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Comptroller General
of the United States

Accessible Version

May 19, 2021

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

Priority Open Recommendations: Department of Health and Human Services

Dear Mr. Secretary:

The purpose of this letter is to provide an update on the overall status of the U.S. Department of Health and Human Services' (HHS) implementation of GAO's recommendations and call your personal attention to areas where recommendations should be given high priority.[1] In November 2020, we reported that on a government-wide basis, 77 percent of our recommendations made 4 years ago were implemented.[2] As of May 2021, HHS had 458 open recommendations with an implementation rate of 64 percent. Implementing all open recommendations could significantly improve HHS's operations.

In our April 2020 letter to the Department, we designated 55 recommendations as priorities for HHS, and HHS has since implemented eight of them. In doing so, HHS has taken steps to improve the quality of care in the Indian Health Service's federally operated facilities, implemented initiatives to improve the accuracy and completeness of Medicaid data to expedite their use for program oversight, strengthened controls over the determination of eligibility for the premium tax credit used to help individuals purchase health insurance coverage through health insurance marketplaces, and developed guidance, policies, and procedures to improve implementation of information security controls among qualified entities and researchers. In addition to the eight priority recommendations HHS implemented, four are no longer included in this letter, for example, because they became a lower priority as a result of statutory or programmatic changes, as discussed below in the relevant sections.

We ask your attention to the 43 priority recommendations remaining from those we identified in the 2020 letter. We also are adding 18 new priority recommendations related to the response to, and recovery from, the Coronavirus Disease 2019 (COVID-19) pandemic and other public health emergency preparedness issues, public health and human services program oversight, Food and Drug Administration (FDA) oversight, and the Medicaid program, bringing the total number of priority recommendations to 61. (See enclosure for a more comprehensive description of all 61 recommendations).

[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 operation; 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 2020*, GAO-21-4SP (Washington, D.C.: Nov. 16, 2020).

The 61 priority recommendations fall into the following 9 areas.

COVID-19 response and other public health emergency preparedness.

The COVID-19 pandemic highlights the critical need for an effective national response to public health emergencies. We have identified 17 priority recommendations that will help improve HHS's preparedness to address the ongoing and evolving challenges of the COVID-19 pandemic—as well as any future public health emergencies. For example:

- In January 2021, we recommended that HHS develop and make publically available a comprehensive national COVID-19 testing strategy that incorporates all six characteristics of an effective national strategy. This includes, for example, clear designation of organizational roles, responsibilities, and coordination as well as resource needs and benchmarks to measure progress. In making this recommendation, we noted that the national strategy could build upon existing strategy documents that HHS has previously produced. HHS partially concurred with our recommendation. In particular, while HHS agreed that the department should take steps to directly incorporate some of the elements of an effective national strategy, officials expressed concerns that producing the strategy at this time would be overly burdensome on federal, state, and local entities responding to the COVID-19 pandemic, and may be outdated by the time it was finalized or potentially obsolete given the rate of technological advancement. We maintain that a comprehensive and public national strategy is an important and worthwhile investment in resources so that all participants have the necessary information to support an informed and coordinated testing response to accomplish shared goals. We also maintain this can be done efficiently and flexibly, without imposing unnecessary burden.
- In September 2020, we recommended that HHS, with support from the Department of Defense, establish a time frame for documenting and sharing a national plan for distributing and administering COVID-19 vaccines. We noted in our report that HHS, in developing such a plan, should ensure that it is consistent with best practices for project planning and scheduling and that this plan should specify an approach for coordinating efforts across federal agencies and nonfederal entities. HHS neither agreed nor disagreed with our recommendation. In September and October 2020, HHS' Centers for Disease Control and Prevention (CDC) released initial planning documents, and in January 2021, the White House issued a national COVID-19 response strategy that broadly outlined various channels for vaccine distribution. In addition, CDC provided a high-level description of its activities in a March 2021 COVID-19 vaccine distribution strategy and noted that more details would be included in future reports to Congress. CDC indicated that it expects to release its next report to Congress in May 2021, and we will evaluate this report once it is issued to determine whether it fully implements our recommendation.
- In September 2020, we recommended that HHS, in consultation with the Centers for Medicare & Medicaid Services (CMS) and CDC, 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. HHS partially agreed with our recommendation. Specifically, HHS agreed that collecting more complete data would be useful for determining the total number of nursing homes affected, the extent of morbidity and mortality, and changes in incidence over time. Further, HHS noted that having complete data would be useful in the review of policies and practices put in place during the pandemic. However, HHS

said that, because retroactively collecting the data may be overly burdensome on health care providers, it does not believe devoting substantial agency or health care provider resources during the pandemic would be prudent. We maintain the importance of developing a strategy to collect data from this critical time period of early COVID-19 spread in nursing homes and that HHS could begin by incorporating data previously reported to CDC or to state or local public health offices, which would ease the burden on nursing homes.

Public health and human services program oversight.

We have identified 11 priority recommendations that would strengthen oversight of public health and human services programs, such as the HHS program that provides care to noncitizen children without lawful immigration status or parents or guardians in the United States, known as unaccompanied children. For example:

- In February 2020, we recommended that HHS and the Department of Homeland Security (DHS) collaborate to address information sharing gaps to ensure that HHS receives information needed to make decisions for unaccompanied children, including those apprehended with an adult. HHS and DHS concurred with our recommendation and, as of May 2021, DHS officials said they plan to meet regularly with HHS to coordinate their efforts, which includes development of an interagency portal for information sharing. Further, in March 2021, DHS components and HHS signed a memorandum of agreement on unaccompanied children information sharing. HHS officials also told us that HHS is developing a new data system, which would be integrated with the portal and allow HHS to retrieve data on a child's status in a more automated manner. DHS and HHS reported that they would provide an update on the status of their efforts by September 2021. Until DHS and HHS implement procedures aimed at improving the efficiency and accuracy of the interagency unaccompanied children referral and placement process, information-sharing gaps will remain. We will continue to monitor and evaluate HHS's actions to determine the extent to which they fully address our recommendation.

FDA oversight.

We have identified five priority recommendations that would help FDA ensure the safety of medical products and food imported into the United States, including addressing any backlog of inspections caused by the COVID-19 pandemic. For example:

- In January 2021, we recommended that the Commissioner of 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. FDA concurred with our recommendation and as of January 2021, stated that the agency is actively tracking the list of sites that need to be inspected. To fully implement our recommendation, FDA should provide documentation that its inspection plans identify, analyze, and respond to the issues presented by the backlog of inspections.

- In September 2017, we recommended that the Commissioner of FDA coordinate and communicate with the U.S. Department of Agriculture Food Safety and Inspection Service (FSIS) in developing methods to test for drug residue in imported seafood, including catfish, and in establishing corresponding maximum residue levels—the

highest level of drug residue allowed in imported seafood before it is considered potentially harmful to human health. FDA concurred with our recommendation and has taken some steps to implement it, including convening quarterly meetings to discuss the establishment of drug residue limits in seafood. However, we found that agencies continue to use different testing methods, which results in the agencies using different maximum residue levels for some drugs. Without the coordination we recommended, the agencies do not have reasonable assurance that they are consistently protecting consumers from unsafe drug residues. To fully implement our recommendation, FDA should coordinate with FSIS on (1) the development of testing methods that both agencies can use on imported seafood, including catfish, and (2) establishing maximum residue levels that would allow the agencies to consistently apply similar standards.

- In December 2016, we recommended that the Commissioner of FDA assess the effectiveness of its foreign offices' contributions to ensuring the safety of imported products. FDA concurred with our recommendation. FDA reported developing new performance measures for these offices as well as a monitoring and evaluation plan in 2018, but as of March 2021 has not reported additional progress. To fully implement our recommendation, FDA should systematically track information to measure whether the offices' activities—such as inspections, import alerts, and warning letters—specifically contribute to drug safety-related outcomes. In addition, as part of our ongoing work in this area, we will continue to obtain updated information on the role of FDA's foreign offices in ensuring the safety of drugs entering the United States.

National efforts to prevent, respond to, and recover from drug misuse.

Drug misuse—the use of illicit drugs and the misuse of prescription drugs—has been a longstanding and persistent problem in the United States and is on GAO's High-Risk List. We have identified one priority recommendation that would address some of the challenges related to treating neonatal abstinence syndrome (NAS)—a withdrawal condition with symptoms including excessive crying and difficulty breathing. Specifically:

- In October 2017, we recommended that the Secretary of HHS expeditiously develop a plan—one that includes priorities, time frames, clear roles and responsibilities, and methods for assessing progress—to effectively implement the NAS-related recommendations that HHS identified in its *Protecting Our Infants Act: Final Strategy*.[3] HHS concurred with our recommendation and finalized a plan in 2019 for implementing the Strategy. The plan includes priorities, time frames, and clear roles and responsibilities for implementing NAS-related recommendations in the Strategy. However, the plan does not specifically identify methods for assessing HHS's progress toward implementing the Strategy's recommendations. In November 2019, HHS stated that the department holds quarterly conference calls to share updates on progress toward implementing the Strategy and that formal written updates will be collected at the end of each year. To fully implement our recommendation, HHS needs to provide

[3]In May 2017, HHS published the *Protecting Our Infants Act: Report to Congress*, which—among other things—presents a strategy that identifies key recommendations related to addressing NAS. Specifically, HHS's strategy—known as the Protecting Our Infants Act: Final Strategy—made 39 recommendations related to the prevention, treatment, and related services for NAS and prenatal opioid use. See Substance Abuse and Mental Health Services Administration, "Protecting Our Infants Act: Report to Congress," May 2017.

documentation—such as the formal written updates—showing how the department assesses its progress in implementing the Strategy's recommendations.

Improper payments in Medicaid and Medicare.

Estimates of improper payments in the Medicaid and Medicare programs continue to be unacceptably high and totaled about $130 billion in fiscal year 2020. We have identified seven priority recommendations that could reduce improper payments by minimizing program risks, expanding the use of prior authorization, and conducting prepayment claim reviews, among other things. For example:

- In May 2018, we recommended that the Administrator of CMS take steps to mitigate the program risks not accounted for in the Medicaid managed care Payment Error Rate Measurement, such as overpayments and unallowable costs. To the extent that overpayments and unallowable costs are unidentified and not removed from the cost data used to set capitation rates, they may lead to inflated Medicaid managed care payments and minimize the appearance of program risks in Medicaid managed care. HHS concurred with our recommendation and stated that it was in the process of developing a strategy to reduce risk in Medicaid managed care. To implement our recommendation, CMS needs to implement its strategy.

- In April 2018, we recommended that the Administrator of CMS take steps, based on the results of evaluations, to continue using prior authorization in Medicare. HHS concurred with our recommendation. Between 2019 and 2020, CMS made some progress toward implementing our recommendation by, for example, adding 18 items to its prior authorization list and resuming or starting five demonstrations. As of March 2021, HHS stated that it will continue evaluating the prior authorization programs. To fully implement our recommendation, CMS needs to take additional steps to evaluate the use of prior authorization by, for example, determining cost savings from its actions. CMS also needs to take additional steps to expand the use of prior authorization, which could include identifying new opportunities for prior authorization for items and services with high unnecessary utilization and high improper payment rates.

- In April 2016, we recommended that CMS seek legislative authority to allow Recovery Auditors to conduct prepayment claim reviews, a step that could better ensure proper Medicare payments and protect Medicare funds. HHS disagreed with our recommendation. HHS noted that other claim review contractors conduct prepayment reviews and that CMS has implemented other programs as part of its strategy to move away from the "pay and chase" process of recovering overpayments, such as enhanced provider enrollment screening. However, we maintain that fully implementing our recommendation is warranted. We found that prepayment reviews better protect agency funds compared with post-payment reviews. Moreover, CMS conducted a demonstration in which the Recovery Auditors conducted prepayment reviews and concluded that the demonstration was a success.

Medicaid program.

We have identified eight priority recommendations in this area that would, among other things, improve oversight of the funding sources for the nonfederal share of payments to providers and improve transparency of Medicaid demonstrations. For example:

- In December 2020, we recommended that the Administrator of CMS collect and document complete and consistent provider-specific information about Medicaid payments to providers and states' sources of funding for the nonfederal share of these payments. HHS neither agreed nor disagreed with our recommendation but acknowledged the need for additional state Medicaid financing and payment data to oversee the Medicaid program. HHS also noted that CMS has taken initial steps to improve the collection of financing and payment information through a revised data collection form and will explore additional actions to do so. In addition, Congress passed and the President signed into law requirements in December 2020 for additional state reporting on Medicaid supplemental payments. To fully implement our recommendation, HHS needs to demonstrate how its ongoing and planned actions in this area, which could include actions in response to the December 2020 law described above, will ensure complete, consistent, and sufficiently documented information about sources of funding for the nonfederal share and payments to providers.

- In April 2019, we recommended that the Administrator of CMS develop a policy for ensuring transparency when states propose significant amendments to section 1115 demonstrations, which allow states to test and evaluate new approaches for delivering Medicaid services. CMS concurred with our recommendation. In December 2020, CMS officials said the agency plans to develop criteria for determining whether an amendment application proposes a substantial change to an existing demonstration and to include this in guidance in 2021. We will evaluate this guidance when it is issued to determine whether it fully addresses our recommendation.

We removed the priority designation from one open recommendation related to CMS oversight of Medicaid supplemental payments that became a lower priority as a result of a statutory change and because the agency could address our primary concern by implementing another related priority recommendation.[4]

Medicare program.

We have identified eight priority recommendations that would help CMS improve the Medicare program's payment policy and design. For example:

- In June 2016, we recommended that the Administrator of CMS account for any Medicaid payments that offset uncompensated care (UC) costs when determining the amount of Medicare UC payments an individual hospital should receive. HHS initially concurred with our recommendation. However, in 2018 and again in March 2021, HHS indicated it was reconsidering whether to implement our recommendation because officials stated that it may not be appropriate to offset Medicare UC payments by Medicaid payments that help offset UC costs. We maintain that CMS should implement our 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.

[4]Specifically, we removed the priority designation from one recommendation related to CMS guidance regarding state reporting of supplemental payments due to a statutory change requiring states to report information about supplemental payments to the Secretary of HHS. We will monitor CMS's implementation of the new reporting requirement through another priority recommendation related to supplemental payments.

- In January 2012, we recommended that CMS take steps to improve the accuracy of the adjustment made to Medicare Advantage (MA) payments to account for differences in diagnostic coding practices between MA and Medicare fee-for-service. These differences in diagnostic coding could lead to beneficiaries in MA plans being assigned inappropriately high risk scores by CMS, which would result in higher than necessary payments. For instance, we found that shortcomings in CMS's adjustment resulted in excess payments to MA plans totaling an estimated $3.2 billion to $5.1 billion over a 3-year period, from 2010 through 2012. HHS concurred with our recommendation and applied the statutory minimum adjustment to MA payments for calendar year 2021. CMS made other changes to its methodology for calculating the diagnostic coding adjustment, which likely have improved accuracy of the adjustment. However, a modified methodology that, for example, incorporates more recent data and accounts for all relevant years of coding differences would better ensure an accurate adjustment in future years. To fully implement our recommendation, CMS needs to provide evidence of the sufficiency of its coding adjustment or re-calculate its adjustment using an updated methodology. Until CMS takes these steps, the agency is at continued risk of making excess payments to MA plans.

Health information technology and cybersecurity.

We identified three priority recommendations that would improve HHS's ability to address cyber-related risks. For example:

- In July 2019, we recommended that the Secretary of HHS (1) develop a cybersecurity risk management strategy and (2) establish a process for conducting an organization-wide cybersecurity risk assessment. HHS concurred with both recommendations. In March 2021, HHS stated that its cybersecurity risk management strategy was undergoing internal review and that the department was developing a process for an organization-wide cybersecurity risk assessment. However, HHS did not provide an estimated date of completion for either the internal review of the risk management strategy or the development of the risk assessment process. To implement our recommendations, HHS needs to ensure that its strategy includes key elements, including a statement of risk tolerance and information on how the department intends to assess, respond to, and monitor cybersecurity risks. In addition, HHS needs to establish a risk assessment process to allow the agency to consider the totality of risk derived from the operation and use of its information systems.

We removed the priority designation from two open recommendations in this area in light of our ongoing work or because additional guidance that HHS needs to implement our recommendation has not been issued.[5] HHS could address our primary concerns by implementing other priority recommendations in this area.

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[5]Specifically, we removed the priority designation from one recommendation related to HHS's establishment of electronic public health situational awareness network capabilities that were mandated by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, as our current work in this area may result in recommendations with higher priority.

In addition, we removed the priority designation from another recommendation related to CMS's plan to discontinue its use of knowledge-based online identity verification approaches. The National Institute of Standards and Technology (NIST) has implemented our priority recommendation to develop additional guidance for agencies and plans to revise this guidance by 2022. The absence of additional guidance from NIST impedes HHS's ability to

Health insurance premium tax credit payment integrity.

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

- In July 2017, we recommended that HHS should annually report improper payment estimates and error rates for the advance PTC program. HHS concurred with our recommendation. In March 2021, CMS reported that it intends to publish an advance PTC improper payment rate in the agency's fiscal year 2022 agency financial report for payments made by the federally-facilitated exchange during benefit year 2020. However, CMS said that developing an advance PTC improper payment rate for payments made by state-based exchanges will be a multi-year process. To fully implement our recommendation, HHS needs to finalize and implement its methodology for producing advance PTC improper payment estimates and publicly report these estimates in its annual financial report.

We closed one recommendation related to tracking cost-sharing reduction subsidies for health plans sold through health insurance marketplaces created by the Patient Protection and Affordable Care Act, even though HHS had not implemented it, because cost-sharing reduction subsidies are no longer paid.

Implementing our priority recommendations could help improve the efficiency and effectiveness of key federal health care programs and funding, including those relevant to the nation's ongoing response to COVID-19. Further, implementing our priority recommendations could be done in conjunction with efforts to address high-risk areas related to HHS. In March 2021, we issued our biennial update to our High-Risk List, which identifies government operations with greater vulnerabilities to fraud, waste, abuse, and mismanagement or the need for transformation to address economy, efficiency, or effectiveness challenges.[6]

The following three high-risk areas center directly on HHS: (1) protecting public health through enhanced oversight of medical products, (2) strengthening Medicaid program integrity, and (3) Medicare program and improper payments. Three additional high-risk areas are shared among multiple agencies, including HHS: (1) improving federal oversight of food safety; (2) national efforts to prevent, respond to, and recover from drug misuse; and (3) enforcement of tax laws. In addition, we identified HHS's leadership and coordination of public health emergencies as an emerging issue in our High-Risk List.[7]

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implement our recommendation in the near future. These two recommendations will remain open until HHS takes appropriate action; however, on their own, these recommendations are not our highest priority.

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

[7]GAO-21-119SP. See pages 14-17 for more information on the emerging issue related to HHS's Leadership and Coordination of Public Health Emergencies.

Several other government-wide high-risk areas also have direct implications for HHS and its operations. These include (1) improving the management of IT acquisitions and operations, (2) improving strategic human capital management, (3) managing federal real property, (4) ensuring the cybersecurity of the nation, and (5) government-wide personnel security clearance process. We urge your attention to the HHS, shared, and 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, and the leadership and staff in agencies, including within HHS.

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

I appreciate HHS's commitment to these important issues. If you have any questions or would like to discuss any of the issues outlined in this letter, please do not hesitate to contact me or A. Nicole Clowers, Managing Director, Health Care at ClowersA@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 458 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
JooYeun Chang, Acting Assistant Secretary, Administration for Children and Families
Norris Cochran, Acting Assistant Secretary for Financial Resources
Rebecca Haffajee, Acting Assistant Secretary for Planning and Evaluation
Nikki Bratcher-Bowman, Acting Assistant Secretary for Preparedness and Response
Rochelle Walensky, Director, Centers for Disease Control and Prevention
Liz Richter, Acting Administrator, Centers for Medicare and Medicaid Services
Janet Woodcock, Acting Commissioner, Food and Drug Administration
Diana Espinosa, Acting Administrator, Health Resources and Services Administration
Elizabeth Fowler, Acting Director, Indian Health Service
The Honorable Shalanda Young, Acting Director, Office of Management and Budget

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

Coronavirus Disease 2019 (COVID-19) Response and Other Public Health Emergency Preparedness

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

Recommendation: The Secretary of HHS should develop and make publicly available a comprehensive national COVID-19 testing strategy that incorporates all six characteristics of an effective national strategy. 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 concurred with our recommendation. In January 2021, HHS agreed that the department should take steps to more directly incorporate some elements of an effective national strategy, but expressed concern that producing such a strategy at this time could be overly burdensome on the federal, state, and local entities that are responding to the pandemic, and that a plan would be outdated by the time it was finalized or potentially rendered obsolete by the rate of technological advancement.[8] Additionally, HHS stated that, to be of value to the whole of nation response to COVID-19, testing plans need to establish guidelines and use metrics that are operationally relevant, which necessitates strategic flexibility in testing plans to guide those managing the response in the use of available resources to address local and state conditions rather than a single static nationwide plan.

As of March 2021, HHS had not implemented our recommendation. While the White House issued a broader COVID-19 National Strategy on January 21, 2021 that includes increasing testing capacity among its seven goals, it does not include all the characteristics of an effective strategy for testing.[9] For example, it does not contain specific performance metrics to be used to measure progress. We maintain that a comprehensive and public national strategy is an important and worthwhile investment in resources so that all participants have the necessary information to support an informed and coordinated testing response to accomplish shared goals. We also maintain this can be done efficiently and flexibly, without imposing unnecessary burden.

Recommendation: To improve the federal government's response to COVID-19 and preparedness for future pandemics, the Secretary of HHS 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.

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[8]The six characteristics of an effective national strategy are: (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).

[9]See White House, *National Strategy for the COVID-19 Response and Pandemic Preparedness,* January 21, 2021.

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 our recommendation. HHS agreed that it should establish a dedicated working group or other mechanism with a focus on addressing COVID-19 data collection shortcomings. However, HHS said because of resource constraints and the ongoing response to the pandemic, it could not commit to immediately doing so. As of March 2021, HHS had not implemented our recommendation. Given the current state of the COVID-19 pandemic and the expanded need for complete and consistent data to assist the federal response and inform the general public (including data on vaccines), we reiterate the importance of immediately establishing an expert committee. Further, we maintain that HHS could use an existing committee, which would help streamline the process and leverage existing resources, to help inform the federal government's response to the pandemic with more complete and consistent COVID-19 data.

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

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

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

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

Actions Needed: HHS disagreed with our recommendation and, as of March 2021, noted, among other things, the work that the department had done to manage the medical supply chain and increase supply availability. We acknowledge those efforts, but maintain that our recommendation is warranted.

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

Actions Needed: HHS disagreed with our recommendation and, as of March 2021, noted, among other things, the work that the department had done to manage the medical supply chain and increase supply availability. We acknowledge those efforts, but we underscore the importance of developing a well-formulated plan to address critical gaps for the remainder of the pandemic.

Recommendation: The Secretary of HHS—who heads one of the agencies leading the COVID-19 response through the Unified Coordination Group—consistent with their roles and responsibilities, should work with relevant federal, state, territorial, and tribal stakeholders to devise interim solutions, such as systems and guidance and

dissemination of best practices, to help states enhance their ability to track the status of supply requests and plan for supply needs for the remainder of the COVID-19 pandemic response.

Actions Needed: HHS disagreed with our recommendation and, as of March 2021, noted, among other things, the work that the department had done to manage the medical supply chain and increase supply availability. We acknowledge those efforts, but maintain our recommendation is warranted.

Recommendation: The Secretary of HHS, with support from the Secretary of Defense, should establish a time frame for documenting and sharing a national plan for distributing and administering COVID-19 vaccine, and in developing such a plan ensure that it is consistent with best practices for project planning and scheduling and outlines an approach for how efforts will be coordinated across federal agencies and nonfederal entities.

Actions Needed: HHS neither agreed nor disagreed with our recommendation. In a March 2021 COVID-19 vaccine distribution strategy, HHS' Centers for Disease Control and Prevention (CDC) provided a high-level description of its activities and noted that more details would be included in future reports to Congress. CDC indicated that it expects to release its next report to Congress in late May 2021, and we will evaluate this report once it is issued to determine whether it fully implements our recommendation.

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

Actions Needed: HHS partially concurred with our recommendation. As of March 2021, no specific action had been taken by HHS, although agency officials stated that they continue to consider how to implement our recommendation. We maintain that collecting data on COVID-19 cases and deaths from nursing homes retroactively would better inform the government's continued response and recovery, and we maintain that HHS could ease the burden by incorporating data previously reported to CDC or to state or local public health offices.

Recommendation: As CDC implements its COVID-19 Response Health Equity Strategy, the Director of CDC should take steps to help ensure CDC's ability to comprehensively assess the long-term health outcomes of persons with COVID-19, including by race and ethnicity.

Actions Needed: CDC concurred with our recommendation. In response to our recommendation, CDC noted in October 2020 that the agency was convening a team to develop a plan to monitor the long-term health outcomes of persons with COVID-19 by identifying health care surveillance systems that can electronically report health conditions to state and local health departments. As of May 2021, the agency had various efforts underway with external partners to assess long-term health outcomes. To fully implement our recommendation, CDC needs to provide public documentation of its

efforts to understand the long-term effects of COVID-19 illness, including documentation of funded studies and analyses of electronic health record data.

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

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

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

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

Actions Needed: HHS concurred with this recommendation. ASPR officials stated that they will work to develop a strategic documented workforce target that considers (1) a nationwide event or multiple concurrent events, (2) the needs of at-risk individuals, and (3) the availability of other medical responders. They also stated that ASPR's ability to realize this workforce target will be subject to the availability of funding. As of March 2021, ASPR officials said they continue to work on implementing this recommendation. To implement our recommendation, ASPR needs to develop an NDMS responder workforce target that accounts for the critical skills and competencies needed to meet current and future programmatic events.

Director: Mary Denigan-Macauley, Health Care

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

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

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

Actions Needed: HHS concurred with this recommendation. As of February 2021, HHS stated that it is developing a process to coordinate its efforts in infectious disease modeling across its components; including efforts to monitor, evaluate and report on that coordination. To implement this recommendation, HHS needs to finalize a process that includes efforts to monitor, evaluate and report on coordination across multiple agencies.

Recommendation: The Secretary of HHS 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: CDC concurred with this recommendation. In February 2021, CDC stated its modelers aim to make forecasts and other modeling products reproducible and accessible. CDC further stated it is focused on transparency and accessibility in its modeling efforts, noting that it broadly disseminates modeling findings to state and local partners. However, CDC has not taken steps to update its guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated to the public. Such guideline modifications could include language relating to model reproducibility, such as model code. To implement this recommendation, CDC needs to provide evidence of updated guidelines that share with the public all permissible appropriate information to ensure the full reproducibility of its research.

Director: Timothy M. Persons, Chief Scientist

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

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

Actions Needed: HHS agreed with our recommendation and, in April 2021, described actions it has taken to implement it, but did not provide supporting documentation that would allow GAO to assess the extent to which these actions respond to the report findings and the recommendation. To fully implement the recommendation, HHS will need to provide evidence of the plan it created to enhance change management including a strategy for communication and evidence of the feedback mechanisms it is using, such as tools used to conduct annual after action reviews of the data collection process and demonstrate how corrective actions based on that feedback have been implemented.

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

Actions Needed: HHS agreed with our recommendation and, in April 2021, described actions it has taken to implement it, but did not provide supporting documentation that would allow GAO to assess the extent to which these actions respond to the report findings and meet the intent of the recommendation. For example, HHS described that standard operating procedures are in development to further codify the annual assessment process. To fully implement this recommendation, HHS will need to provide evidence of these standard operating procedures—and the procedures must outline how the Biodefense Coordination Team plans to account for nonfederal capabilities in its annual assessment. HHS also needs to provide other guidance documents established for the annual assessment that clearly articulate the methods to be used.

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

Actions Needed: HHS agreed with our recommendation and, in April 2021, described actions it has taken to implement it, but did not provide supporting documentation that would allow GAO to assess the extent to which these actions respond to the report findings and meet the intent of the recommendation. For example, HHS submitted a budget request for $5 million to support implementation of the National Biodefense Strategy. To fully implement this recommendation, HHS will need to provide a detailed plan on how such budget requests will be used to staff, support, and sustain ongoing implementation efforts. This is particularly important because the Biodefense Coordination Team is comprised of 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.

Recommendation: The Secretary of HHS should direct the Biodefense Coordination Team to clearly document agreed upon processes, roles, and responsibilities for making and enforcing enterprise-wide decisions.

Actions Needed: HHS agreed with our recommendation and, in April 2021, described actions it has taken to implement it, but did not provide supporting documentation that would allow GAO to assess the extent to which these actions respond to the report findings and meet the intent of the recommendation. To fully implement this recommendation, HHS will need to provide supporting evidence of the governance documents, including charters and processes developed for enterprise-wide decisions that address the deficiencies identified in our report.

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

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

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

Recommendation: ASPR should work with support agencies to develop and finalize memorandums of agreement that include information on the capabilities and limitations of these agencies to meet emergency support functions (ESF) #8 core capabilities.[10]

Actions Needed: ASPR disagreed with this recommendation, and reiterated that disagreement in March 2021. HHS proposed the continued use of interagency liaison officers at the HHS emergency operations center, as they can provide real-time updates on available resources during a response. We agree that HHS should continue this practice; however, as evidenced by the capabilities misalignment we identified in our report, this action was not adequate during the response to Hurricanes Irma and Maria in the U.S. Virgin Islands and Puerto Rico, respectively. Further, as we reported, ASPR officials acknowledged that more needs to be done to better understand the resources available from its support agencies. We maintain that it is essential for ASPR to take

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

steps to ensure it has a sufficient understanding of each ESF #8 support agency's potential capabilities and limitations.

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

Actions Needed: ASPR agreed with this recommendation. As of March 2021, ASPR officials stated that their incident response framework includes a long-term goal of creating an incident response team that will establish an initial ESF #8 presence at local emergency operations centers and manage resources and capabilities. If implemented, this strategy may allow ASPR to provide more liaisons on the ground during a response and address the staffing deficiency we identified in our report. To fully implement this recommendation, ASPR officials will need to provide us with evidence that this team has been used successfully to ensure at least one liaison is consistently stationed at emergency operations centers.

Director: Mary Denigan-Macauley, Health Care

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

Public Health and Human Services Program Oversight

Unaccompanied Children: Actions Needed to Improve Grant Application Reviews and Oversight of Care Facilities. GAO-20-609. Washington, D.C.: Sep. 15, 2020.

Recommendation: The Director of the Office of Refugee Resettlement (ORR) should take steps to develop, and ensure that officials reviewing grant applications implement, a process to verify the accuracy and completeness of information reported by grant applicants on state licensing status, eligibility, allegations and concerns.

Actions Needed: HHS agreed with this recommendation. As of April 2021, ORR developed and finalized a guide for project officers reviewing grant applications that included an assessment of licensing information included in the application. HHS's guidance document poses a few basic questions about the applicant's licensing status and instructs the project officer to request documentation from an applicant whose license has been restricted, suspended, or revoked. However, it does not specify any other steps the project officer should take to verify the licensing information included in the application, such as searching the state licensing agency's website or contacting the licensing agency directly when licensing information is not available online. To fully implement this recommendation, HHS needs to provide evidence of guidance instructing project officers to take these or similar steps, and provide documentation showing this guidance has been incorporated into the project officer training curriculum.

Recommendation: The Director of ORR should ensure that the grant review process includes a documented review of applicants' past performance on ORR grants for those that have previously received grants to care for unaccompanied children. This could include, for example, a systematic review of previous quarterly and annual performance reports and a review of corrective actions issued by all ORR monitoring staff to all ORR-funded facilities previously operated by the applicant.

Actions Needed: HHS agreed with this recommendation. As of April 2021, HHS stated that ORR was developing guidance for project officers on conducting and documenting reviews of grantee performance. HHS provided a copy of guidance that directs staff to review a grantee's quarterly performance reports to determine whether the grantee's funding should be continued for another budget period and to document this review. To fully implement this recommendation, HHS needs to provide evidence that project officers review past grantee performance when existing grantees apply for new grants, and provide documentation showing that this guidance has been incorporated into the project officer training curriculum.

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

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Southwest Border: Actions Needed to Improve DHS Processing of Families and Coordination between DHS and HHS. GAO-20-245. Washington, D.C.: Feb.19, 2020.

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

Actions Needed: HHS and DHS concurred with our recommendation. As of March 2021, HHS and DHS had signed a memorandum of agreement regarding unaccompanied children information sharing, which outlined the use of a new data system HHS is developing that would be integrated with an interagency portal being developed by DHS. Connecting this data system to the portal would allow HHS to retrieve data regarding a child's status in a more automated manner. As of May 2021, DHS officials said they plan to meet regularly with HHS to coordinate their efforts. DHS and HHS reported that they would provide an update on the status of their efforts by September 2021. Until DHS and HHS implement procedures aimed at improving the efficiency and accuracy of the interagency unaccompanied children referral and placement process, information-sharing gaps will remain. We will continue to monitor and evaluate HHS's actions to determine the extent to which they fully address our recommendation.

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.: Sept. 13, 2019.

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

Actions needed: HHS concurred with our recommendation, and told us in March 2021 that the Administration for Children and Families is on track to complete the initial Fraud

Risk Assessment for OHS by the end of 2021. Such an assessment could help OHS better identify and address the fraud risk vulnerabilities we identified. We will assess these actions once completed to determine the extent to which they fully implement our recommendation.

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

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

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

Actions Needed: HHS concurred with our recommendation. In March 2021, HHS said CMS is developing the ability to review survey trends related to alleged perpetrator and alleged abuse types and aims to implement our recommendation by June 2021. To fully implement our 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.

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

Actions Needed: HHS concurred with our recommendation. In March 2021, HHS said CMS will require state survey agencies to immediately refer complaints upon receipt and surveys to law enforcement (and, when applicable, to Medicaid Fraud Control Units) if they have a reasonable suspicion that a crime against a resident has occurred, and aims to implement this requirement by June 2021. We will evaluate CMS's implementation of this requirement upon completion to determine the extent to which it fully addresses our recommendation.

Director: John E. Dicken, Health Care

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

Recommendation: The Secretary of HHS should revise HHS's process for conducting improper payment risk assessments for Head Start to help ensure that it results in a reliable assessment of whether the program is susceptible to significant improper payments. This should include preparing sufficient documentation to support its risk assessments.

Actions needed: HHS concurred with our recommendation. In March 2021, HHS stated that it has revised its risk assessment process, including the questionnaire and scoring methodology, and implemented a new tool, the Risk Assessment Portal (RAP) to capture responses. According to HHS, the revised questionnaire and RAP tool facilitates a systematic approach to conducting a reliable assessment of any HHS program, including Head Start, to determine whether the program is susceptible to significant improper payments. The RAP tool enables programs to add information through an expanded modal screen and allows users to attach supplemental documentation supporting their risk assessment and questionnaire responses. HHS also developed RAP User and Reference Guides to support the end user and documents the process HHS uses to provide a reasonable basis for making to risk determinations. HHS needs to provide us with documentation that supports the corrective actions HHS stated it has taken so we can assess and determine if those actions fully implement this recommendation.

Recommendation: The Secretary of HHS 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.[11]

Actions needed: HHS concurred with our recommendation. In March 2021, HHS stated that it has used its new, risk-based methodology for two years to recommend programs for assessment. According to HHS, the results of this methodology, and the coverage recommended each year, are documented annually. The HHS Office of Inspector General reviewed the fiscal year 2019 methodology as part of the annual inspector general review of HHS's improper payment reporting under the Improper Payments Elimination and Recovery Act of 2010 and provided no feedback or recommendations for improvement. HHS also stated that it plans to refine the methodology as needed and ensure annually that leaders are aware of which programs are above the threshold and should be assessed for susceptibility to significant improper payments. HHS needs to provide us with documentation that supports the corrective actions HHS stated it has taken so we can assess and determine if those actions fully implement this recommendation.

Director: Beryl H. Davis, Financial Management and Assurance

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

Recommendation: The Administrator of the Health Resources and Services Administration (HRSA) should issue guidance to covered entities on the prevention of

[11]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. Although PIIA repealed the legal provisions underlying our recommendation, it also enacted substantially similar requirements as a new subchapter in Title 31 of the U.S. Code. We therefore have not altered the status of this recommendation.

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 concurred with our recommendations, though as of March 2021, it has not taken steps to implement them. To implement our recommendations, HHS should issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care. After this guidance has been issued, HHS should also incorporate into its audit process an assessment of covered entities' compliance with the prohibition of duplicate discounts.

Director: Debra A. Draper, Health Care

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

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

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

Actions needed: HHS and DHS concurred with our recommendation. As of March 2021, HHS and DHS had signed a memorandum of agreement regarding unaccompanied children information sharing. The agreement outlined the use of a new data system HHS is developing that would be integrated with an interagency portal being developed by DHS. Connecting this data system to the portal would allow HHS to retrieve data regarding a child's status in a more automated manner. As of May 2021, DHS officials said they plan to meet regularly with HHS to coordinate their efforts. DHS and HHS reported that they would provide an update on the status of these efforts by September 2021. To fully implement our recommendation, DHS and HHS should ensure that they have implemented procedures aimed at improving the efficiency and accuracy of the interagency unaccompanied children referral and placement process.

Director: Rebecca Gambler, Homeland Security and Justice

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Food and Drug Administration Oversight

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

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

Actions Needed: FDA concurred with our recommendation and as of January 2021, stated that it is actively tracking the list of sites that need to be inspected. To fully implement our recommendation, FDA should provide documentation that its inspection plans identify, analyze, and respond to the issues presented by the backlog of 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

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

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

Actions Needed: FDA concurred with our recommendation and has taken some steps to implement it, including convening quarterly to discuss the establishment of drug residue limits in seafood. However, we found that agencies continue to use different testing methods, which results in the agencies using different maximum residue levels from some drugs. As of January 2021, according to FDA officials, FDA and FSIS do not have any plans to work on a multi-residue method that both agencies can use. To implement our recommendation, FDA should coordinate with FSIS on (1) the development of testing methods that both agencies can use on imported seafood, including catfish, and (2) establishing maximum residue levels that would allow the agencies to consistently apply similar standards.

High-risk area: Improving Federal Oversight of Food Safety

Director: Steve Morris, Natural Resources & Environment

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

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

Actions Needed: FDA concurred with our recommendation and in July 2018 reported developing new performance measures for foreign offices as well as a monitoring and evaluation plan. As of March 2021, FDA has not provided evidence of progress toward implementing our recommendation. To fully implement our recommendation, FDA should systematically track information to measure whether the offices' activities—such as inspections, import alerts, and warning letters—specifically contribute to drug safety-related outcomes.

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.: Jan. 30, 2015.

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

Actions Needed: FDA concurred with our recommendation. As of March 2021, FDA officials said that they cannot meet the number of foreign inspections required under FSMA due to capacity constraints, and FDA's current strategy for the safety of imported food relies on multiple programs—in addition to foreign inspections—that could take a number of years to be fully implemented. As these new FSMA programs initiate and mature over time, FDA officials said they will comprehensively weigh outcomes and oversight from these programs and produce a data-driven assessment on the appropriate number or range of foreign inspections that provide appropriate oversight of the safety of the imported food supply. To fully implement our recommendation, FDA should report this information to Congress and GAO.

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.: Oct. 7, 2014.

Recommendation: To better inform users of the annual monitoring report about the frequency and scope of pesticide tolerance violations, the Secretary of HHS 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: FDA concurred with this recommendation. In a March 2021 update, FDA acknowledged that some pesticides with EPA-established tolerances were not part of FDA's testing scope in its September 2020 annual pesticide residue monitoring report. In addition, FDA does not know the extent to which exposure to these pesticides may occur in the foods that FDA regulates. FDA included in this report an appendix listing all pesticides analyzed by FDA pesticide methods in that fiscal year. To fully implement our 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.

High-risk area: Improving Federal Oversight of Food Safety

Director: Steve Morris, Natural Resources & Environment

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

National Efforts to Prevent, Respond to, and Recover from Drug Misuse

Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome. GAO-18-32. Washington, D.C.: Oct. 4, 2017.

Recommendation: The Secretary of HHS should expeditiously develop a plan—that includes priorities, time frames, clear roles and responsibilities, and methods for assessing progress—to effectively implement the neonatal abstinence syndrome (NAS)-related recommendations identified in the *Protecting Our Infants Act: Final Strategy*.

Actions needed: HHS concurred with our recommendation. HHS's Behavioral Health Coordinating Council finalized a plan in 2019 for implementing the Strategy. The plan includes priorities, timeframes, and clear roles and responsibilities for implementing NAS-related recommendations in the Strategy. However, the plan does not specifically identify methods for assessing HHS's progress toward implementing the Strategy's recommendations. In November 2019, HHS officials stated that the department holds quarterly conference calls to share updates on progress toward implementing the Strategy and that formal written updates will be collected at the end of each year. As of March 2021, we have not received any further updates. To fully implement our recommendation, HHS needs to provide documentation—such as formal written updates—showing how the department assesses its progress in implementing the Strategy's recommendations.

High-risk area: National Efforts to Prevent, Respond to, and Recover from Drug Misuse

Director: Mary Denigan-Macauley, Health Care

Contact information: DeniganMacauleyM@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.: Mar. 27, 2019.**

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

Actions needed: HHS concurred with our recommendation. As of March 2021, 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. However, to implement our recommendation, CMS needs to take steps to assess documentation requirements in both programs to better understand how the variation in the programs' requirements affects estimated improper payment rates.

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

Director: Carolyn L. Yocom, Health Care

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

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

Actions needed: HHS concurred with our 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 March 2021, the tool remains suspended, and HHS officials have not informed us of any additional actions taken to implement our recommendation. We will continue to monitor CMS's action to complete this assessment to implement our recommendation.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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

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

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

Actions needed: HHS concurred with our recommendation and, as of March 2021, has highlighted for states and audit contractors the importance of conducting collaborative audits. In addition, CMS stated in September 2019 that it was evaluating several process improvements as a result of feedback and recommendations received through a meeting with states and audit contractors. However, it is unclear whether CMS's actions have removed impediments to audits of Medicaid MCOs or will cause the number of audits to increase. To fully implement our recommendation, CMS needs to provide evidence that the agency has removed impediments to audits of Medicaid MCOs by ensuring that they are conducted regardless of whether the state or the MCO recoups identified overpayments.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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

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

Actions needed: HHS concurred with our recommendation and, as of March 2021, stated that it was in the process of developing a strategy to reduce risk in Medicaid managed care. To implement our recommendation, CMS would need to implement its strategy to mitigate the managed care program risks not measured in the PERM.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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

Medicare: CMS Should Take Actions to Continue Prior Authorization Efforts to Reduce Spending. GAO-18-341. Washington, D.C.: Apr. 20, 2018.

Recommendation: The Administrator of CMS should take steps, based on results from evaluations, to continue prior authorization. These steps could include: (1) resuming the paused home health services demonstration; (2) extending current demonstrations; or (3) identifying new opportunities for expanding prior authorization to additional items and services with high unnecessary utilization and high improper payment rates.

Actions needed: HHS initially neither agreed nor disagreed with our recommendation, but as of March 2021, the agency concurred. CMS has taken steps to evaluate and continue its prior authorization programs. Between 2019 and 2020, CMS made some progress toward implementing our recommendation by, for example, adding 18 items to its prior authorization list and resuming or starting five demonstrations. As of March 2021, HHS stated that it will continue evaluating the prior authorization programs. To fully implement our recommendation, CMS needs to take additional steps to evaluate the use of prior authorization by, for example, determining cost savings from its actions. CMS also needs to take additional steps to expand the use of prior authorization, which could include identifying new opportunities for prior authorization for items and services with high unnecessary utilization and high improper payment rates.

High-risk area: Medicare Program & Improper Payments

Director: Jessica Farb, 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.: Apr. 13, 2016.

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

Actions needed: HHS disagreed with our recommendation and, as of March 2021, has not taken steps to seek legislative authority to allow the RAs to conduct prepayment claim reviews. We maintain that CMS should seek such authority.

High-risk area: Medicare Program & Improper Payments

Director: Jessica Farb, 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.: Apr. 8, 2016.

Recommendation: As CMS continues to implement and refine the contract-level risk adjustment data validation (RADV) audit process to improve the efficiency and effectiveness of reducing and recovering improper payments, the Administrator should

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

Actions needed: HHS concurred with our recommendation and reaffirmed its commitment to identifying and correcting improper payments in the MA program. HHS stated that, as of March 2021, 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 implement our 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. CMS stated that, as of March 2021, the agency was gathering documentation to demonstrate that the recommendation had been implemented. We will evaluate any documentation upon receipt to determine whether CMS's actions fully implement our recommendation.

High-risk area: Medicare Program & Improper Payments

Director: Jessica Farb, Health Care

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Medicaid Program

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

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

Actions needed: HHS neither agreed nor disagreed with our recommendation but acknowledged the need for additional state Medicaid financing and payment data to oversee the Medicaid program. HHS also noted that CMS has begun work to improve the collection of financing and payment information through a revised data collection form and that CMS would explore additional actions to do so. In addition, Congress passed and the President signed into law requirements in December 2020 for additional state reporting on Medicaid supplemental payments. To fully implement our recommendation, HHS needs to demonstrate how its ongoing and planned actions in this area, which could include actions in response to the December 2020 law described

above, will ensure complete, consistent, and sufficiently documented information about sources of funding for the nonfederal share and payments to providers.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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Medicaid Providers: CMS Oversight Should Ensure State Implementation of Screening and Enrollment Requirements. GAO-20-8. Washington, D.C.: Oct. 10, 2019.

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

Actions Needed: CMS concurred with our recommendation. In June 2020, CMS stated that it planned to reach out to states that had not yet participated in optional consultations to discuss their progress towards implementing these requirements and outline steps the states should take to come into full compliance with the requirements. However, in February 2021, CMS reported that all states opted to waive certain provider screening and enrollment requirements in an effort to relieve the burden on providers during the COVID-19 pandemic. CMS stated that the agency would recognize these waivers until the end of the public health emergency. Consequently, as of March 2021, CMS did not have further details on state compliance with provider enrollment requirements, including states that have not used CMS's optional consultations. To fully implement our recommendation, CMS would need to complete and provide evidence of its review of all states' implementation of the provider screening and enrollment requirements. We will continue to monitor CMS's progress.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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

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

Actions Needed: HHS concurred with our 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. This is a positive step, yet any new data system will also need to address known limitations in the current blood lead screening data, such as the under-counting of blood lead screening tests not paid for by Medicaid. To fully implement our recommendation, CMS should ensure that its new data system addresses limitations in blood lead screening data to better monitor compliance with the agency's blood lead screening policy.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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

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

Actions Needed: HHS concurred with our recommendation. As of March 2021, 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 for new demonstrations. In December 2020, CMS said the agency plans to develop criteria for determining whether an amendment application proposes a substantial change to an existing demonstration and to include this in guidance in 2021. We will evaluate HHS guidance when it is issued to determine whether it fully addresses our recommendation.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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Medicaid Assisted Living Services: Improved Federal Oversight of Beneficiary Health and Welfare Is Needed. GAO-18-179. Washington, D.C.: Jan. 5, 2018.

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

Actions needed: HHS neither agreed nor disagreed with our recommendation. As of March 2021, CMS completed three national training courses for state officials regarding the findings of its national survey of incident management systems. During these trainings, CMS reported on the wide variation among state systems, including the types of incidents identified as critical. CMS developed a proposed incident reporting template,

but converted it to an optional incident reporting tool that the agency may share with states in providing technical assistance. To fully implement our recommendation, CMS should establish standard Medicaid reporting requirements for all states to report critical incidents annually.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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

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

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

Actions needed: HHS initially stated it was considering options to address our recommendation, and as of March 2021, the agency concurred. In December 2020, Congress passed and the President signed into law requirements for additional state reporting on Medicaid supplemental payments that may address our recommendation. The new law includes a requirement for states to report the criteria used to determine which providers are eligible to receive the supplemental payments. We will continue monitoring implementation of the new reporting requirement to determine the extent to which it fully implements our recommendation.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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

Medicaid: CMS Oversight of Provider Payments Is Hampered by Limited Data and Unclear Policy. GAO-15-322. Washington, D.C.: Apr. 10, 2015.

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

Actions needed: HHS concurred with our recommendation. In December 2020, Congress passed and the President signed into law requirements for additional state reporting on Medicaid supplemental payments, including for states to describe how these payments are economical and efficient. As of March 2021, we have not received any further updates. We will continue monitoring the implementation of the new reporting requirements to determine the extent to which they fully implement our recommendation.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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

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

Actions needed: HHS disagreed with our recommendation. However, we have reiterated the need for increased attention to fiscal responsibility in the approval of the section 1115 Medicaid demonstrations in subsequent 2008 and 2013 reports.[12] As of March 2021, HHS has taken some action to address this recommendation. In August 2018, HHS issued written guidance through a State Medicaid Directors Letter documenting four key changes it made in 2016 to its budget neutrality policy. These changes addressed some, but not all, of the questionable methods we identified in our reports. To fully implement our recommendation, HHS should also address these other questionable methods, such as setting demonstration spending limits based on hypothetical costs—what the state could have paid—rather than payments actually made by the state. We have found that the use of hypothetical costs has the potential to inflate spending limits and thus threatens budget neutrality of demonstrations.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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Medicare Program

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

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 concurred with our recommendation. However, in 2018 and again in March 2021, HHS indicated it was reconsidering whether to implement our recommendation because officials stated that it may not be appropriate to offset Medicare UC payments by Medicaid payments that help offset UC costs. CMS stated that because Medicare UC payments are distributed based on hospitals' relative (not actual) UC costs, it may not be appropriate to account for Medicaid payments that reduce hospital UC. We maintain that CMS should implement our recommendation because it would (1) ensure that Medicare UC payments are based on accurate levels of

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

UC costs, (2) result in CMS better targeting billions of dollars in Medicare UC payments to hospitals with the most UC costs, and (3) avoid Medicare UC payments to hospitals with little or no UC costs.

High-risk area: Medicare Program & Improper Payments

Director: Carolyn L. Yocom, Health Care

Contact information: YocomC@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.

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

Actions needed: HHS concurred with our recommendation. Although CMS reported using MA encounter data for purposes other than risk adjustment, as of March 2021, the agency had not fully developed specific plans and time frames for such uses. Although CMS continues to develop additional uses for MA encounter data, the agency's plans for using the data for comprehensive oversight purposes remain limited. For example, although CMS intends to use MA encounter data for program integrity purposes, it has not yet developed specific plans and time frames to do so. To fully implement our recommendation, CMS should establish specific plans and time frames for using MA encounter data for all intended purposes in addition to risk adjusting payments to MAOs.

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

Actions needed: HHS concurred with our recommendation but, as of March 2021, had not committed to completing data validation before using MA encounter data for risk adjustment. To fully implement our recommendation, CMS needs to complete all necessary steps to validate MA encounter data, including verifying the data by reviewing medical records, before using the data for risk adjustment payments or other intended purposes.

High-risk area: Medicare Program & Improper Payments

Director: Jessica Farb, Health Care

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

Recommendation: To reduce the incentive for dialysis facilities to restrict their service provision to avoid reaching the low-volume payment adjustment (LVPA) treatment threshold, the Administrator of CMS should consider revisions such as changing the LVPA to a tiered adjustment.[13]

Actions needed: HHS concurred with our recommendation and stated in March 2021 that the agency had extensive discussions with the Medicare Payment Advisory Commission regarding the Commission's suggestions for modifying the LVPA. CMS also stated that the agency was analyzing the design of the LVPA as part of its evaluation of the End-Stage Renal Disease Prospective Payment System. To fully implement our recommendation, CMS needs to provide documentation of the steps—such as those described above—that the agency has taken to consider revisions to the LVPA.

High-risk area: Medicare Program & Improper Payments

Director: Jessica Farb, Health Care

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

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

Actions needed: HHS disagreed with our recommendation and, as of March 2021, had no plans to take further action. CMS believes that a new checkbox on the claim form identifying self-referral would be complex to administer and that providers may not characterize referrals accurately. We maintain that such a flag on Part B claims would likely be the easiest and most cost-effective way for CMS to identify self-referred advanced imaging services and monitor the behavior of those providers who self-refer these services.

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

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[13]To have been eligible to receive the LVPA in 2011, a dialysis facility must have provided fewer than 4,000 total dialysis treatments during each of the 3 previous years, among meeting other CMS regulatory criteria. We stated in our report that the design of the LVPA raised concerns because it provides facilities with an adverse incentive to restrict their service provision to avoid reaching the 4,000 treatment threshold. Facilities that reach this threshold lose eligibility for the next 3 calendar years.

Actions needed: HHS disagreed with our recommendation and, as of March 2021, had no plans to take further action. CMS did not believe that a payment reduction would address overutilization that occurs as a result of self-referral and that the agency's multiple procedure payment reduction policy for advanced imaging already captures efficiencies inherent in providing multiple advanced imaging services by the same physician. Further, CMS does not think a payment reduction for self-referred services would be effective. We maintain that CMS should determine and implement a payment reduction to recognize efficiencies for advanced imaging services referred and performed by the same provider.

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

Actions needed: HHS initially stated that it would consider our recommendation, but as of March 2021, the agency disagreed and had no plans to take further action. However, we maintain that our 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 (CT) services, which involve the use of ionizing radiation. To implement our recommendation, CMS should determine and implement an approach to ensure the appropriateness of advanced imaging services referred by self-referring providers.

High-risk area: Medicare Program & Improper Payments

Director: Jessica Farb, Health Care

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Medicare Advantage: CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practices. GAO-12-51. Washington, D.C.: Jan. 12, 2012.

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

Actions needed: HHS initially did not comment on our recommendation, but as of March 2021, the agency concurred. CMS applied the statutory minimum adjustment to MA payments for calendar year 2021. CMS made other changes to its methodology for calculating the diagnostic coding adjustment (i.e., excluding diagnosis codes that were differentially reported in Medicare fee-for-service and MA), which likely have improved accuracy of the adjustment. However, a modified methodology that, for example,

incorporates more recent data and accounts for all relevant years of coding differences would better ensure an accurate adjustment in future years. To fully implement our recommendation, CMS needs to provide evidence of the sufficiency of its coding adjustment or re-calculate its adjustment using an updated methodology. Until CMS takes these steps, the agency is at continued risk of making excess payments to MA plans.

High-risk area: Medicare Program & Improper Payments

Director: Jessica Farb, Health Care

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Health Information Technology and Cybersecurity

Cybersecurity: Agencies Need to Fully Establish Risk Management Programs and Address Challenges. GAO-19-384. Washington, D.C.: July 25, 2019.

Recommendation: The Secretary of HHS should develop a cybersecurity risk management strategy that includes the key elements identified in this report.

Actions needed: HHS concurred with our recommendation and, as of March 2021, stated that its cybersecurity risk management strategy is undergoing internal review. However, HHS did not provide a date that the review would be completed. To implement our recommendation, HHS needs to ensure that its strategy includes key elements, including a statement of risk tolerance and information on how the department intends to assess, respond to, and monitor cybersecurity risks.

Recommendation: The Secretary of HHS should establish a process for conducting an organization-wide cybersecurity risk assessment.

Actions needed: HHS concurred with our recommendation and, as of March 2021, stated that a process for an organization-wide cybersecurity risk assessment is still under development. However, the department did not provide an estimated date of completion. To implement our recommendation, HHS needs to establish a risk assessment process to allow the agency to consider the totality of risk derived from the operation and use of its information systems.

High-risk area: Ensuring the Cybersecurity of the Nation

Director: Nick Marinos, 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.: Feb. 15, 2018.

Recommendation: The Secretary of HHS, in cooperation with the Secretary of USDA, should take steps to consult with respective sector partner(s), such as the sector coordinating council, DHS, and National Institute of Standards and Technology (NIST),

as appropriate, to develop methods for determining the level and type of framework adoption by entities across their respective sector.

Actions needed: HHS concurred with our recommendation and, as of March 2021, stated that it would work with appropriate entities to assist in sector adoption. HHS officials, in collaboration with NIST and a Joint Cybersecurity Working Group, developed 10 best practices (Health Industry Cybersecurity Practices) for the Healthcare and Public Health Services sector—allowing stakeholders to identify how to use the framework. The working group also discussed the challenges associated with measuring the use and impact of the NIST framework. To fully implement our recommendation, HHS needs to develop methods to determine the level and type of framework adoption. Implementing our recommendation to gain a more comprehensive understanding of the framework's use by critical infrastructure sectors is essential to the success of protection efforts.

High-risk area: Ensuring the Cybersecurity of the Nation

Director: Vijay D'Souza, Information Technology and Cybersecurity

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Health Insurance Premium Tax Credit (PTC) Payment Integrity

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

Recommendation: To improve annual reporting on PTC improper payments, control activities related to eligibility determinations, and calculations of advance PTC, the Secretary of HHS should direct the Administrator of CMS to annually report improper payment estimates and error rates for the advance PTC program.

Actions needed: HHS concurred with our recommendation. In March 2021, CMS reported that it intends to publish an advance PTC improper payment rate in CMS's fiscal year 2022 agency financial report for payments made by the federally-facilitated exchange during benefit year 2020. CMS said that developing an advance PTC improper payment rate for payments made by state-based exchanges will be a multi-year process. To fully implement our recommendation, HHS needs to finalize and implement its methodology for producing advance PTC improper payment rate estimates and publicly report these estimates in its annual financial report.

High-risk area: Enforcement of Tax Laws

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