Director, Indian Health Service
The Honorable Shalanda Young, Director, Office of Management and Budget

Enclosure 1

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

COVID-19 Response and Other Public Health Emergency Preparedness

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 Threat-Based Reviews. 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. After developing plans and analyses to support a reformed PHEMCE, HHS relaunched it in February 2022.

As of January 2023, HHS reported that it was hiring staff to support the PHEMCE and continuing to develop and implement new operating procedures, noting that the PHEMCE was operating under interim business rules. Until HHS finalizes and fully implements PHEMCE operating procedures, HHS risks being unable to fulfill its 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

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

Year recommendations made: 2021

Recommendation: The Secretary of Health and Human Services should develop and make publicly available a comprehensive national COVID-19 testing strategy that

[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 priority letter, we refer to ASPR under the organizational name and structure in place at the time the recommendations were made.

incorporates all six characteristics of an effective national strategy.[2] Such a strategy could build upon existing strategy documents that HHS has produced for the public and Congress to allow for a more coordinated pandemic testing approach.

Actions needed: HHS partially agreed with this recommendation. In March 2022, the White House updated its general COVID-19 strategy, which provided new strategic elements related to testing. However, this updated strategy did not contain all of the elements of an effective national strategy, such as clearly defined performance metrics and benchmarks related to COVID-19 testing, which would be necessary to fully implement this recommendation. As of January 2023, HHS had not demonstrated additional progress toward implementing this recommendation.

To fully implement our recommendation, HHS needs to incorporate additional elements of an effective national strategy into its existing COVID-19 strategy documentation or develop a new strategy related to COVID-19 testing. We maintain that a comprehensive and public national strategy is an important investment in resources so that all participants have the necessary information to support an informed and coordinated testing response across all phases of the pandemic and that progress toward recovery can be measured. We also maintain that this can be done efficiently and flexibly, without imposing unnecessary burden, by building upon existing strategy documentation. Such a strategy could also be a living document, allowing for changes to be made publicly and transparently as new information is gained.

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

Actions needed: HHS partially agreed with this recommendation. In July 2021, HHS stated that an existing workgroup established as part of HHS's COVID-19 response has helped to align COVID-19 data collection and reporting efforts. HHS said it continues to consider ways to establish more permanent workgroups to incorporate best practices for ongoing interagency data needs.

To fully implement our recommendation, HHS needs to establish an expert committee or use an existing one that includes knowledgeable health care professionals outside the federal government, which, as of January 2023, HHS had not done. We maintain that including knowledgeable health care professionals from the public and private sectors, academia, and nonprofits is important to help inform the federal government's response to the COVID-19 pandemic and its preparedness for future pandemics.

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

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

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

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

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

Year recommendation made: 2021

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

Actions needed: HHS agreed with this recommendation. However, as of January 2023, no specific action had been taken by HHS. Agency officials stated that they are evaluating the potential use of DPA authorities to respond to future pandemics and national emergencies, but have not identified specific actions taken to implement the recommendation. Identifying how the DPA and similar actions will be used to increase domestic production of medical supplies in the future can help inform efforts to reduce reliance on foreign manufacturers and increase domestic production of essential medical items.

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

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

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

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

Year recommendation made: 2020

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

Actions needed: HHS partially agreed with this recommendation. However, as of January 2023, no specific action had been taken by HHS. The agency noted that while retrospective reporting may provide some value to understand the historic trajectory of

the pandemic and its effect on nursing homes, HHS does not believe that obtaining these data would lead to different or additional actions for emergency response purposes. We maintain that collecting data on COVID-19 cases and deaths from nursing homes retroactively would provide HHS with a more complete picture of the toll of the pandemic.

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

Directors: John E. Dicken, Health Care

Contact information: DickenJ@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 January 2023, HHS reiterated the response it provided in 2021 and 2022—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 provided any information on steps taken to develop this process and 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 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. CDC further stated it had also added language to a resource document for publication authors, encouraging them to include information on model type and code in publications that use models. Finally, CDC noted it is undergoing a process to modernize how it provides information.

To fully implement this recommendation, CDC needs to finish updating 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 Howard, Science, Technology Assessment, and Analytics

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

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

Year recommendations made: 2020

Recommendations:

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

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

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

Actions needed: HHS agreed with these recommendations. As of February 2023, HHS said that the issuance of the updated National Biodefense Strategy and associated plans in October 2022 fundamentally changed the governance structure for the Strategy's implementation and said it could not take further action on these recommendations. In April 2021, HHS described actions it had taken to implement the recommendations, but did not provide supporting documentation that would allow GAO to assess the extent to which these actions responded to the report findings and the recommendations. We are assessing the National Biodefense Strategy and associated plans and awaiting supporting documentation for steps taken by HHS to determine whether actions taken prior to changes in the governance structure addressed the intent of our recommendations.

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

We previously reported that to fully implement the second recommendation, HHS needed to document standard operating procedures it said it was developing, and the procedures must outline how the Biodefense Coordination Team plans to account for

nonfederal capabilities in its annual assessment. HHS also needs to provide other guidance documents established for the annual assessment that clearly articulate the methods to be used. Until HHS fully implements this recommendation, the federal agencies that support national biodefense capabilities will be limited in their ability to effectively use established processes to support an enterprise-wide risk management approach.

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

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

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

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

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

Year recommendation made: 2019

Recommendation: ASPR should work with support agencies to develop and finalize memorandums of agreement that include information on the capabilities and limitations of these agencies to meet emergency support function (ESF) #8 core capabilities.[3]

Actions needed: HHS disagreed with this recommendation. As of January 2023, HHS stated that the National Response Framework articulates how ESFs operate during incident response, and that further agreements are not needed to outline functions and responsibilities. In addition, HHS stated that it does not plan to develop a list of capabilities because capabilities can change, and due to the structure of the National Response Framework, all agency partners can quickly come together during a response to collaborate and coordinate resources.

We agree that HHS and all of its partners may be able to come together quickly to collaborate and coordinate resources during a response; however, as evidenced by the capabilities misalignment identified in our report, this was not enough during the response to Hurricanes Irma and Maria in the U.S. Virgin Islands and Puerto Rico, respectively. Further, as we reported, ASPR officials acknowledged that more needs to be done to better understand the resources available from its support agencies.

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

We maintain that ASPR needs to take steps to ensure it has a sufficient understanding of each ESF #8 support agency's potential capabilities and limitations. Without taking these steps, the agency remains unprepared to respond to future large-scale disasters and 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

Public Health and Human Services Program Oversight

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.

Year recommendation made: 2022

Recommendation: The Administrator of the Administration for Community Living (ACL) should identify a collaborative mechanism to facilitate sustained information sharing on all populations at risk of falls and in need of evidence-based falls prevention, home modifications, or home assessments. For example, this could be accomplished by establishing an interagency working group or by building upon the existing efforts to expand the reach of the Housing and Services Resource Center.

Actions needed: HHS agreed with this recommendation and, as of February 2023, took steps to implement it. For example, in summer 2022, the Housing and Services Resource Center began a six-week training program on home modification for disability and aging organizations. ACL officials also said they met with CDC officials to share information about programs and studies. Additionally, ACL officials said they began discussing collaborative opportunities with officials from the Department of Veterans Affairs (VA) on home modification and falls prevention programs.

To fully implement this recommendation, HHS needs to develop a plan to sustain information sharing and collaboration, including with VA, to address additional populations at risk of falls, such as veterans. Until it does so, ACL will not be able to ensure that all agencies with useful knowledge and skills contribute to efforts to help people stay in their homes and communities.

Director: Kathryn Larin, Education, Workforce, and Income Security

Contact information: LarinK@gao.gov, 202-512-7215

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, including those apprehended with an adult.

Actions needed: HHS and the Department of Homeland Security (DHS) agreed with this recommendation. DHS, in coordination with HHS, implemented its Unified Immigration Portal, which provides real-time data to track unaccompanied children from time of apprehension to their referral and placement in HHS-funded facilities, including those apprehended with an adult. Additionally, HHS continues to implement its updated data system, which automates the process for referring unaccompanied children from DHS to HHS. However, as of January 2023, the information gaps we highlighted in our report continued to exist. In particular, ORR officials stated they do not consistently receive information from DHS about the adults who arrived with unaccompanied children, which would help ORR make placement and release decisions. Also, DHS officials told us they lacked clarity from ORR on such gaps, including the specific information about family separations that ORR requires.

To fully address this recommendation, DHS and HHS should collaborate to address information sharing gaps identified to ensure that HHS's ORR receives information needed to make decisions for unaccompanied children, including those apprehended with an adult. Doing so would 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

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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 January 2023, 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 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 included changes to how it oversees abuse investigations. As of January 2023, we requested additional information from CMS on this guidance, and we will evaluate this information upon receipt to determine whether it fully implements our recommendation. Taking the actions we recommended will help ensure that CMS has key information needed to address the most prevalent types of abuse and perpetrators.

Director: John E. Dicken, Health Care

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

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

Year recommendations made: 2019

Recommendation: The Secretary of Health and Human Services should revise HHS's procedures for conducting improper payment risk assessments to help ensure that all programs and activities are assessed for susceptibility to significant improper payments at least once every 3 years, as required by the Improper Payments Information Act of 2002, as amended.[4]

Actions needed: HHS agreed with this recommendation and has taken actions that partially addressed it. In February 2023, HHS provided documents indicating that it was extending the amount of time HHS divisions have to complete their improper payment risk assessments; revising questions in its risk assessment template; and in the process of finalizing a program inventory and schedule for a 3-year cycle of assessments for all programs and activities with more than $10 million in annual outlays.

To fully implement this recommendation, HHS needs to finalize its program inventory and assessment schedule and provide procedural or guidance documents that incorporate HHS's new improper payment risk assessment procedures and processes. Until it has properly designed risk assessments in place, HHS's efforts to reduce improper payments may be hindered.

Director: M. Hannah Padilla, Financial Management and Assurance

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[4]On March 2, 2020, the Payment Integrity Information Act of 2019 (PIIA) repealed the Improper Payments Information Act of 2002, the Improper Payments Elimination and Recovery Act of 2010, and the Improper Payments Elimination and Recovery Improvement Act of 2012. See Pub. L. No. 116-117, § 3(a)(1)-(3),134 Stat. 113, 133 (2020). Although PIIA repealed the legal provisions underlying this recommendation, it also enacted substantially similar requirements in 31 U.S.C. § 3352(a). We therefore have not altered the status of this recommendation.

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

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

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

Actions needed: HHS agreed with these recommendations; however, as of January 2023, it had not taken steps to implement them. HRSA has expressed concerns that, because guidance is not enforceable, it cannot implement these recommendations until the agency has regulatory authority, which HRSA has requested Congress provide.

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

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

Year recommendation made: 2021

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

Actions needed: HHS agreed with this recommendation. In June 2022, FDA reported that the number of risk-based surveillance inspections was increasing and outlined a plan for largely addressing the backlog within 3 years, assuming global conditions that limit travel do not worsen. In January 2023, FDA reiterated this approach.

To fully implement this recommendation, FDA needs to provide documentation of the implementation of this approach—such as in its fiscal year 2024 inspection plans—to

ensure that its inspection plans account for, and respond to, the backlog of drug manufacturing inspections. Until it does so, FDA's backlog of inspections may jeopardize its strategic goal of shifting toward exclusively risk-driven inspections.

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

Director: Mary Denigan-Macauley, Health Care

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

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 said 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.

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

High-risk area: Improving Federal Oversight of Food Safety

Director: Mary Denigan-Macauley, Health Care

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. As of March 2023, FDA described multiple strategic planning efforts it was undertaking to assess the effectiveness of its overseas offices and to track activities that specifically contribute to drug safety outcomes. For example, FDA developed and implemented performance measures related to inspections conducted by overseas office staff and has described plans to develop additional measures not related to inspections.

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.

FDA officials stated they were continuing to develop their cumulative oversight approach. For example, in addition to conducting foreign inspections, the agency reported in January 2023 that it was exploring the use of regulatory partnerships with India, Indonesia, and Ecuador to leverage data and information on imported shrimp. FDA also reported it completed 95 foreign remote regulatory assessments in fiscal year 2022 and three foreign remote regulatory assessments as of January 2023.

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 Morris, Natural Resources & Environment

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

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

Year recommendation made: 2015

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

Actions needed: HHS agreed with this recommendation. As of January 2023, FDA acknowledged in its August 2022 monitoring report that some pesticides with EPA-established tolerances were not in the scope of FDA's testing. In addition, the report acknowledged that FDA does not know the extent to which exposure to these pesticides may occur in the foods that FDA regulates. FDA also included an appendix listing all pesticides analyzed by FDA pesticide methods in that fiscal year.

To fully implement this recommendation, FDA must disclose in its annual pesticide residue monitoring report which pesticides with EPA-established tolerances the agency did not test for in its pesticide monitoring program. Implementing this recommendation could provide users of FDA's annual report with more accurate information and reduce potential misinterpretation of its results.

High-risk area: Improving Federal Oversight of Food Safety

Director: Steve Morris, Natural Resources & Environment

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

Medicaid Program

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

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 but acknowledged the need for additional state Medicaid financing and payment data to oversee the Medicaid program. Regarding supplemental payments, in December 2021, CMS issued guidance on new reporting requirements for payments made in or after October 2021. Regarding state directed managed care payments, in January 2023, CMS officials said the agency has developed tools and a process for collecting standardized information, including on the source of funding of the nonfederal share.

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 January 2023, 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 provide evidence of 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 January 2023, CMS officials said that the agency is planning to update 2016 lead screening guidance in 2023 and will emphasize the importance of complete and accurate data.

To fully implement this recommendation, CMS needs to address limitations in blood lead screening data to better monitor compliance with the agency's blood lead screening policy. Until it does so, CMS will be unable to determine how many eligible beneficiaries have received, or not received, blood lead screenings.

High-risk area: Strengthening Medicaid Program Integrity

Director: Michelle B. Rosenberg, Health Care

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

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. 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 January 2023, HHS officials had not informed us of any additional actions taken to implement this recommendation.

To fully implement this recommendation, CMS needs to issue the policy guidance as it previously indicated was planned. Until it does so, CMS and the public may lack key

information to fully understand the potential impact of changes being proposed, including on beneficiaries and costs.

High-risk area: Strengthening Medicaid Program Integrity

Director: Catina B. Latham, Health Care

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

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 reported that the agency would have to explore whether establishing standard, annual reporting requirements would require rulemaking.

To fully implement this recommendation, CMS needs to establish standard Medicaid reporting requirements for all states to report critical incidents annually. Implementing this recommendation would provide evidence that an effective system is in place, provide information on the extent beneficiaries are subject to actual or potential harm, and allow for tracking trends over time.

High-risk area: Strengthening Medicaid Program Integrity

Director: Catina B. Latham, Health Care

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

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

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 2023, CMS had not issued written guidance on this policy. We maintain that CMS should

issue written guidance to all states 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.[5] Despite disagreeing with this recommendation, as of February 2023, HHS had taken some action to address it. In August 2018, HHS issued written guidance through a State Medicaid Directors Letter documenting four key changes it made in 2016 to its budget neutrality policy. 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.

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

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

Medicare Program

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

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[5]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).

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 initially agreed with this recommendation; however, in 2018 and again in January 2023, HHS indicated it was reconsidering whether to implement this recommendation because officials stated that it may not be appropriate to account for Medicaid payments that offset UC costs when determining the amount of Medicare UC payments a hospital should receive. As of January 2023, CMS had not taken any action to implement this recommendation. We maintain that CMS should implement this recommendation because it would (1) ensure that Medicare UC payments are based on accurate levels of UC costs, (2) result in CMS better targeting billions of dollars in Medicare UC payments to hospitals with the most UC costs, and (3) avoid Medicare UC payments to hospitals with little or no UC costs.

Potential financial benefit if implemented: Billions

High-risk area: Medicare Program & Improper Payments

Director: Leslie V. Gordon, Health Care

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

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 generally agreed with this recommendation. As of February 2023, CMS made progress in examining the completeness and accuracy of MA encounter data, but more work remains to fully validate 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 January 2023, CMS stated that the agency was reviewing the LVPA methodology as part of an in-depth analysis of the end-stage renal disease prospective payment system. CMS obtained input on the LVPA and stated that it planned to use this input to inform potential proposals for refining the LVPA in upcoming rulemaking cycles.

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

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

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

Year recommendations made: 2012

Recommendations:

- In order to improve CMS's ability to identify self-referred advanced imaging services and help CMS address the increases in these services, the Administrator of CMS should insert a self-referral flag on its Medicare Part B claims form and require providers to indicate whether the advanced imaging services for which a provider bills Medicare are self-referred or not.
- In order to improve CMS's ability to identify self-referred advanced imaging services and help CMS address the increases in these services, the Administrator of CMS should determine and implement a payment reduction for self-referred advanced imaging services to recognize efficiencies when the same provider refers and performs a service.
- In order to improve CMS's ability to identify self-referred advanced imaging services and help CMS address the increases in these services, the Administrator of CMS should determine and implement an approach to ensure the appropriateness of advanced imaging services referred by self-referring providers.

Actions needed: HHS disagreed with the first two recommendations and, as of January 2023, had no plans to take further action. For the first recommendation, CMS believes that a new checkbox on the claim form identifying self-referral would be complex to administer and that providers may not characterize referrals accurately. We maintain that such a flag on Part B claims would likely be the easiest and most cost-effective way for CMS to identify self-referred advanced imaging services and monitor the behavior of those providers who self-refer these services.

For the second recommendation, CMS does not believe that a payment reduction would address overutilization that occurs as a result of self-referral and that the agency's multiple procedure payment reduction policy for advanced imaging already captures efficiencies inherent in providing multiple advanced imaging services by the same physician. Further, CMS does not think a payment reduction for self-referred services would be effective. We maintain that CMS should determine and implement a payment reduction to recognize efficiencies for advanced imaging services referred and performed by the same provider.

HHS initially stated that it would consider the third recommendation, but as of January 2023, the agency disagreed and had no plans to take further action. However, we maintain that this recommendation is valid, in part because we found that providers who began to self-refer advanced imaging services substantially increased their referral of such services relative to other providers in 2010. To the extent that these additional referrals are unnecessary, they pose an unacceptable risk for beneficiaries, particularly in the case of computerized tomography services, which involve the use of ionizing radiation. We maintain that this recommendation is warranted to help address the increases in these services and help protect beneficiaries.

High-risk area: Medicare Program & Improper Payments

Director: Jessica Farb, Health Care

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

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: As of March 2021, the agency agreed with this recommendation. CMS applied the statutory minimum adjustment to MA payments for calendar year 2023; however, as of January 2023, 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

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

Improper Payments in Medicaid and Medicare

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

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. As of January 2023, CMS noted that the agency had clarified and amended several Medicare documentation requirements as part of an agency initiative to assess such requirements. CMS further stated that Medicaid documentation requirements are generally established at the state level and that the agency has taken steps to identify best practices for documentation requirements and share them with states.

To fully implement this recommendation, CMS needs to assess documentation requirements in both programs to better understand how the variation in the programs' requirements affects estimated improper payment rates. Until it does so, CMS may not have the information it needs to ensure that the programs' documentation requirements are effective and appropriately address program risks.

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

Director: Leslie V. Gordon, Health Care

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

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

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; however, CMS has suspended steps to conduct a comprehensive national risk assessment. CMS developed a standard tool to assess risk and staff capacity in October 2019, but the implementation of this tool was suspended in November 2019 when the agency initiated a reorganization of its regional office functions, including financial oversight. According to CMS, the reorganization is intended to improve coordination between central and regional offices so that financial operations are consistent across the nation. As of January 2023, the tool remained suspended, and HHS officials had not informed us of any additional actions taken to implement this recommendation. We maintain that completing a risk assessment is still necessary to 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 and, as of January 2023, had not taken steps to seek legislative authority to allow the RAs to conduct prepayment claim reviews. We maintain that prepayment reviews protect agency funds better than postpayment reviews, and we believe that seeking this authority is consistent with CMS's strategy to pay claims properly the first time. Until CMS seeks and implements 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

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

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. HHS stated that, as of January 2023, CMS had taken steps to improve the timeliness of the contract-level RADV audit process, such as aligning the time frames in CMS's contract-level RADV audits with those of the national RADV audits.

To fully implement this recommendation, CMS will need to provide evidence that it has completed steps such as these and that the agency's actions have enhanced the timeliness of CMS's contract-level RADV process. Implementing this recommendation would potentially allow CMS to 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 Information Technology and Cybersecurity

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. In September 2022, HHS said 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 2023, we were awaiting HHS's first update on any actions it has taken on this recommendation. Implementing this recommendation would help ensure consistent focus on privacy among senior leadership, facilitate cross-agency coordination, and elevate the importance of privacy.

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. As of January 2023, HHS 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, completing a procurement to ensure HHS Protect's continued operation through September 30, 2023, and approving a new governance structure.

To fully implement this recommendation, HHS should ensure that the PAHPAIA work plan includes specific long-term actions in addition to near-term actions to show progress in the network's development. Until HHS fully implements this recommendation, it may not be able to show that it is making significant progress in developing the network.

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 January 2023, 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 (OMB) 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.[6]

Actions needed: HHS agreed with this recommendation. As of January 2023, HHS stated that ASPR and the Office for Civil Rights were taking several steps to promote the National Institute of Standards and Technology framework in the healthcare and public health sector, such as including references to the framework in a security risk assessment tool, newsletters, and other outreach. While HHS has encouraged and supported the use of the framework, to protect critical infrastructure, the agency needs to implement this recommendation so it can gain a more comprehensive understanding of the framework's use.

In addition, as of January 2023, HHS coordinated with the Department of Agriculture in taking initial steps to determine framework adoption across the sector by distributing two requests for information to food and agriculture sector members in the past 2 years. 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. As of February 2023, the Department of Agriculture stated that it has collaborated with HHS and the DHS to determine if alternative methods for collecting and assessing more substantive information, but the agencies have not yet identified alternative approaches.

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

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

Director: David B. Hinchman, Information Technology and Cybersecurity

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