U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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Washington, DC 20548

Comptroller General
of the United States

April 23, 2020

The Honorable Alex M. Azar II
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 to call your personal attention to areas where open recommendations, including some related to the Coronavirus Disease 2019 (COVID-19) pandemic, should be given high priority.[1] We recognize that HHS and its component agencies are focused on the nation's efforts to respond to and recover from the COVID-19 pandemic. As HHS is able to refocus its efforts, addressing the high priority recommendations identified below has the potential to substantially improve HHS's operations.

In November 2019, we reported that on a government-wide basis, 77 percent of our recommendations made 4 years ago were implemented.[2] As of April 2020, HHS had 405 open recommendations with an implementation rate of 61 percent. Fully implementing all open recommendations could significantly improve HHS's operations.

In our March 2019 letter, we designated 54 recommendations as priorities for HHS. HHS has implemented 13 of these recommendations. In doing so, HHS has, for example, improved tracking of Medicare beneficiaries at high risk of harm from opioids; issued guidance for states about overpayments and setting rates in Medicaid managed care, which should help reduce financial risks to the Medicaid program; and has strengthened controls over the determination of eligibility for the premium tax credit used to help individuals purchase health insurance coverage through health insurance marketplaces. In addition to the 13 priority recommendations HHS implemented, four recommendations are no longer open priority recommendations, primarily because they became a lower priority due to recent policy changes or agency actions, as discussed below.

[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 2019*, GAO-20-1SP (Washington, D.C.: Nov.19, 2019).

We ask your continued attention to the 37 priority recommendations remaining from those we identified in the 2019 letter. We also are adding 18 new priority recommendations related to the Medicaid program, Medicare and Medicaid improper payments, Head Start risk assessments, health information technology and cybersecurity, and public health-related programs and issues, bringing the total number of priority recommendations to 55. (See enclosure for the list of recommendations).

The 55 priority recommendations fall into the following 10 areas.

Improper payments in Medicare and Medicaid. Estimates of improper payment in the Medicare and Medicaid programs continue to be unacceptably high and totaled over $103 billion in fiscal year 2019. Furthermore, based on projections from the Centers for Medicare & Medicaid Services' (CMS) Office of the Actuary, CMS expects federal spending in Medicare and Medicaid to continue to increase. As a result, actions to reduce improper payments in these programs are of critical importance. The seven priority recommendations in this area specify actions CMS could take to help reduce improper payments by assessing documentation requirements, taking steps to minimize program risks, and conducting prepayment claims reviews, among other things. For example:

- In March 2019, we recommended that the Administrator of CMS routinely assess differences in Medicare and Medicaid documentation requirements and ensure that the requirements are effective for demonstrating compliance with coverage policies. Although Medicare and Medicaid pay for similar services, the same documentation for the same service can be sufficient in one program but not the other. The substantial variation in the programs' improper payments raises questions about how well the programs' documentation requirements help identify causes of program risks. In February 2020, CMS noted that it had clarified and amended several Medicare documentation requirements as part of an agency initiative to assess such requirements and had also taken steps to identify best practices for Medicaid documentation requirements and share them with states.

  However, we believe that CMS needs to take additional steps to assess documentation requirements in both programs to better understand how the variation in the programs' requirements affects estimated improper payment rates. Without such an assessment, CMS may not have the information it needs to ensure that Medicare and Medicaid documentation requirements are effective at demonstrating compliance and appropriately address program risks.

- In May 2018, we recommended that the Administrator of CMS take steps to mitigate the program risks that are 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 allow inflated Medicaid managed care payments and minimize the appearance of program risks in Medicaid managed care. HHS agreed with this recommendation and stated in its fiscal year 2021 budget justification that it was in the process of developing a strategy to reduce risk in Medicaid managed care. To implement this recommendation, CMS would need 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. At the time of

our report, CMS had paused, ended, or scheduled to end its Medicare demonstrations of prior authorization, despite positive results. CMS has since taken steps to partially implement this recommendation by, for example, issuing a final report on the independent evaluation of one demonstration and resuming two paused demonstrations with changes. To fully implement this recommendation, CMS would need to take additional steps to evaluate and expand the use of prior authorization. These efforts to expand the use of prior authorization 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 the Administrator of 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 this recommendation in its initial comments on the report. HHS noted that other claim review contractors conduct prepayment reviews, and 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 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. In February 2020, HHS noted in its fiscal year 2021 budget justification that CMS would consider the recommendation as it develops future legislative proposals. To implement this recommendation, CMS should seek legislative authority to allow Recovery Auditors to conduct prepayment claim reviews. We would support this request.

Medicaid program. Medicaid is one of the nation's largest sources of funding for health care services for low income and medically needy individuals. This federal-state program was projected to cover about 76 million people in fiscal year 2019 at an estimated cost of approximately $667 billion. Addressing our nine open priority recommendations in this area would, among other things, improve state compliance with blood lead screening requirements for children and improve the oversight, accountability, and transparency of Medicaid spending, including spending through demonstrations, which accounted for over one-third of all federal Medicaid spending in fiscal year 2017. For example:

- In August 2019, we recommended that the Administrator of CMS work with states and relevant federal agencies to collect accurate and complete data on blood lead screening for Medicaid beneficiaries and ensure states' compliance with CMS's blood lead screening policy. CMS is planning to use a new data system to generate the report that includes states' blood lead screening data. This is a positive step, yet any new data system will also need to consider how to help address known limitations in the current blood lead screening data. To implement this recommendation, CMS should fully address limitations in blood lead screening data to better monitor compliance with the agency's blood lead screening policy.

- 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. These demonstrations allow states to test and evaluate new approaches for delivering Medicaid services. Transparency is increasingly important as new flexibilities begin to be tested under demonstrations, including Indiana's January

2020 request to extend their demonstration for 10 years and to be allowed to make mid-course changes to certain provisions without CMS approval or public input.

HHS stated that it would implement a policy that applies transparency requirements for significant amendments to section 1115 demonstrations that are comparable to the transparency requirements for new demonstrations. This would, for example, require states that propose a significant amendment to a section 1115 demonstration to use multiple methods to seek public input on the amendment. Implementing this policy would address this recommendation.

- In February 2016, we recommended that the Administrator of CMS issue written guidance that clearly articulates its policy for states that requires a link between the distribution of supplemental payments and the provision of Medicaid-covered services. This would promote consistency in the distribution of such payments among states and with CMS policy. While CMS has issued clarifying letters to some states, it has not issued written guidance to all states explaining this requirement. In November 2019, CMS issued a proposed rule that, if finalized, may clarify this requirement for all states.

  The agency says the proposed rule would require states to report to CMS a comprehensive description of the methodology used to calculate the amount and distribution of supplemental payments and the provider metrics used to calculate payment amounts, such as Medicaid utilization or costs. We will continue to monitor the status of the proposed rule and will review a final rule, if one is issued, to determine the extent to which it addresses our concern. Implementing this recommendation would help CMS ensure that Medicaid supplemental payments are economical and efficient and distributed to providers based on the provision of Medicaid services.

We removed the priority designation from two open recommendations related to Medicaid that became a lower priority because the agency could address our primary concern by implementing other, related priority recommendations.[3]

Medicare program. The Medicare program presents one of the highest financial risks facing the federal government. Addressing Medicare's short-term and long-term challenges is vitally important—for the taxpayers who finance the program, the health care providers whose services are compensated by the program, the millions of aged and disabled individuals who depend upon the program for health care coverage, and the families of these individuals who might otherwise bear the cost of their health care. In 2019, Medicare was projected to finance health services for about 61 million elderly and disabled beneficiaries with estimated total expenditures of over $775 billion. The aging of the population and the growth in health care spending per beneficiary will magnify these challenges over time.

Our eight open priority recommendations in this area identify steps that CMS can take to improve the 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 costs when determining the amount of

[3]We removed the priority designation from two recommendations related to CMS oversight of Medicaid payments to individual providers and on improving state submissions related to the Medicaid data system. These recommendations were related to or bundled with related priority recommendations which HHS should focus on closing first. These two recommendations will remain open until HHS takes appropriate action; however, on their own, these recommendations are not our highest priority.

Medicare uncompensated care payments an individual hospital should receive. HHS initially concurred with this recommendation. However, HHS later indicated in its fiscal year 2021 budget justification that it was reconsidering whether to implement this recommendation. We continue to believe that CMS should implement this recommendation, because it would ensure that Medicare uncompensated care payments are based on accurate levels of uncompensated care costs and would result in CMS better targeting billions of dollars in Medicare uncompensated care payments to hospitals with the most uncompensated care costs while avoiding making payments to hospitals with little or no uncompensated care costs.

- In January 2012, we recommended that CMS take steps to improve the accuracy of the adjustment made for differences in diagnostic coding practices between Medicare Advantage and Medicare Fee-for-Service. These differences in diagnostic coding could lead to beneficiaries in Medicare Advantage plans being assigned inappropriately high risk scores by CMS, which would result in higher than necessary payments. To address this, CMS could, for example, better account for additional beneficiary characteristics, such as sex and residential location, and use more current and refined data in determining Medicare Advantage payments.

  We reiterated the importance of our recommendation in a January 2013 report, where we found that shortcomings in CMS's adjustment resulted in excess payments to Medicare Advantage plans totaling an estimated $3.2 billion to $5.1 billion over a 3-year period from 2010 through 2012. In its fiscal year 2021 budget justification, HHS said it considered the recommendation closed.

  However, CMS has not yet provided us with evidence of the sufficiency of the coding adjustment, nor has it implemented an adjustment based on analysis using an updated methodology. Until CMS takes these steps, payments to Medicare Advantage plans may not accurately account for differences in diagnostic coding between these plans and traditional Medicare providers. This places CMS at continued risk of making excess payments to Medicare Advantage plans.

Health information technology and cybersecurity. The nation's critical infrastructure—including health care—relies extensively on computerized systems and electronic data to support its missions. However, serious cybersecurity threats to the infrastructure continue to grow and represent a significant national security challenge. The seven open priority recommendations within this area, among other things, outline steps HHS should take to ensure that (1) HHS has a cybersecurity risk management strategy that includes key risk-related elements, (2) CMS develops processes and procedures to ensure that researchers and other qualified entities have implemented information security controls effectively throughout their agreements with CMS, and (3) progress is made toward the implementation of information technology (IT) enhancements needed to establish the electronic public health situation awareness network. 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 reported in January 2020 that the department was drafting a new cybersecurity risk management memo that will provide additional details of its cybersecurity risk management strategy. HHS also reported that this updated risk management strategy would include defining a process for conducting an organization-wide cybersecurity risk assessment. To fully address our

recommendations, HHS must ensure that its strategy includes key elements, including a statement of risk tolerance and information on how the agency 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 one priority recommendation in this area—related to developing performance measures to assess the outcomes of Electronic Health Record (EHR) programs—because HHS restructured its EHR programs and the federal investment in incentive payments related to EHRs has decreased substantially since 2014 when we made this recommendation.

Food and Drug Administration oversight. The Food and Drug Administration (FDA) is responsible for ensuring the safety of medical products marketed in the United States. FDA reports that about 80 percent of active pharmaceutical ingredient manufacturers are located outside of the United States. In addition, FDA is responsible for ensuring the safety of virtually all domestic and imported food products, except for some meat, poultry, and egg products. FDA established foreign offices to obtain better information on products coming from overseas and perform inspections, among other things. Addressing our four open priority recommendations in this area would help FDA ensure the safety of medical products and food imported into the United States. For example:

- In December 2016, we recommended that the Commissioner of FDA assess the effectiveness of its foreign offices' contributions to drug safety. FDA has since developed new performance measures for these offices as well as a monitoring and evaluation plan. In addition, FDA plans to train its staff on the results of its tracking program in fiscal year 2020. To fully implement this 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, our ongoing work in this area will provide updated information on the status of the role of FDA's foreign offices in ensuring the safety of drugs entering the United States.

- In September 2017, we recommended that the Commissioner of FDA coordinate and communicate with the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service in developing methods to test for drug-residue in imported seafood, including catfish, and establishing corresponding maximum residue levels—the highest level of drug residue allowed in imported seafood before it is considered potentially harmful to human health. HHS agreed with the recommendation and FDA has taken some steps to implement it. FDA officials told us that they shared a method with the Food Safety and Inspection Service for detecting two unapproved drugs. In addition, FDA told us in December 2019 that it has taken a step to implement this recommendation by sharing with Food Safety and Inspection Service information on their testing methods and instrumentation.

  However, FDA and the Food Safety Inspection Service continue to use different multi-residue testing methods, which results in the agencies using different maximum residue levels for some drugs. Furthermore, the agencies do not have any plans to work on a multi-residue method both agencies can use. As we recommended, FDA should coordinate with USDA on (1) developing testing methods that both agencies can use on

seafood, including catfish; and on (2) establishing maximum residue levels that will allow the agencies to consistently apply similar standards.

Indian Health Service health care. The Indian Health Service (IHS) is charged with providing health care services to approximately 2.6 million American Indian/Alaska Native (AI/AN) people who are members or descendants of 574 tribes. The life expectancy of AI/AN people born today is 5.5 years lower than all races in the United States. Historically, these individuals have experienced challenges accessing health care services and they continue to die from preventable causes at higher rates than other Americans. Implementing our open priority recommendation in this area would help IHS address the quality of its health care services as follows:

- In January 2017, we recommended that the Secretary of HHS direct the Director of IHS to ensure that agency-wide standards for the quality of care provided in its federally operated facilities are developed, that facility performance in meeting these standards is systematically monitored, and that enhancements are made to its adverse event reporting system. In March 2020, IHS officials told us the agency had completed a pilot test in three sites, and that one site had gone live with the adverse events reporting system.

  However, the COVID-19 pandemic response has diverted IHS resources that would be required for successful implementation of the software and adoption of new workflows for managing adverse events. Therefore, IHS is temporarily halting further roll-out of the system until such time as the COVID-19 national emergency has resolved or a determination is made by IHS leadership that IHS can reasonably be expected to manage a new software release despite on-going disaster response. We agree and will assess HHS's actions when implemented.

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. It represents a serious risk to public health and has resulted in significant loss of life and effects to society and the economy, including billions of dollars in costs. According to the Centers for Disease Control and Prevention (CDC), over 67,000 people died as a result of a drug overdose in 2018. The rising opioid epidemic has contributed to an increase in the number of infants born with neonatal abstinence syndrome (NAS)—a withdrawal condition with symptoms including excessive crying and difficulty breathing. Implementing our open priority recommendation in this area would address some of the challenges related to treating NAS as follow:

- In October 2017, we recommended that the Secretary of HHS should 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 HHS identified in its Protecting Our Infants Act: Final Strategy.[4] HHS finalized a plan for implementing the Strategy in 2019. 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

[4]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.

methods for assessing HHS's progress toward implementing the plan's recommendations, but HHS officials told us in November 2019 that the department holds quarterly conference calls to share updates and that formal written updates will be collected at the end of each year. To implement our recommendation, HHS needs to provide documentation—such as the formal written updates—showing how the department assesses its progress implementing the plan's recommendations.

Public health related programs and issues. The priority recommendations in this area address public health-related issues such as the nation's strategy for protecting the American people from biological threats. Catastrophic biological threats highlight the link between security and public health concerns. These threats—including naturally occurring threats like the COVID-19 pandemic—have the potential to cause loss of life and sustained damage to the economy, societal stability, and global security. We have reported on the fragmentation inherent in the biodefense enterprise, which includes partners at all levels of government and the private sector. Another issue addressed by priority recommendations in this area is CMS oversight of nursing homes, which provide care to about 1.4 million nursing home residents. CMS is responsible for ensuring that nursing homes meet federal quality standards, including that residents are free from abuse.

Addressing the nine open priority recommendations in this area would help ensure that relevant federal agencies are coordinating, managing risks, and have the resources they need to respond to biological threats such as the COVID-19 pandemic. In addition, addressing these priority recommendations would also improve oversight of nursing homes to better protect residents from abuse, among other things. For example:

- In February 2020, we recommended that the Secretary of HHS direct the Biodefense Coordination Team—a team of stakeholders from federal agencies with a role in responding to biological threats—to document the processes, roles, and responsibilities for making and enforcing enterprise-wide decisions.[5] HHS stated that the Biodefense Coordination Team has developed charters and guidance to govern its activities, but these documents were still pending approval. Implementing this recommendation could help guide agencies towards a common operating picture and a shared understanding of the efforts—beyond their individual missions—needed to respond to a biological threat like COVID-19.

- In June 2019, we recommended that the Administrator of CMS require state survey agencies, which by agreements with CMS conduct surveys of each state's nursing homes and investigate complaints and incidents, to immediately refer nursing home complaints and surveys to law enforcement if they have a reasonable suspicion that a crime against a resident has occurred. In February 2020, HHS told us that CMS will require state survey agencies to immediately refer complaints upon receipt and surveys to law enforcement if they have a reasonable suspicion that a crime against a resident has occurred. HHS told us it expects to implement this requirement by December 2020.

[5]The Biodefense Coordination Team was established by the National Security Presidential Memorandum-14, which established a structure and process for relevant federal agencies to assess enterprise-wide biodefense capabilities. The Biodefense Coordination Team is administratively located within HHS and its members include representatives from: HHS (including the Office of the Assistant Secretary for Preparedness and Response, CDC, the National Institutes of Health, and FDA), Department of Defense, Department of Homeland Security, Environmental Protection Agency, USDA, Department of Justice (including the Federal Bureau of Investigation), Department of State, Department of Veterans Affairs, the Office of the Director of National Intelligence, the U.S. Agency for International Development, and the Departments of Commerce, Energy, Treasury, Interior, Transportation, and Labor.

Ensuring timely referrals of abuse to law enforcement is important in light of CMS's decision in March 2020 to temporarily pause its regular surveys of nursing homes to focus on combatting COVID-19. This temporary change means that surveyors will visit nursing homes less frequently and may therefore be less likely to identify and observe abuse of a resident. Implementing this recommendation would help address gaps in CMS's oversight of abuse in nursing homes, including the timely investigation of abuse, and better protect residents from abuse.

Health insurance premium tax credit payment integrity and enrollment controls. 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. Individuals can have the federal government pay the PTC to their issuers in advance on their behalf, known as the advance PTC, which lowers their monthly premium. With those subsidies and other costs, PPACA represents a significant, long-term fiscal commitment for the federal government.

Addressing our six open priority recommendations in this area would, among other things, help HHS to better oversee the efficacy of PPACA's enrollment control process; better monitor costs, risk, and program performance; assist with tax compliance; strengthen the eligibility determination process; provide applicants with improved customer service and up-to-date information about submission of eligibility documentation; better document agency activities; and reduce improper payments in the PTC program. For example:

- In July 2017, we recommended that HHS should annually report improper payment estimates and error rates for the advance PTC program to improve its annual reporting on PTC improper payments, control activities related to eligibility determinations, and calculations of advance PTC.[6] CMS is currently in the process of developing an improper payment measurement for the advance PTC and HHS stated in its fiscal year 2021 budget justification that it will be a multi-year process that consists of the development of measurement policies, procedures, and tools.

  We believe HHS should develop this improper payment measurement more quickly. In fiscal year 2016, CMS assessed its advance PTC program as susceptible to significant improper payments. Until CMS develops an improper payment measurement and annually reports improper payment estimates and error rates for the advance PTC program, HHS's overall improper payments estimate will continue to be understated, and Congress and others will continue to lack key payment integrity information for monitoring HHS's improper payments.

Head Start risk assessments. The Head Start program, overseen by the Office of Head Start (OHS) within HHS, seeks to promote school readiness by supporting comprehensive development of low-income children. OHS plays an important role in ensuring that grantees implement eligibility-verification requirements to ensure qualified and more-vulnerable families are prioritized for services. In fiscal year 2019, Congress appropriated over $10 billion for

[6]On March 2, 2020, the President signed into law the Payment Integrity Information Act of 2019 (PIIA). This statute repealed the improper payments statutes in place at the time of our audit; in their place, it enacted a new Subchapter in Title 31 of the U.S. Code, containing substantially similar provisions. Specifically, the provisions enacted by PIIA include requirements regarding risk assessment, estimation, corrective actions, recovery audits, and related reporting that are, in relevant part, at least as stringent as those previously applicable to HHS. As such, we have not changed the status of these recommendations.

programs under the Head Start Act to serve approximately 1 million children through about 1,600 Head Start grantees and their centers nationwide. Addressing our three open priority recommendations in this area would help HHS ensure that grantees actually provide the requisite services to fulfill their grant requirements. For example:

- In September 2019, we recommended that the Director of OHS perform a fraud risk assessment for the Head Start program. HHS told us in February 2020 that the Administration for Children and Families is developing a Fraud Risk Assessment template for all of its programs, including the Head Start program, and is on track to complete the initial Fraud Risk Assessment for its pilot program by June 30, 2020. Upon completion of this assessment, the Administration for Children and Families anticipates completing its initial Fraud Risk Assessment for OHS by March 31, 2021. We will assess these actions once completed to determine whether they implement our recommendation.

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In March 2019, we issued our biennial update to our high-risk program, 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.[7] Our high-risk program has served to identify and help resolve serious weaknesses in areas that involve substantial resources and provide critical services to the public.

Five of our high-risk areas—Medicare program and improper payments, strengthening Medicaid program integrity, protecting public health through enhanced oversight of medical products, improving federal oversight of food safety, and improving federal management of programs that serve tribes and their members—center directly on HHS. Several other government-wide high-risk areas also have direct implications for HHS and its operations. These include (1) the government-wide personnel security clearance process, (2) ensuring the cybersecurity of the nation, (3) improving the management of IT acquisitions and operations, and (4) managing federal real property.

In addition, as we recently reported, we plan to designate national efforts to prevent, respond to, and recover from drug misuse as a high-risk area in our 2021 High Risk Update.[8] We urge your attention to the HHS 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.[9]

[7]GAO, *High-Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas*, GAO-19-157SP (Washington, D.C.: Mar. 6, 2019).

[8]GAO, *Drug Misuse: Sustained National Efforts are Necessary for Prevention, Response, and Recovery*, GAO-20-474 (Washington, D.C.: Mar. 26, 2020).

[9]GAO-19-157SP. See pages 241-249 for Medicare Program & Improper Payments, pages 250-258 for Strengthening Medicaid Program Integrity, pages 198-203 for Protecting Public Health through Enhanced Oversight of Medical Products, pages 195-197 for Improving Federal Oversight of Food Safety, pages 128-133 for Improving Federal

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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, and Homeland Security and Governmental Affairs, United States Senate; and the Committees on Appropriations, Budget, and Oversight and Reform, House of Representatives. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

I appreciate HHS's continued commitment to these important issues. If you have any questions or would like to discuss any of the issues outlined in this letter, please do not hesitate to contact me or 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 of the 405 open recommendations. Thank you for your attention to these matters.

Sincerely yours,

Gene L. Dodaro
Comptroller General
of the United States

Enclosure - 1

cc: Eric D. Hargan, Deputy Secretary, Department of Health and Human Services
Lynn Johnson, Assistant Secretary, Administration for Children and Families (ACF)
Jennifer Moughalian, Acting Assistant Secretary for Financial Resources (ASFR)
Brenda Destro, Deputy Assistant Secretary for Planning and Evaluation (ASPE)
Robert Kadlec, M.D., Assistant Secretary for Preparedness and Response (ASPR)
Seema Verma, Administrator, Centers for Medicare and Medicaid Services (CMS)
Stephen M. Hahn, M.D., Commissioner, Food and Drug Administration (FDA)
Thomas J. Engels, Administrator, Health Resources and Services Administration (HRSA)
RADM Michael D. Weahkee, Principal Deputy Director, Indian Health Service (IHS)

Management of Programs that Serve Tribes and Their Members, pages 170-177 for Government-wide Personnel Security Clearance Process, pages 178-184 for Ensuring the Cybersecurity of the Nation, pages 123-127 for Improving the Management of IT Acquisitions and Operations, and pages 78-85 for Managing Federal Real Property.

Enclosure

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

Improper Payments in Medicare and Medicaid

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 the Centers for Medicare & Medicaid Services (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 this recommendation. In February 2020, CMS noted that it 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, we believe that CMS still 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. Without an assessment of how the programs' documentation requirements affect estimates of improper payments, CMS may not have the information it needs to ensure that Medicare and Medicaid documentation requirements are effective at demonstrating compliance and appropriately address program risks.

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

Directors: James C. Cosgrove and Carolyn L. Yocom, Health Care

Contact information: cosgrovej@gao.gov, yocomc@gao.gov, (202) 512-7114

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 this recommendation, according to its fiscal year 2021 budget justification.[10] As of October 2019, CMS had developed a standard tool to assess risk and staff capacity. CMS indicated that once the assessment is complete, it will identify opportunities to increase resources, review the current allocation of financial staff, and

[10]To address the requirements of the Good Accounting Obligation in Government Act, the components of HHS reported on the public recommendations issued by GAO and the HHS Office of Inspector General that remained unimplemented for at least a period of one year from the annual budget justification submission date. Newer priority recommendations, those made within a year of HHS' fiscal year 2021 annual budget justification, were not addressed in the HHS reports. While some HHS components, including CMS and FDA, produce their own budget justifications, in this letter we refer to all budget justifications for fiscal year 2021 as "the HHS budget justification."

determine the appropriate allocation of staff by state. To implement this recommendation, CMS should execute the agency's current plan for completing an assessment.

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, as noted in its fiscal year 2021 budget justification. In September 2019, CMS reported that CMS held a July 2019 meeting with states and collaborative audit contractors to discuss coordination of managed care audits, including a wide range of challenges with managed care audits. As a result of the feedback and recommendations received, CMS is evaluating several process improvements and reiterated that audit contractors will continue to work with states to provide support and assistance in Medicaid managed care, and that Medicaid managed care audits should not be limited by MCO contract language. Although CMS has communicated to states the need to increase audits in managed care and address identified issues, it is unclear if these actions will remove known impediments to managed care audits or result in an increase in the number of collaborative audits. Implementing our July 2018 recommendation is needed because few audits of Medicaid managed care have been conducted, and overpayments can be significant based on the findings from federal and state audits and investigations that have been completed. To implement this recommendation, CMS should ensure that managed care audits are conducted regardless of which entity recoups any 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: In its fiscal year 2021 budget justification, HHS agreed with this recommendation and stated that CMS is developing a plan to reduce risk in Medicaid managed care. CMS reported that it has published or is in the process of finalizing several guidance documents, such as guidance for states and managed care plans on managed care delivery and oversight to reduce program risks. In order to implement this recommendation, CMS would

need to implement its plan to mitigate the managed care program risks that are not measured in the PERM.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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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 concurred with this recommendation, according to its fiscal year 2021 budget justification. CMS has recently taken steps to evaluate and continue its prior authorization programs. In June 2019, CMS issued a final report on the independent evaluation of the non-emergency hyperbaric oxygen therapy demonstration. While the agency does not plan to conduct additional demonstrations on this service, CMS officials reported in December 2019 that the agency may consider this service for the new prior authorization process for certain hospital outpatient department services, established in a 2019 final rule. In April 2019, CMS issued a Federal Register notice that added 12 items—seven power wheelchairs and five pressure reducing support surfaces—to its required prior authorization list for the permanent program. CMS officials said in December 2019 that the agency was in the process of determining cost savings from this action, and that additional items would be added to the list in early 2020. CMS resumed the home health services demonstration with changes in one state in June 2019 and in another state in September 2019. The agency plans to extend the demonstration to three additional states in 2020. In September 2019, CMS extended the repetitive scheduled non-emergency ambulance service demonstration for 1 year through November 2020. To fully implement this recommendation, CMS would need to take additional steps to evaluate its recent prior authorization efforts to determine if they resulted in cost savings and expand the use of prior authorization. These efforts to expand the use of prior authorization 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: James C. Cosgrove, 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: To better ensure proper Medicare payments and protect Medicare funds, the Secretary of HHS should direct the Administrator of CMS to seek legislative authority to allow the Recovery Auditors (RA) to conduct prepayment claim reviews.

Actions needed: HHS disagreed with this recommendation and, in its fiscal year 2021 budget justification, did not include a proposal for such authority. We continue to believe CMS should seek legislative authority to allow RAs to conduct these reviews. Until CMS seeks and implements this authority, it will be missing an opportunity to help identify improper payments before they are made.

High-risk area: Medicare Program & Improper Payments

Director: 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 this recommendation in its fiscal year 2021 budget justification. HHS reaffirmed its commitment to identifying and correcting improper payments in the MA program. HHS has begun taking steps to improve the timeliness of the contract-level RADV audit process, such as aligning the time frames in CMS's contract-level RADV audits with those of the national RADV audits. To fully address this recommendation, CMS will need to complete steps such as these and provide us evidence that the agency's actions have enhanced the timeliness of CMS's contract-level RADV process.

High-risk area: Medicare Program & Improper Payments

Director: James C. Cosgrove, Health Care

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Medicaid Program

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 February 2020, CMS communicated its plans to expand its review of states' implementation of provider screening and enrollment requirements to include states that have not yet participated in optional consultations to discuss their progress towards implementing these requirements. CMS also outlined steps that these states should take to come into full compliance with the provider screening and enrollment requirements. In order to fully address this 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: In February 2020, CMS reported that the agency is planning 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 address this 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 this recommendation and 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 January 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 by the end of the year. We will evaluate this 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 this recommendation. According to its fiscal year 2021 budget justification, the agency expects to issue subregulatory guidance pertaining to health and welfare of Medicaid beneficiaries in residential facilities by the close of calendar year 2020. To fully implement this recommendation, the subregulatory guidance should establish standard Medicaid reporting requirements for all states to report critical incidents annually. We will evaluate this 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: Further Action Needed to Expedite Use of National Data for Program Oversight. GAO-18-70. Washington, D.C.: Dec. 8, 2017.

Recommendation: The Administrator of CMS, in partnership with the states, should take additional steps to expedite the use of Transformed Medicaid Statistical Information System (T-MSIS) data for program oversight. Such steps should include, but are not limited to, efforts to (1) obtain complete information from all states on unreported T-MSIS data elements and their plans to report applicable data elements; (2) identify and share information across states on known T-MSIS data limitations to improve data comparability; and (3) implement mechanisms, such as the Learning Collaborative, by which states can collaborate on an ongoing basis to improve the completeness, comparability, and utility of T-MSIS data.

Actions needed: HHS concurred with this recommendation and noted in its fiscal year 2021 budget justification that its efforts were in progress. CMS has taken steps to improve T-MSIS data quality, but further efforts are needed to expedite the data's use in oversight. With regard to obtaining complete information from all states, CMS released additional guidance in March 2019

on state compliance with T-MSIS requirements. This guidance includes the need to resolve data issues associated with 12 top priority items and missing data elements, both of which are key for using T-MSIS data. Further, CMS identified an additional 11 top priority items, noting it also expected states to resolve data issues with these items. CMS reports that it has helped resolve data issues related to these 23 top priority items by sending states summary data on compliance with associated reporting requirements. CMS has notified states of their compliance status and asked non-compliant states to submit corrective action plans. However, CMS reports that the level of states' T-MSIS data completeness varies and agency state liaisons and technical assistants continue to work individually with states to identify, prioritize, and resolve key missing data elements. With regard to identifying and sharing information, CMS has made some T-MSIS data available for use through five T-MSIS analytical files, which include data on Medicaid and CHIP enrollment, demographics, service utilization, and payments. Further, CMS has created resources to support researchers in their use of these analytical files, including information on the completeness and accuracy of certain data elements. CMS's progress has been more limited with regard to implementing mechanisms for collaboration across states. In particular, CMS's efforts to create a mechanism for states to disseminate information about T-MSIS data and its comparability across states remain limited and the agency has not launched its proposed Learning Collaborative to facilitate ongoing feedback and collaboration. To fully address this recommendation, CMS will need to take additional steps to expedite the use of T-MSIS data for program oversight, such as establishing mechanisms for ongoing feedback and collaboration across states.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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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 requires a link between the distribution of supplemental payments and the provision of Medicaid-covered services.

Actions needed: HHS stated in its fiscal year 2021 budget justification that it concurred with this recommendation. CMS issued a proposed rule in November 2019 that, if finalized, may clarify this requirement for states. According to the agency, the rule would promote state accountability, improve federal oversight, and strengthen the fiscal integrity of Medicaid. Specifically, the agency said the rule would require states to report to CMS a comprehensive description of the methodology used to calculate the amount and distribution of supplemental payments and the provider metrics used to calculate payment amounts, such as Medicaid utilization or costs. We will monitor the status of the rule and, if it is finalized, will review it to determine the extent to which it addresses our recommendation.

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 stated in its fiscal year 2021 budget justification that it concurred with this recommendation. CMS issued a proposed rule in November 2019 that, if finalized, may address this issue. According to the agency, the rule would promote state accountability, improve federal oversight, and strengthen the fiscal integrity of Medicaid. Specifically, the proposed rule would clarify the agency policy that Medicaid payments may not be contingent on the availability of local funding, according to agency officials. We will monitor the status of the rule and, if it is finalized, will review it to determine the extent to which it addresses our recommendation.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care

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Medicaid: CMS Oversight of Provider Payments Is Hampered by Limited Data and Unclear Policy. GAO-15-322. Washington, D.C.: 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 stated in its fiscal year 2021 budget justification that it concurred with this recommendation. In November 2019, CMS issued a proposed rule that the agency said would (1) require states to demonstrate to CMS that supplemental payments to individual providers are economical and efficient and (2) require states to end, and then seek CMS approval to renew supplemental payments every three years. We will monitor the status of the rule and, if it is finalized, will review it to determine the extent to which it addresses the 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, we recommended that the Secretary of HHS 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.[11]

Actions needed: HHS stated in its fiscal year 2021 budget justification that it disagreed with this 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

[11]Under section 1115 of the Social Security Act, the Secretary of HHS may waive certain federal Medicaid requirements and allow costs that would not otherwise be covered for experimental, pilot, or demonstration projects that are likely to promote Medicaid objectives. 42 U.S.C. § 1315(a).

and 2013 reports.[12] As of January 2020, HHS has taken some steps to change some aspects of the methods used to determine budget neutrality and demonstration spending limits. 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 address this 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

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

Actions needed: HHS initially concurred with this recommendation. However, in its fiscal year 2021 budget justification, HHS indicated that it was reconsidering whether to offset Medicare UC payments by Medicaid's UC payments. 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. However, in some states Medicaid payments reduce or even eliminate hospital UC costs, which can result in an inequitable distribution of payments. Because the total amount of Medicare UC payments is capped, not accounting for Medicaid payments will result in hospitals that have little or no UC costs receiving a higher proportion of Medicare UC payments than warranted, resulting in less funding for hospitals that actually have UC costs. Implementing our recommendation would ensure that Medicare UC payments are based on accurate levels of UC costs and result in CMS better targeting billions of dollars in Medicare UC payments to hospitals with the highest UC costs, while avoiding making payments to hospitals with little or no UC costs.

High-risk area: Medicare Program & Improper Payments

Director: Carolyn L. Yocom, Health Care

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[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).

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 Medicare Advantage (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 this recommendation, according to its fiscal year 2021 budget justification. Although CMS reported using MA encounter data for purposes other than risk adjustment, as of February 2020 the agency has not fully developed specific plans and time frames for such uses. CMS reported that it has begun testing the use of MA encounter data for public health purposes, such as identifying beneficiaries with a history of opioid-related overdose and with other conditions, such as cancer and sickle cell. Further, CMS used MA encounter data to help identify beneficiaries at risk in areas affected by public health emergencies. CMS reported that its Office of the Actuary (OACT) has used MA encounter data to analyze MA beneficiary utilization of certain Medicare Part B drugs. Further, OACT reported that it intends to assess other areas where it could use MA encounter data, such as analyses comparing Medicare fee-for-service and MA. However, as of February 2020, CMS had not developed specific plans and time frames for using MA encounter data for certain purposes in addition to risk adjusting payments to MAOs. 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 address 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 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 this recommendation, according to its fiscal year 2021 budget justification. However, HHS did not commit to completing data validation before using MA encounter data for risk adjustment. As of February 2020, CMS has continued to make progress in examining the completeness and accuracy of MA encounter data, but more work remains to fully validate these data. CMS has developed and is implementing an MA Encounter Data Integrity and Monitoring plan, which includes data analysis, guidance, and monitoring. As part of this plan, CMS has established preliminary performance metrics for MA encounter data completeness and accuracy. CMS is also conducting analyses related to accuracy and completeness, but has not established performance benchmarks for these analyses. While the agency plans to communicate findings from the analyses to MAOs, it has not yet done so. Finally, CMS has not verified MA encounter data by reviewing medical records. To fully address our recommendation, CMS should complete all the steps necessary to validate these data before using these data to risk adjustment payments or for other intended purposes. Without fully validating the completeness and accuracy of MA encounter data, CMS would be unable to confidently use these data for risk adjustment or other program management or policy purposes.

High-risk area: Medicare Program & Improper Payments

Director: James C. Cosgrove, 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.

Actions needed: HHS concurred with this recommendation, as noted in its fiscal year 2021 budget justification. CMS stated in February 2020 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. This recommendation remains open because CMS has not provided documentation of steps such as those described above that the agency has taken to consider revisions to the LVPA. To fully address this recommendation, CMS needs to provide us with documentation of these steps.

High-risk area: Medicare Program & Improper Payments

Director: James C. Cosgrove, 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.: Sept. 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 did not concur with this recommendation, according to its fiscal year 2021 budget justification. CMS believes that a new checkbox on the claim form identifying self-referral would be complex to administer, and providers may not characterize referrals accurately. In addition, as of January 2020, CMS continued to indicate it will not take additional actions to address this recommendation. We continue to believe 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, even though the agency has no plans to take further action.

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

Actions needed: HHS did not concur with this recommendation, according to its fiscal year 2021 budget justification. In addition, as of January 2020, the agency had no plans to take

further action regarding this recommendation. 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. For example, the agency believes that providers in self-referring arrangements could avoid this reduction by having one provider refer an advanced imaging service while having another perform the service. Finally, CMS questioned whether implementing our recommendation would violate the Medicare statute prohibiting paying a differential by physician specialty for the same service. Our recommendation, however, refers to specific self-referral arrangements in which the same provider refers and performs an imaging service, and therefore would not be addressed by CMS's multiple procedure payment reduction policy. As noted in our report, this payment reduction would affect about 10 percent of advanced imaging services referred by self-referring providers. In addition, while CMS raised questions about whether implementing our recommendation would violate Medicare's prohibition on paying a differential by physician specialty for the same service, our report shows that self-referring providers generally referred more MRI and CT services, regardless of differences in specialties, and CMS did not indicate how this recommendation would implicate the prohibition on paying a differential by specialty. We continue to believe 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 did not concur with this recommendation, according to its fiscal year 2021 budget justification. However, we continue to believe that this recommendation is valid, in part because we found that providers who began to self-refer advanced imaging services substantially increased their referral of such services relative to other providers in 2010. To the extent that these additional referrals are unnecessary, they pose an unacceptable risk for beneficiaries, particularly in the case of CT services, which involve the use of ionizing radiation. To fully implement this 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: James C. Cosgrove, 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 (FFS). 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 did not comment on our recommendation when we initially issued our report. In April 2019, CMS stated that it will apply the statutory minimum adjustment of 5.90 percent for calendar year 2020. Although the application of the 5.90 percent adjustment likely brings CMS's adjustment closer to what our analysis projected to be an accurate adjustment, a modified methodology that incorporates more recent data and accounts for all relevant trends in coding differences would better ensure an accurate adjustment in future years. In its fiscal year 2021 budget justification, HHS said it considered this recommendation closed. However, we will keep this recommendation open because CMS has not yet provided us with evidence of the sufficiency of the coding adjustment, nor has it implemented an adjustment based on analysis using an updated methodology. Until CMS takes these steps, payments to MA plans may not accurately account for differences in diagnostic coding between these plans and traditional Medicare providers.

High-risk area: Medicare Program & Improper Payments

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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 this recommendation. In January 2020, HHS stated that it is drafting a new cybersecurity risk management memo that will detail its risk management strategy, including how the department will assess, respond to, and monitor risk. Once the department has provided evidence of these actions, we will determine whether these actions fully address our recommendation.

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

Actions needed: HHS concurred with this recommendation. In January 2020, HHS stated that it is drafting a cybersecurity risk management memo and capability model that will include a process for an organization-wide assessment of cybersecurity risk. These actions—along with those needed for the recommendation above—would help HHS lower the risk of cyber-based incidents that threaten national security and personal privacy. Once the department has provided evidence of these actions, we will determine whether these actions fully address our recommendation.

High-risk area: Ensuring the Cybersecurity of the Nation

Director: Nick Marinos, Information Technology & Cybersecurity

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Data Protection: Federal Agencies Need to Strengthen Online Identity Verification Processes. GAO-19-288. Washington, D.C.: May 17, 2019.

Recommendation: The Administrator of CMS should develop a plan with time frames and milestones to discontinue knowledge-based verification, such as by using Login.gov or other alternative verification techniques.

Actions needed: HHS, on behalf of CMS, did not concur with this recommendation. In its February 2020 response to us, HHS stated that current National Institute of Standards and Technology (NIST) guidance to agencies was insufficient and that CMS would look forward to future guidance from NIST and the Office of Management and Budget to help guide consideration of non-knowledge-based verification options. We continue to believe that our recommendation is valid because a variety of alternative methods to knowledge-based verification are available that CMS can consider to address the diverse population it serves. Further, NIST has agreed with our recommendation to develop additional guidance for agencies, and CMS may be able to use that guidance to identify a verification approach that does not rely on knowledge-based techniques. To fully implement our recommendation, CMS should develop a plan with time frames and milestones to discontinue knowledge-based verification, such as by using Login.gov or other alternative verification techniques. Until CMS takes the needed steps to strengthen its online identify verification processes, individuals who rely on such processes will remain at risk for identity fraud.

High-risk area: Ensuring the Cybersecurity of the Nation

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Cybersecurity Workforce: Agencies Need to Accurately Categorize Positions to Effectively Identify Critical Staffing Needs. GAO-19-144. Washington, D.C.: Mar. 12, 2019.

Recommendation: The Secretary of HHS should take steps to review the assignment of the "000" code to any positions in the department in the 2210 IT management occupational series and assign the appropriate National Initiative for Cybersecurity Education (NICE) framework work role codes.

Actions needed: HHS concurred with our recommendation and stated that it would complete a review of the assignment of the "000" code to its positions in the 2210 IT management occupational series and assign the appropriate NICE framework work role codes. As of March 2020, HHS had made significant progress toward reviewing the assignment of work role codes to its positions in the 2210 IT management occupational series and ensuring that such positions are not coded with the "000" code. To fully implement this recommendation, HHS will need to provide evidence that it has assigned the appropriate NICE framework work role codes to all or nearly all of its positions in the 2210 IT management occupational series.

High-risk area: Ensuring the Cybersecurity of the Nation

Director: Carol Harris, Information Technology & Cybersecurity

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Electronic Health Information: CMS Oversight of Medicare Beneficiary Data Security Needs Improvement. GAO-18-210. Washington, D.C.: Mar. 6, 2018.

Recommendation: The Administrator of CMS should develop processes and procedures to ensure that qualified entities and researchers have implemented information security controls effectively throughout their agreements with CMS.

Actions needed: HHS concurred with this recommendation. In its fiscal year 2021 budget justification, HHS stated that its work to address this recommendation was in progress. To fully implement this recommendation, CMS should develop processes and procedures to ensure that qualified entities and researchers have implemented information security controls effectively throughout their agreements with CMS.

High-risk area: Ensuring the Cybersecurity of the Nation

Director: Nick Marinos, Information Technology & 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 Agriculture, should take steps to consult with respective sector partner(s), such as the sector coordinating council (SCC), Department of Homeland Security (DHS), and the 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.[13]

Actions needed: HHS stated in its fiscal year 2021 budget justification that it concurred with this recommendation and has initiated steps to determine framework 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. However, HHS has yet to development methods to determine the level and type of framework adoption.

High-risk area: Ensuring the Cybersecurity of the Nation

Director: Vijay D'Souza, Information Technology & Cybersecurity

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Public Health Information Technology: HHS Has Made Little Progress toward Implementing Enhanced Situational Awareness Network Capabilities. GAO-17-377. Washington, D.C.: Sept. 6, 2017.

[13]Federal policy identifies 16 critical infrastructure sectors, including the financial services, energy, transportation, and communications sectors. SCCs were formed to serve as the voice of each sector and principal entry point for the government to collaborate with each sector. NIST is a component within the Department of Commerce. NIST's mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards and technology in ways that enhance economic security and improve our quality of life.

Recommendation: To ensure progress is made toward the implementation of any IT enhancements needed to establish electronic public health situational awareness network capabilities mandated by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA), the Secretary of HHS should direct the Assistant Secretary for Preparedness and Response to conduct all IT management and oversight processes related to the establishment of the network in accordance with Enterprise Performance Life Cycle Framework guidance, under the leadership of the HHS CIO.

Actions needed: In its fiscal year 2021 budget justification, HHS stated it concurred with this recommendation. However, as of February 2020, we have not received any information demonstrating progress made to address our recommendation. Until then, HHS may continue to lack the necessary progress needed in order to establish an electronic public health situational awareness network capability mandated by PAHPRA. To fully address this recommendation, HHS needs to direct the Assistant Secretary for Preparedness and Response to conduct all IT management and oversight processes related to the establishment of the network in accordance with Enterprise Performance Life Cycle Framework guidance.

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

Director: Vijay D'Souza, Information Technology & Cybersecurity

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Food and Drug Administration Oversight

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 the Food and Drug Administration (FDA) should coordinate and communicate with the 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: As noted in its fiscal year 2021 budget justification, HHS agreed with our September 2017 recommendation. FDA told us that it shared a method with FSIS for detecting two unapproved drugs. In addition, in December 2019, FDA stated that the agencies share information on their testing methods and instrumentation. Once FDA establishes an import tolerance level, FDA communicates the corresponding analytical method information and tolerance level to FSIS, according to FDA. We commend FDA and FSIS for taking these steps to share information on testing methods. However, we found that the agencies continue to use different multi-residue testing methods that look for different numbers of drugs—99 for FSIS and 40 for FDA—which results in the agencies using different maximum residue levels (MRLs) for some drugs. FDA's method can detect drugs that FSIS's does not and can detect some drugs at lower levels. FSIS's multi-residue method can detect 59 more drugs than FDA's method. The agencies do not have any plans to work on a multi-residue method both agencies can use. We maintain that further action is needed because, without this coordination, the agencies do not have reasonable assurance that they are consistently protecting consumers from unsafe drug residues. To fully implement this recommendation, FDA should coordinate with USDA on (1) the development of testing methods that both agencies can use on imported seafood, including catfish, and on (2) MRLs that will 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 Programs (OIP) strategic workforce plan, the Commissioner of FDA should assess the effectiveness of the foreign offices' contributions by systematically tracking information to measure whether the offices' activities specifically contribute to drug safety-related outcomes, such as inspections, import alerts, and warning letters.

Actions needed: HHS concurred with this recommendation, as noted in its fiscal year 2021 budget justification. HHS told us that FDA plans to conduct internal annual reviews of its foreign offices' performances and track their contributions by type of commodity. FDA has since developed new performance measures for these offices and a monitoring and evaluation plan. FDA intends to continue to develop intermediate outcomes that link to final outcomes of ensuring drug safety and to train staff on tracking program results in fiscal year 2020. We will assess these actions once they have been completed to determine whether they fully implement our recommendation.

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

Director: Mary Denigan-Macauley, Health Care

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Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food. GAO-15-183. Washington, D.C.: Jan. 30, 2015.

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

Actions needed: As noted in its fiscal year 2021 budget justification, HHS concurred with this recommendation. FDA has begun to implement a range of new oversight tools that it believes will help ensure the safety of imported food. However, to fully address the recommendation, FDA should complete an analysis to determine the annual number of foreign food inspections that is sufficient to ensure comparable safety of imported and domestic food; if the inspection numbers from that evaluation are different from the inspection targets mandated in the FDA FSMA, FDA should report the results to Congress and recommend appropriate legislative changes. Without such an analysis, FDA is not in a position to know what a sufficient number of foreign inspections is and, if appropriate, request a change in the mandate.

High-risk area: Improving Federal Oversight of Food Safety

Director: Steve Morris, Natural Resources & Environment

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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: HHS did not concur with this recommendation, and in February 2020, FDA told us the recommendation should be closed, not implemented. We continue to believe in the importance of the recommended actions and note that disclosing the pesticides that are not included in FDA's testing program would be consistent with Office of Management and Budget best practices for reporting limitations relevant to analyzing and interpreting results from a data collection effort. We also note that, since our last update, USDA has implemented a similar recommendation to disclose information about its pesticide program. Therefore the recommendation remains open, and, for us to close it, HHS needs to direct the Commissioner of FDA to disclose in the agency's annual pesticide monitoring program report which pesticides with EPA-established tolerances the agency did not test for in its pesticide monitoring program and the potential effect of not testing for those pesticides.

High-risk area: Improving Federal Oversight of Food Safety

Director: Steve Morris, Natural Resources & Environment

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Indian Health Service Health Care

Indian Health Service: Actions Needed to Improve Oversight of Quality of Care. GAO-17-181. Washington, D.C.: Jan. 9, 2017.

Recommendation: To help ensure that quality care is provided to American Indian/Alaska Native (AI/AN) people, as part of the implementation of its quality framework, the Secretary of HHS should direct the Director of the Indian Health Service (IHS) to ensure that agency-wide standards for the quality of care provided in its federally operated facilities are developed, that facility performance in meeting these standards is systematically monitored over time, and that enhancements are made to its adverse event reporting system.

Actions needed: HHS concurred with this recommendation and cited steps that have been taken to improve the quality of care in IHS's federally-operated facilities, including establishing an IHS Office of Quality, and developing a dashboard of standards for quality of care. In addition, IHS awarded a contract to a software development firm in December 2018 to design a

new adverse event reporting and tracking system for the agency. In March 2020, IHS officials told us the agency had completed a pilot test in three sites, and that one site had gone live with the adverse events reporting system. However, the COVID-19 pandemic response has diverted IHS resources that would be required for successful implementation of the software and adoption of new workflows for managing adverse events. Therefore, IHS is temporarily halting further roll-out of the system until such time as the COVID-19 national emergency has resolved, or a determination is made by IHS leadership that IHS can reasonably be expected to manage a new software release despite on-going disaster response. As such, the recommendation remains open. Once IHS is able to complete its planned activities, we will assess them to determine whether they fully implement our recommendation.

High-risk area: Improving Federal Management of Programs that Serve Tribes and Their Members

Director: Jessica Farb, Health Care

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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 this recommendation. HHS' Behavioral Health Coordinating Council finalized a plan for implementing the Strategy in 2019. The plan includes priorities, timeframes, and clear roles and responsibilities for implementing NAS-related recommendations in the Strategy. The plan does not specifically identify methods for assessing progress on the recommendations, but HHS officials told us in November 2019 that the department holds quarterly conference calls to share updates and that formal written updates will be collected at the end of each year. To fully implement this recommendation, HHS needs to provide documentation—such as, the formal written updates—to show how the department assesses progress on the recommendations.

Director: Mary Denigan-Macauley, Health Care

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Public Health Related Programs and Issues

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 concurred with the recommendation. HHS identified change management practices it has implemented to include strategies for feedback, communication, and education. Specifically, HHS described plans to institutionalize an after-action survey following interagency data collections each year and a communications and outreach plan that was informed by multiple sources of stakeholder impact. These actions, if implemented effectively, are important steps toward addressing our recommendation. To fully address our recommendation, HHS will need to effectively implement these and other change management strategies to enhance understanding of and accountability for shared national security missions.

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 concurred with the recommendation. HHS described assessment steps it has already taken and noted the Biodefense Coordination Team's limited responsibilities to address nonfederal resources in its annual assessments. We recognize the challenges associated with assessing nonfederal capabilities but disagree with HHS's characterization of the Biodefense Coordination Team's responsibilities. According to the National Security Presidential Memorandum-14 (NSPM-14), the foundation for the United States Government's role in the biodefense enterprise is the National Biodefense Strategy and its implementation plan. The memorandum further states that agency biodefense activities shall be conducted consistent with the National Defense Authorization Act for Fiscal Year 2017 (NDAA), which provides that the strategy is to include an articulation of related whole-of-government activities required to support the strategy. We have previously reported that parts of the biodefense enterprise, such as the resources that support surveillance capabilities, are heavily reliant on nonfederal resources. Moreover, the National Biodefense Strategy states that it is broader than a federal government strategy—rather, it is a call to action for various nonfederal entities. To fully address our recommendation, HHS should develop and document clear guidance for the data collection and analytical methods that will support the NDAA's call for articulation of the capabilities that support national biodefense and recommendations for strengthening those capabilities.

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 concurred with the recommendation. HHS said it requested $5 million in no-year funding in its fiscal year 2020 budget request to support the administrative management of the National Biodefense strategy. However, the HHS appropriations for fiscal year 2020 did not include the $5 million HHS requested, and officials from multiple agencies reported that the initial planning for the staffing and responsibilities of the Biodefense Coordination Team had not been finalized. To fully address our recommendation, HHS will need to establish a resource plan that would describe how the Biodefense Coordination Team plans to staff, support, and sustain its efforts.

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 concurred with the recommendation. HHS stated that the Biodefense Coordination Team had developed charters and guidance to govern its activities, but said that these documents were still pending the approval of the Biodefense Steering Committee. We will continue to evaluate these actions to determine the extent to which they fully address our recommendation. To fully address our recommendation, HHS—in partnership with other participating federal agencies—should agree upon and document clear guidance, roles, and responsibilities for addressing shared national security concerns with interagency resources and solutions that transcend the mission and capabilities of the individual agencies. Irrespective of NSPM-14, clarifying decision making processes should help the agencies identify the recommendations for improved capabilities, authorities, command structures, and interagency coordination called for by the NDAA and make incremental progress over time toward implementing those recommendations.

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

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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 this recommendation. In February 2020, HHS said CMS is developing the ability to review survey trends related to alleged perpetrator and alleged abuse types and aims to implement this recommendation by December 2020. To fully implement this 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 this recommendation. In February 2020, 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 December 2020.We will evaluate CMS's actions upon completion to determine the extent to which they fully implement our recommendation.

Director: John E. Dicken, Health Care

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

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

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

Actions needed: HHS concurred with these recommendations. To fully implement these 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

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

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

Actions needed: HHS concurred with our recommendation, as noted in its fiscal year 2021 budget justification. Since our 2015 report, DHS and HHS developed two documents to guide interagency procedures related to the processing of UAC. Specifically, in April 2018, HHS and DHS established a memorandum of agreement regarding information sharing for UAC. Subsequently, on July 31, 2018, DHS and HHS issued a Joint Concept of Operations to memorialize interagency policies, procedures, and guidelines related to the processing of UAC. However, in February 2020, we reported that DHS and HHS officials' indicated that, in practice, the agencies have not resolved long-standing differences in opinion about whether and how agencies are to share information, and what type of information is needed to inform decisions about the care and placement of UAC. In commenting on our draft report, DHS stated that its components are working with HHS to document current information sharing practices, to validate remaining information sharing gaps, and to draft a joint plan between DHS and HHS to ensure that HHS receives information needed to make decisions for UAC. In their comments, HHS officials stated that they intend to reach out to counterparts at DHS in June 2020 to discuss potential periodic updates to the Joint Concept of Operations. To fully address the recommendation, DHS and HHS should ensure that they have implemented procedures aimed at improving the efficiency and accuracy of the interagency UAC referral and placement process.

Director: Rebecca Gambler, Homeland Security and Justice

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Health Insurance Premium Tax Credit Payment Integrity and Enrollment Controls

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 Premium Tax Credit (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 this recommendation. According to the fiscal year 2021 budget justification, CMS is currently in the process of developing an improper payment measurement for the advance PTC. To fully address this recommendation, HHS will need to annually report improper payment estimates and error rates for the advance PTC program.

High-risk area: Enforcement of Tax Laws

Director: Beryl H. Davis, Financial Management and Assurance

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Patient Protection and Affordable Care Act: CMS Should Act to Strengthen Enrollment Controls and Manage Fraud Risk. GAO-16-29. Washington, D.C.: Feb. 23, 2016.

Recommendation: As part of efforts to better oversee the efficacy of PPACA's enrollment control process; to better monitor costs, risk, and program performance; to assist with tax compliance; to strengthen the eligibility determination process; to provide applicants with improved customer service and up-to-date information about submission of eligibility documentation; and to better document agency activities, we recommend that the Secretary of Health and Human Services direct the Administrator of CMS to track the value of advance premium tax credit and cost-sharing reduction (CSR) subsidies that are terminated or adjusted for failure to resolve application inconsistencies, and use this information to inform assessments of program risk and performance.

Actions needed: HHS initially agreed with our recommendation. In April 2016, HHS reported it had expanded the use of analytics to analyze the value of premium tax credit and CSR subsidies that are eliminated or adjusted for 2015 actions at the policy level, and that CMS continues to analyze the data to develop future operations changes. HHS reported that as a result of these actions, it considers our February 2016 recommendation to be addressed.

In May 2016, we requested documentation of these actions, including (1) information produced using the capability described; (2) ways in which this information is being used for analysis for purposes such as program operations, monitoring, risk assessment, or fraud screening; and (3) a description of the future operational changes contemplated based on the analyses done. In March 2019, CMS reversed its initial concurrence with the recommendation. The agency said that in the case of the premium tax credit, it did not have access to certain tax data it considered necessary. For CSR payments, it cited a legal opinion from the U.S. Attorney General regarding the lack of an appropriation for those payments. Based on that opinion, CMS had halted CSR payments in October 2017.

In December 2019, after HHS reiterated its non-concurrence, we disagreed with the agency—saying the issues HHS raised were not relevant—and maintained the importance of implementation. For the premium tax credit, we told CMS the recommendation was not dependent on the tax data. For CSR payments, even though CMS has discontinued the payments, we maintain the recommendation still has value—for CSR payments made before the agency halted them, and in the event Congress appropriates funds for these payments, as the President has requested in his budget request to Congress, and CMS resumes the payments in the future. By not tracking the magnitude of subsidies eliminated or reduced for failure to resolve application inconsistencies, CMS does not collect and have available key financial information relevant to effective program management, including information to determine whether a particular control is cost-effective.

Recommendation: As part of efforts to better oversee the efficacy of PPACA's enrollment control process; to better monitor costs, risk, and program performance; to assist with tax compliance; to strengthen the eligibility determination process; to provide applicants with improved customer service and up-to-date information about submission of eligibility documentation; and to better document agency activities, we recommend that the Secretary of Health and Human Services direct the Administrator of CMS to identify and implement procedures to resolve Social Security number (SSN) inconsistencies where the Marketplace is unable to verify SSNs or applicants do not provide them.

Actions needed: HHS agreed with our recommendation. In April 2016, HHS reported that it was working on implementing functionality for updating consumers' SSNs and their eligibility based on the correct SSN. HHS reported that it was targeting deployment of the SSN update functionality in 2017. However, as of December 2018, HHS officials had not provided us with evidence that the agency has implemented our February 2016 recommendation. SSN inconsistencies are a potential fraud vulnerability in the application process. In addition, SSN inconsistencies also affect tax compliance, because SSNs are a key identifier for tax reconciliation required under the act. In December 2019, HHS told us it continues to evaluate steps necessary to implement the recommendation, and expects full implementation by October 2020.

Recommendation: As part of efforts to better oversee the efficacy of PPACA's enrollment control process; to better monitor costs, risk, and program performance; to assist with tax compliance; to strengthen the eligibility determination process; to provide applicants with improved customer service and up-to-date information about submission of eligibility documentation; and to better document agency activities, we recommend that the Secretary of Health and Human Services direct the Administrator of CMS to re-evaluate CMS's use of Prisoner Update Processing System (PUPS) incarceration data and make a determination to either (a) use the PUPS data, among other things, as an indicator of further research required in individual cases, and to develop an effective process to clear incarceration inconsistencies or terminate coverage, or (b) if no suitable process can be identified to verify incarceration status, accept applicant attestation on status in all cases, unless the attestation is not reasonably compatible with other information that may indicate incarceration, and forego the inconsistency process.

Actions needed: HHS agreed with our recommendation. In April 2016, HHS reported that in 2015, it made the determination to no longer require application filers to submit documentation regarding incarceration status. Hence, HHS considers the February 2016 recommendation to be closed. We were aware of that determination, but the recommendation was to reevaluate use of PUPS from the specific standpoint of using the data as they were intended to be used as an

indicator of further research and then draw a conclusion on the use of the data. In May 2016, we requested documentation demonstrating that in the period since we made this recommendation, CMS has undertaken the reevaluation in the fashion that we indicated. In December 2019, HHS told us it continues to evaluate steps necessary to implement the recommendation, and expects full implementation by October 2021. By not using PUPS data as an indicator of further research required in individual cases, and by relying on applicant attestation in the alternative, CMS may be granting eligibility to, and making subsidy payments on behalf of, individuals who are ineligible to enroll in qualified health plans.

Recommendation: As part of efforts to better oversee the efficacy of PPACA's enrollment control process; to better monitor costs, risk, and program performance; to assist with tax compliance; to strengthen the eligibility determination process; to provide applicants with improved customer service and up-to-date information about submission of eligibility documentation; and to better document agency activities, we recommend that the Secretary of Health and Human Services direct the Administrator of CMS to create a written plan and schedule for providing Marketplace call center representatives with access to information on the current status of eligibility documents submitted to CMS's documents processing contractor.

Actions needed: HHS agreed with our recommendation. In April 2016, HHS reported that since May 2015, call center representatives have received daily updates on the status of eligibility documentation. HHS reported that it is working to provide call center representatives with real-time data. HHS reported it considers this February 2016 recommendation to be closed.

In May 2016, we noted that its February 2016 recommendation was focused on providing such real-time capability and requested (1) confirmation that call center representatives currently have on-demand, real-time access to up-to-date, application-level document status; and documentation showing development and implementation of this capability; or (2) a written plan and schedule for providing this capability as recommended. In December 2019, the agency provided new evidence of implementation, for which we requested supporting information.

The inability of call center representatives to obtain current document status information after the application process is complete is not only a potential vulnerability for efficient and effective operation of the system, but can also be a frustration for consumers attempting to provide requested eligibility information, and could cause them to not file documentation as appropriate. In turn, that could affect CMS's goal of extending health-insurance coverage to all qualified applicants.

Recommendation: As part of efforts to better oversee the efficacy of PPACA's enrollment control process; to better monitor costs, risk, and program performance; to assist with tax compliance; to strengthen the eligibility determination process; to provide applicants with improved customer service and up-to-date information about submission of eligibility documentation; and to better document agency activities, we recommend that the Secretary of Health and Human Services direct the Administrator of CMS to fully document prior to implementation, and have readily available for inspection thereafter, any significant decision on qualified health plan enrollment and eligibility matters, with such documentation to include details such as policy objectives, supporting analysis, scope, and expected costs and effects.

Actions needed: HHS initially agreed with our recommendation. In April 2016, HHS reported CMS prepares an annual Marketplace and Related Programs Cycle Memo to fulfill reporting requirements for internal control. The memo describes all significant eligibility and enrollment policy and process changes, including new internal key controls associated with these changes, and the 2015 Memo was released in September 2015.

HHS reported it considers this recommendation to be closed. However, in May 2016, we notified HHS that its actions do not address the recommendation. Information contained in the memos is after the fact and while useful, does not meet the full range of documentation contemplated by the recommendation, especially development and analysis of changes prior to implementation.

In December 2019, HHS reversed its initial concurrence with the recommendation, and said it would provide additional information on that decision. We continue to maintain the importance of implementation. Without clearly identifying and fully documenting, on a contemporaneous basis, the policy objectives, supporting analysis, scope, and expected costs and effects of implementing significant decisions on enrollment and eligibility matters, CMS undermines transparency and its ability to communicate most effectively with both internal and external stakeholders. CMS also may undermine confidence in the applicant verification process and compromise program integrity.

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

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Head Start Risk Assessments

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 this recommendation, and, in February 2020, told us that the Administration for Children and Families is developing a Fraud Risk Assessment template for all of its programs—including OHS—and is on track to complete the initial Fraud Risk Assessment for its pilot program by June 30, 2020. Upon completion of the Fraud Risk Assessment for the Administration for Children and Families pilot program, the Administration for Children and Families anticipates completing its initial Fraud Risk Assessment for OHS, by March 31, 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.

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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 this recommendation. In fiscal year 2020, HHS indicated that the implementation of its Risk Assessment Portal is underway and went into production in March 2020. In addition, HHS stated that it has revised its improper payment questionnaire and scoring process to ensure HHS performs a reliable assessment of susceptibility to significant improper payments. Further, HHS stated it will leverage its Risk Assessment Portal, new questionnaire, and revised scoring process in the fiscal year 2020 risk assessment reporting period. To fully implement this recommendation, HHS should continue to develop policies, procedures, and supporting tools aimed at improving its processes for conducting improper payment risk assessments.

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.

Actions needed: HHS concurred with this recommendation. In fiscal year 2020, HHS reported that it continues to refine its use of the Digital Accountability and Transparency Act of 2014 (DATA Act) information to create an inventory of programs and activities that could potentially be subject to improper payment risk assessment requirements. In addition, HHS indicated that its Office of the Inspector General (OIG) is currently reviewing the risk-based methodology, which HHS developed for selecting programs and activities for review using the DATA Act files. Lastly, HHS stated that it would implement any feedback from the OIG, as well as lessons learned from the fiscal year 2019 and 2020 risk assessment-reporting period, in fiscal year 2021. To fully implement this recommendation, HHS should continue refining and finalizing its risk-based methodology and provide evidence that the actions taken by the agency ensures that all programs and activities are assessed for susceptibility to significant improper payments at least once every 3 years.

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