U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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Comptroller General
of the United States

March 28, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
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 continued personal attention to areas where open recommendations should be given high priority.[1] In November 2018, we reported that, across all government agencies, 77 percent of our recommendations that were made 4 years ago have been implemented.[2] HHS's recommendation implementation rate was 75 percent. As of January 2019, HHS had 392 open recommendations. We believe fully implementing these open recommendations may significantly improve HHS's operations.

HHS has implemented 13 of the 57 priority recommendations included in our April 4, 2018, letter. In doing so, HHS has improved, for example, the transparency of the process for reviewing and approving spending limits for Medicaid demonstrations; the effectiveness of states' and plans' Medicaid managed care plan provider screening efforts; and Medicare's recovery audit program operations and contractor oversight. In addition to the 13 recommendations HHS implemented, we removed the priority designation from two recommendations because they were either superseded by new priority recommendations or became a lower priority due to recent policy changes, as discussed below.

HHS has 42 priority recommendations remaining from those we identified in our 2018 letter. We ask your continued attention on these remaining recommendations. We are also adding 12 new recommendations as priorities this year related to the Medicare program, the Medicaid program, health information technology, improving oversight of food safety, and Public Health Service Act programs. This brings the total number of priority recommendations to 54. (See enclosure I for the list of these recommendations.)

The 54 priority recommendations fall into the following 10 areas.

[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 2018*, GAO-19-1SP (Washington, D.C.: Nov. 15, 2018).

Medicare program. As we discuss below, this is one of the highest risks facing the government. Addressing Medicare's short-term and long-term challenges is vitally important, not only for the millions of aged and disabled individuals who depend upon the program for health care coverage, but also for the families of these individuals who might otherwise bear the cost of their health care, the taxpayers who finance the program, and the health care providers who depend upon receiving fair compensation for their services. In 2018, Medicare was projected to finance health services for about 60 million elderly and disabled beneficiaries with estimated total expenditures of over $700 billion, and account for 17 percent of federal spending. The aging of the population, coupled with the growth in per capita health care costs, will magnify these challenges over time.

Our nine open priority recommendations in this area generally address steps that the Centers for Medicare & Medicaid Services (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 Medicaid payments a hospital has received that offset uncompensated care (UC) costs when determining hospital uncompensated care costs for the purposes of making Medicare UC payments to individual hospitals. Medicare UC payments that are not adjusted to reflect Medicaid payments undermine CMS's efforts to efficiently pay for health care services.
- 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 (MA) and Medicare Fee-For-Service (FFS). For example, CMS could better account for additional beneficiary characteristics, such as sex and residential location, and use more current and refined data in determining MA 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 MA plans totaling an estimated $3.2 billion to $5.1 billion over a 3-year period from 2010 through 2012. In 2018 CMS stated that it disagreed with our recommendation and that it would apply the statutory minimum adjustment for calendar year 2019. However, CMS has not provided GAO any documentation to date of the basis for its determination. To fully address the recommendation, the agency should demonstrate the sufficiency of the coding adjustment or implement an adjustment using an updated methodology, as we recommended.

Medicaid program. As we discuss below, this also is one of the highest risks facing the government. Medicaid is the second largest health program as measured by expenditures, second only to Medicare, and the largest as measured by enrollment. This federal-state program was projected to cover about 75 million low-income and medically needy people in fiscal year 2018, at an estimated cost of approximately $629 billion. Addressing our 10 open priority recommendations in this area would, among other things, help CMS track critical incidents involving Medicaid beneficiaries, and improve the oversight, accountability, and transparency of Medicaid spending, including through demonstrations, which accounted for about one-third of all federal Medicaid spending in 2016. For example:

- We recommended in January 2018 that the Administrator of CMS establish standard Medicaid reporting requirements for all states to report key information on critical incidents on an annual basis, including the type of critical incidents involving Medicaid beneficiaries, and the type of residential facilities, including assisted living facilities,

where these incidents occurred. Effective state and federal oversight is necessary to ensure that the health and welfare of Medicaid beneficiaries receiving assisted living services are protected, especially given the particular vulnerability of many of these beneficiaries to abuse, neglect, or exploitation. In June 2018, CMS issued a bulletin to states to highlight the importance of critical incident reporting and provide steps states could consider to improve their critical incident reporting systems. To implement this recommendation, HHS would need to establish standard Medicaid reporting requirements for all states to annually report key information on critical incidents.

- In February 2016, we recommended that the Administrator of CMS issue written guidance clarifying its policy that requires a link between the distribution of supplemental payments and the provision of Medicaid-covered services to promote consistency in the distribution of such payments among states and with CMS policy. HHS is considering a proposed rule to address this issue. If a final rule is issued, we will assess the extent to which it addresses our recommendation.

We removed the priority designation from one open recommendation in this area because it was superseded by new recommendations we made in 2018.[3]

Medicare and Medicaid improper payments. Improper payments in the Medicare and Medicaid programs are unacceptably high. Improper payment estimates for the programs totaled over $84 billion in 2018. Based on HHS's fiscal year 2018 agency financial report, federal spending in Medicare and Medicaid is expected to continue to increase. Consequently, it is critical that actions are taken to reduce improper payments in these programs. The eight open priority recommendations in this area outline actions CMS could take to help address the growing number of Medicare and Medicaid improper payment issues through guidance, assessments, collaboration, and claims reviews, among other things. For example:

- In July 2018, we recommended that the Administrator of CMS eliminate impediments to collaborative audits in Medicaid managed care conducted by audit contractors and states to ensure that audits are conducted regardless of which entity recoups any identified overpayments. CMS is conducting audits of individual managed care organization providers in multiple regions with the goal of addressing challenges identified in prior audits. In order to implement this recommendation, the Administrator of CMS should ensure that managed care audits are conducted.
- In May 2018, we recommended that the Administrator of CMS should consider and take steps to mitigate the program risks that are not accounted for in the Medicaid managed care Payment Error Rate Measurement (PERM), such as overpayments and unallowable costs. Such efforts could benefit from focusing additional audit resources on managed care and state auditors that are uniquely qualified to partner with CMS in its oversight of Medicaid. CMS is developing a corrective action plan and finalizing other guidance. In order to implement this recommendation, CMS would need to implement its corrective action plan and finalize its guidance.
- In April 2018, we recommended that the Administrator of CMS take steps to continue using prior authorization, a payment approach that could potentially save millions of dollars in unnecessary Medicare spending. CMS has used prior authorization in

[3]In 2015, we recommended that CMS improve its oversight of Medicaid eligibility determinations. See GAO, *Medicaid: Additional Efforts Needed to Ensure that State Spending is Appropriately Matched with Federal Funds,* GAO-16-53 (Washington, D.C.: Oct. 16, 2015). This recommendation has been superseded in this letter by new recommendations we made in 2018. For these new recommendations, see the Enclosure below.

Medicare since 2012 through four fixed-length demonstrations as well as through one permanent program. At the time of our report, the four fixed-length demonstrations had been paused, ended, or were scheduled to end in 2018, despite positive results. CMS has since taken steps to continue prior authorization by, for example, extending one of these demonstrations. To fully implement this recommendation, CMS would need to take additional steps to continue prior authorization that could include, for example, resuming or extending the remaining demonstrations or identifying new opportunities for expanding prior authorization to additional items and services with high unnecessary utilization and high improper payment rates.

- To better ensure proper Medicare payments and protect Medicare funds, we recommended in April 2016 that the Administrator of CMS seek legislative authority to allow Recovery Auditors (RA) to conduct prepayment claim reviews. HHS disagreed with this recommendation. 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 prior authorization initiatives. However, we found that prepayment reviews better protect agency funds compared with post-payment reviews. Moreover, CMS conducted a demonstration in which the RAs conducted prepayment reviews, and concluded that the demonstration was a success.

Health information technology. The nation's critical infrastructure provides the essential services—including health care—that underpin American society. The infrastructure 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. Additionally, recent data breaches have highlighted the importance of ensuring the security of health information, including Medicare beneficiary data. Such data are created, stored, and used by a wide variety of entities, such as health care providers, insurance companies, financial institutions, researchers, and others. The four open priority recommendations within this area outline steps to ensure HHS can effectively monitor the effect of electronic health record (EHR) programs and progress made toward goals, encourage adoption of important cybersecurity processes and procedures among healthcare entities, protect Medicare beneficiary data accessed by external entities, and ensure progress is made toward the implementation of information technology (IT) enhancements needed to establish the electronic public health situation awareness network. For example:

- We recommended in March 2018 that the Administrator of the Centers for Medicare & Medicaid Services develop processes and procedures to ensure that qualified entities and researchers have implemented information security controls effectively throughout their agreements with CMS. CMS will be engaging a contractor to review the current data security framework and make recommendations on specific controls and implementation requirements that would be appropriate for those entities. To fully implement this recommendation, CMS needs to develop appropriate processes and procedures for implementing these controls.

Food and Drug Administration oversight. The Food and Drug Administration (FDA) reports that about 80 percent of active pharmaceutical ingredient manufacturers are located outside of the U.S. In addition, FDA is responsible for ensuring the safety of virtually all domestic and imported food products. FDA established foreign offices to obtain better information on products coming from overseas and perform inspections, among other things. Addressing our five 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 March 2018, we recommended that FDA and the U.S. Department of Agriculture (USDA) develop a mechanism to coordinate the development of methods to detect contaminants in food, including arsenic in rice. To fully implement this recommendation, FDA and USDA should clearly describe what steps they will take to proactively address joint research needs, in addition to sharing information on research the agencies have already approved.
- In September 2017, we recommended that the Commissioner of FDA coordinate and communicate with USDA's 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.[4] FDA stated that it shared its testing methods for two drugs with FSIS and it made recommendations to FSIS on maximum levels for drug residues. In addition, FDA provided FSIS information about its development of new methodologies. However, the agencies continue to use different multi-residue testing methods that look for different numbers of drugs—61 for FSIS and 28 for FDA—which results in the agencies using different maximum residue levels for some drugs. To fully implement this recommendation, FDA should coordinate with USDA on (1) the development of testing methods that both agencies can use on seafood, including catfish, and on (2) 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 2.2 million American Indian/Alaska Native (AI/AN) people who are members or descendants of 573 tribes. AI/AN people born today have a life expectancy that is 5.5 years lower than all races in the United States. They continue to die at higher rates than other Americans from preventable causes and have experienced long-standing problems accessing health care services. Addressing our two open priority recommendations in this area would help IHS address quality and timeliness of health care services. For example:

- In March 2016, we recommended that IHS monitor patient wait times and ensure corrective actions are taken when wait time standards are not met. IHS is updating its patient wait time policy to include emergency department wait times, and is working to automate and aggregate the reporting of patient wait time data for effective monitoring. To fully implement this recommendation, once the standards are fully developed and monitoring is underway, IHS will also need to ensure corrective actions are taken when standards are not met.

Opioid use disorders. The misuse of prescription opioid pain relievers and illicit opioids, such as heroin, has contributed to increases in overdose deaths. According to the most recent Centers for Disease Control and Prevention (CDC) data, in 2017 over 70,000 people died of drug overdose deaths, and about 68 percent of them involved an opioid. For those who are addicted to or misuse opioids, medication-assisted treatment (MAT)—behavioral therapy combined with medication—can help. The rising opioid epidemic has also contributed to an increase in the number of babies born with neonatal abstinence syndrome (NAS)—a withdrawal condition with symptoms including excessive crying and difficulty breathing. Addressing our

[4]FSIS is the public health regulatory agency responsible for ensuring the safety of meat, poultry, and processed eggs. Beginning in April 2016, FSIS became responsible for ensuring the safety of imported catfish.

three open priority recommendations in this area would help HHS evaluate its efforts at expanding MAT, gather important data on opioid prescribing patterns within the Medicare population, and ensure that the agency's recommendations for addressing NAS are implemented.

- In October 2017, we recommended that the Assistant Secretary for Planning and Evaluation establish performance measures with targets related to expanding access to MAT for opioid use disorders. HHS stated that it will continue to work to develop robust performance measures, including measures related to MAT, as part of its overall Opioid Strategy. However, while HHS has established a goal to expand access to MAT, it has yet to establish performance measures to track the treatment capacity of medical practitioners who provide MAT. To fully implement this recommendation, HHS should establish these measures.
- Also in October 2017, we recommended that the Administrator of CMS gather information over time on the complete number of Medicare beneficiaries at risk of harm from opioids. CMS's current opioid monitoring criteria focus on beneficiaries who (1) receive prescriptions of high doses of opioids, (2) receive prescriptions from four or more providers, and (3) fill the prescriptions at four or more pharmacies. This approach misses some beneficiaries who do not meet these criteria but could be at risk of harm because they received high doses of opioids. CMS stated that the agency tracks these additional beneficiaries through patient safety measures. However, these patient safety measures currently do not include all at-risk beneficiaries. In addition, while CMS uses the patient safety measures to assess plan sponsor performance, the data are relatively new, and CMS has not yet used them to report progress over time toward its goals. To fully implement this recommendation, HHS would need to demonstrate that it is tracking the complete number of at-risk beneficiaries over time to help determine progress toward its goals.
- Also in October 2017, we recommended that 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 NAS-related recommendations identified in the Protecting Our Infants Act: Final Strategy.[5] HHS has taken steps to develop a plan for implementing the Strategy but has not yet finalized the plan. To fully implement this recommendation, HHS would need to provide documentation that this plan includes priorities, time frames, clear roles and responsibilities, and methods for assessing progress.

Public Health Service Act programs. The 340B Drug Pricing Program—which is authorized by the Public Health Service Act—requires drug manufacturers to sell outpatient drugs at a discount to covered entities, including certain hospitals and federal grantees (such as federally qualified health centers) to have their drugs covered by Medicaid. In addition, the Medicaid Drug Rebate Program requires manufacturers to pay rebates on covered outpatient drugs dispensed to Medicaid beneficiaries, which is an important source of savings for states and the Federal government. Covered entities are prohibited from subjecting manufacturers to "duplicate discounts" in which drugs prescribed to Medicaid beneficiaries are subject to both the 340B discount and a rebate through the Medicaid Drug Rebate Program. Without addressing our two

[5]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.

open priority recommendations in this area, HHS does not have assurance that covered entities are complying with program requirements, which puts manufacturers at risk of being required to erroneously provide duplicate discounts for Medicaid prescriptions.

- In June 2018, we recommended that 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. We also recommended that HRSA incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts into its audit process and ensure that identified violations are rectified by the entities. To fully implement these recommendations, HHS would need to issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care and implement updated audit procedures.

Health insurance premium tax credit payment integrity and enrollment controls. The Patient Protection and Affordable Care Act (PPACA) provides for the establishment of health insurance marketplaces where consumers can select private health insurance plans. For individuals who meet certain requirements, PPACA provides subsidies, including a premium tax credit (PTC), to help cover costs. With those subsidies and other costs, PPACA represents a significant, long-term fiscal commitment for the federal government. Addressing our nine open priority recommendations in this area would 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 to improve annual reporting on PTC improper payments, control activities related to eligibility determinations, and calculations of advance PTC, HHS should annually report improper payment estimates and error rates for the advance PTC program. CMS is currently in the process of developing an improper payment measurement for the advance PTC and stated 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 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 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.

We removed the priority designation from one recommendation in this area—related to Cost Sharing Reduction (CSR) subsidies—because in October 2017, HHS announced it was discontinuing payments to issuers for CSRs due to the lack of an appropriation for the payments.

Oversight of federal awards and research grants. In fiscal year 2017, federal agencies outlaid over $650 billion in federal awards to state and local governments, according to the Office of Management and Budget (OMB). Additionally, the federal government obligated nearly $30 billion for university research in fiscal year 2017. To allow for oversight of these funds, Congress and research funding agencies established administrative requirements that universities must comply with as part of grants they apply for and receive. Addressing our two

open priority recommendations in this area would help HHS ensure that it is conducting the required effective oversight of the federal funds it has awarded and that the administrative workload and costs for complying with requirements for receiving university research funding are not overly burdensome. For example:

- In June 2016, we recommended that to further standardize administrative research requirements, HHS should coordinate through the Office of Science and Technology Policy's (OSTP) Research Business Models working group to identify additional areas where the agency can standardize requirements and report on these efforts.[6] In May 2018, the Research Business Models working group, which includes representatives from the Department of Energy, HHS, NASA, National Science Foundation (NSF) and other research-funding agencies, issued its first annual report under the American Innovation and Competitiveness Act. The report identified several potential areas for standardization or harmonization of requirements, such as the policy for what constitutes a financial conflict of interest. By continuing to coordinate through the working group to standardize administrative requirements for federal research grants, agencies could achieve reductions in universities' administrative workload and costs while maintaining accountability over grant funds. We will continue to monitor HHS's actions related to this recommendation.

In March, 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. 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.

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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

[6]OSTP is responsible for advising the President on the federal budget for research and shapes research priorities across agencies with significant portfolios in science and technology. OSTP also helps develop and implement government-wide science and technology policies and coordinate interagency research initiatives.

[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).

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 392 open recommendations. Thank you for your attention to these matters.

Sincerely yours,

Gene L. Dodaro
Comptroller General
of the United States

Enclosure

cc: Eric D. Hargan, Deputy Secretary, Department of Health and Human Services
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)
Scott Gottlieb, M.D., Commissioner, Food and Drug Administration (FDA)
George Sigounas, M.S., Ph.D., Administrator, Health Resources and Services Administration (HRSA)
RADM Michael D. Weahkee, Principal Deputy Director, Indian Health Service (IHS)
Don Rucker, M.D., National Coordinator for Health Information Technology (ONC)

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

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 the Centers for Medicare & Medicaid Services (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 concurred with this recommendation. However, in December 2017 HHS indicated that it was reconsidering whether to offset Medicare UC payments by Medicaid's uncompensated care payments because of differences in how Medicare and Medicaid define uncompensated care. Although Medicare and Medicaid define uncompensated care costs somewhat differently, a common and significant cost in their definitions is the uncompensated care costs for uninsured individuals.

We continue to believe that CMS should account for Medicaid payments when determining hospital uncompensated care costs. Without accounting for such payments, CMS is at risk of making Medicare uncompensated care payments to hospitals that do not have any uncompensated care costs. To fully implement this recommendation, 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 UC payments to individual hospitals.

High-risk area: Medicare Program & Improper Payments

Director: Carolyn L. Yocom, Health Care
Contact information: yocomc@gao.gov, (202) 512-7114

Medicare Advantage: CMS Should Fully Develop Plans for Encounter Data and Assess Data Quality before Use, GAO-14-571. Washington, D.C.: July 31, 2014.

Recommendation: To ensure that 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 generally agreed with this recommendation. We reported in January 2017 that CMS had made progress in developing plans for using MA encounter data for risk adjustment, but had not specified plans and time frames for most other purposes.[8] Since that time, CMS has begun using MA encounter data for additional purposes, and has plans to use

[8]GAO, *Medicare Advantage: Limited Progress Made to Validate Encounter Data Used to Ensure Proper Payments,* GAO-17-223 (Washington, D.C.: Jan. 17, 2017).

the data to develop care coordination measures. However, the agency has not fully developed specific plans and time frames for using the data for all intended purposes. We will continue to monitor CMS's progress.

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 generally agreed with this recommendation. However, HHS did not commit to completing data validation before using MA encounter data for risk adjustment. Without fully validating the completeness and accuracy of MA encounter data, CMS would be unable to confidently use these data for risk adjustment or any other program management or policy purposes. To address this recommendation, CMS needs to undertake activities that fully address encounter data accuracy, such as reviewing medical records to verify encounter data.

High-risk area: Medicare Program & Improper Payments

Director: James C. Cosgrove, Health Care
Contact information: cosgrovej@gao.gov, (202) 512-7114

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

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 and has been monitoring the impact of the LVPA treatment threshold to determine whether modifying it is warranted. To fully implement this recommendation, HHS needs to provide documentation that the Department has considered revisions such as changing the LVPA to a tiered adjustment.

High-risk area: Medicare Program & Improper Payments

Director: James C. Cosgrove, Health Care
Contact information: cosgrovej@gao.gov, (202) 512-7114

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

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. 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. 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. To address this recommendation, CMS would need to 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.

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. In particular, HHS questioned whether it had statutory authority to impose a payment reduction for the subset of physicians who self-refer, citing a 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. To address this recommendation, CMS would need to determine and implement a payment reduction for self-referred advanced imaging services to recognize efficiencies when the same provider refers and performs a service.

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 said it would consider this recommendation when refining the agency's medical review strategy for advanced imaging services. 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
Contact information: cosgrovej@gao.gov, (202) 512-7114

Medicare Special Needs Plans: CMS Should Improve Information Available about Dual-Eligible Plans' Performance, GAO-12-864. Washington, D.C.: September 13, 2012.

Recommendation: To increase dual-eligible special needs plans' (D-SNP) accountability and ensure that CMS has the information it needs to determine whether D-SNPs are providing the services needed by dual-eligible beneficiaries, especially those who are most vulnerable, the Administrator of CMS should conduct an evaluation of the extent to which D-SNPs have provided sufficient and appropriate care to the population they serve, and report the results in a timely manner.

Actions needed: HHS concurred with this recommendation. In order to address this recommendation, CMS needs to conduct an evaluation of the extent to which D-SNPs have provided sufficient and appropriate care to the population they serve and report the results in a timely manner.

High-risk area: Medicare Program & Improper Payments

Director: James C. Cosgrove, Health Care
Contact information: cosgrovej@gao.gov, (202) 512-7114

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

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: In October 2018, HHS stated that it disagreed with our recommendation. The agency stated that, given the complexity of measuring coding changes attributable to plan behavior and the difficulty of measuring countervailing factors, there is not a single correct factor within the viable range of adjustment factors. In addition, the agency noted that there is policy discretion with respect to the appropriate adjustment factor for the payment year.

CMS noted in April 2018 that it will apply the statutory minimum adjustment of 5.9 percent for calendar year 2019. To date, CMS has not provided GAO any documentation of its analysis and the basis for its determination. Although the application of the 5.9 percent adjustment likely brings CMS's adjustment closer to what GAO's analysis projects to be an accurate adjustment, a modified methodology that incorporates more recent data, accounts for all relevant years of coding differences, and incorporates the effect of coding difference trends would better ensure an accurate adjustment in future years.

To fully implement this recommendation, CMS needs to provide us with evidence of the sufficiency of the coding adjustment or implement an adjustment based on analysis using an updated methodology.

High-risk area: Medicare Program & Improper Payments

Director: James C. Cosgrove, Health Care
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Medicaid Program

Medicaid Managed Care: Additional CMS Actions Needed to Help Ensure Data Reliability, GAO-19-10. Washington, D.C.: October 19, 2018.

Recommendation: The Administrator of CMS should provide states with information on the circumstances under which CMS would defer or disallow matching funds in response to noncompliant encounter data submissions.

Actions needed: HHS neither agreed nor disagreed with our recommendation and noted steps the agency has already taken to remind states of their obligation to submit timely, quality encounter data, and prioritize data quality. In January 2019, HHS identified a possible step CMS could take in the event it finds deficiencies in states' encounter data reporting that cannot be resolved through informal monitoring and discussions with state Medicaid agencies. In particular, HHS noted that CMS would issue guidance on the parameters by which the agency would impose financial penalties on states for noncompliant encounter data submissions, if necessary. To fully implement this recommendation, the Administrator of CMS should provide states with this information.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care
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Medicaid Demonstrations: Evaluations Yielded Limited Results, Underscoring Need for Changes to Federal Policies and Procedures, GAO-18-220. Washington, D.C.: January 19, 2018.

Recommendation: The Administrator of CMS should establish and implement a policy for publicly releasing findings from federal evaluations of demonstrations, including findings from rapid cycle, interim, and final reports, and this policy should include standards for timely release.

Actions needed: HHS concurred with this recommendation. CMS is piloting a written procedure for the clearance of federal evaluation reports. HHS stated that CMS would finalize the process once the agency gained appropriate experience with it. To fully implement this recommendation, CMS needs to finalize the agency's written procedures specifying standards for the timely release of findings from federal evaluations.

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.: January 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. In June 2018, CMS issued a bulletin to states to highlight the importance of critical incident reporting and

provide steps states could consider to improve their critical incident reporting systems. To fully implement this recommendation, HHS would need to establish standard Medicaid reporting requirements for all states to annually report key information on critical incidents.

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.: December 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. HHS stated that it developed a database on data quality findings, which could be used to identify solutions for common problems across states, and has begun to develop a data quality scorecard for T-MSIS users, which aggregates data quality findings in a user-friendly tool. HHS stated that it will (1) continue to work to obtain complete T-MSIS information from all states; (2) take additional steps to share information across states on T-MSIS data limitations; and (3) implement ways for states to collaborate regarding T-MSIS. Taking these steps would address our recommendation. We will monitor HHS's implementation of these steps.

High-risk area: Strengthening Medicaid Program Integrity

Director: Carolyn L. Yocom, Health Care
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Medicaid: Program Oversight Hampered by Data Challenges, Underscoring Need for Continued Improvements, GAO-17-173. Washington, D.C.: January 6, 2017.

Recommendation: The Administrator of CMS should take immediate steps to assess and improve the data available for Medicaid program oversight, including, but not limited to, T-MSIS. Such steps could include (1) refining the overall data priority areas in T-MSIS to better identify those variables that are most critical for reducing improper payments, and (2) expediting efforts to assess and ensure the quality of these T-MSIS data.

Actions needed: HHS concurred with this recommendation. With all states now reporting at least some T-MSIS data, CMS is focused on assessing and improving data quality. CMS identified 12 Top Priority Items (TPI) and issued a State Health Official letter in August 2018 that informed states they are expected to resolve data quality issues related to TPIs within 6 months. CMS stated it will request states that do not meet this time frame to submit a corrective action

plan. CMS also noted that it intends to expand data reviews beyond the 12 TPIs, but has not specified a time frame for completing this and other data quality efforts. Once initiatives to improve T-MSIS data quality are further developed and CMS determines that T-MSIS data are of sufficient quality for oversight purposes the agency identifies, we can close the recommendation.

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.: February 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 concurred with this recommendation. CMS has issued clarifying letters to some states, but has not issued written clarification to all states explaining that the distribution of supplemental payments be linked to the provision of Medicaid-covered services. CMS announced in fall 2018 that it is planning a proposed rule that may address this issue. The agency plans to release the proposed rule for comment in 2019. If a final rule is issued, we will assess 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 did not concur with this recommendation, although it did agree that the issue is a concern and stated it was considering additional options to address the issue. In light of our finding that, among selected states reviewed, supplemental payments were often contingent on availability of local funding, we maintain that HHS should issue written guidance to all states, communicating its policy prohibiting Medicaid payments contingent on the availability of local funding.

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.: April 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.

Recommendation: To improve CMS's oversight of Medicaid payments, the Administrator of CMS should, once criteria are developed, develop a process for identifying and reviewing payments to individual providers in order to determine whether they are economical and efficient.

Actions needed: HHS concurred with these recommendations. To fully address these recommendations, CMS would need to develop a policy establishing criteria for when Medicaid payments at the provider level are economical and efficient, and once criteria are developed, develop a process for identifying and reviewing payments to individual providers in order to determine whether they are economical and efficient. CMS announced in fall 2018 that it is planning a proposed rule that may address these issues. The agency plans to release the proposed rule for comment in spring 2019. If a final rule is issued and guidance is developed, we will assess the extent to which these actions address our recommendations.

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.[9]

Actions needed: HHS 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 and 2013 reports.[10] HHS has taken steps to change some aspects of 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 GAO identified in its 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. GAO has 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

[9]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).

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

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Medicare and Medicaid Improper Payments

Medicaid: CMS Needs to Better Target Risks to Improve Oversight of Expenditures, GAO-18-564. Washington, D.C.: August 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. To implement this recommendation, CMS should execute the agency's current plan for completing an assessment. In November 2018, CMS indicated that the agency plans to complete a comprehensive, national risk assessment. Specifically, CMS regional offices plan to use a standard form to assess risk and staff capacity. The agency indicated that once the assessment is complete, CMS will identify opportunities to increase resources, review the current allocation of financial staff, and determine the appropriate allocation of staff by state. We will continue to monitor CMS's actions to complete this assessment.

High-risk area: Strengthening Medicaid Program Integrity

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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. CMS is conducting audits of individual MCO network providers in multiple regions with the goal of addressing challenges identified in prior audits. To implement this recommendation, the Administrator should ensure that managed care audits are conducted regardless of which entity recoups any identified overpayments.

Recommendation: The Administrator of CMS should require states to report and document the amount of MCO overpayments to providers and how they are accounted for in capitation rate-setting.

Actions needed: HHS concurred with our recommendation. CMS is updating its 2019–2020 rate-setting guidance to include state reporting on overpayments and how they are considered in capitation rate development. To implement this recommendation, CMS should develop and implement this guidance.

High-risk area: Strengthening Medicaid Program Integrity

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

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

Actions needed: HHS concurred with this recommendation. CMS is developing a corrective action plan for this recommendation and finalizing other guidance. In order to implement this recommendation, CMS would need to implement its corrective action plan and finalize other guidance.

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.: April 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. CMS has used prior authorization in Medicare since 2012 through four fixed-length demonstrations, as well as through one permanent program. At the time of our report, the four fixed-length demonstrations had been paused, ended, or were scheduled to end in 2018, despite positive results. CMS has since taken steps to continue prior authorization by, for example, extending one of these demonstrations. To fully implement this recommendation, CMS would need to take additional steps to continue prior authorization that could include, for example, resuming or extending the remaining demonstrations or identifying new opportunities for expanding prior authorization to additional 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.: April 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. 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 prior authorization initiatives and 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 RAs conducted prepayment reviews, and concluded that the demonstration was a success. To implement this recommendation, CMS should seek legislative authority to allow RAs to conduct these reviews.

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.: April 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 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 and reaffirmed its commitment to identifying and correcting improper payments in the MA program. HHS said it 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. CMS expects to complete these actions by the end of fiscal year 2019. Once completed, CMS needs to provide evidence that the actions taken by the agency 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 Information Technology: CMS Supports Use of Program Integrity Systems but Should Require States to Determine Effectiveness, GAO-15-207. Washington, D.C.: January 30, 2015.

Recommendation: To ensure that the federal government's and states' investments in information systems result in outcomes that are effective in supporting efforts to save funds through the prevention and detection of improper payments in the Medicaid program, the Secretary of Health and Human Services should direct the Administrator of CMS to require states to measure quantifiable benefits, such as cost reductions or avoidance, achieved as a result of operating information systems to help prevent and detect improper payments. Such measurement of benefits should reflect a consistent and repeatable approach and should be reported when requesting approval for matching federal funds to support ongoing operation and maintenance of systems that were implemented to support Medicaid program integrity purposes.

Actions needed: In December 2017, CMS officials stated that they no longer concur with this recommendation. CMS noted that the agency is taking steps to reduce the regulatory and reporting burden for states and that requiring states to measure benefits achieved as a result of implementing systems for program integrity and other purposes is not feasible.

Unless CMS requires states to measure such benefits, it cannot determine whether the potentially billions of dollars of federal funds spent to support the implementation, operation, and maintenance of the systems used by the states for program integrity purposes result in savings for the Medicaid program. As such, we continue to believe that steps should be taken by CMS to ensure financial benefits are achieved as a result of federal information technology (IT) investment in states' continuing operation and maintenance of systems to support Medicaid program integrity efforts. In order to fully address this recommendation, HHS should direct the Administrator of CMS to require states to measure quantifiable benefits achieved as a result of operating information systems to help prevent and detect improper payments.

High-risk area: Strengthening Medicaid Program Integrity

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Health Information Technology

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

Recommendation: The Administrator of the Centers for Medicare and Medicaid Services 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 and has begun taking steps to address the recommendation. 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.: February 15, 2018.

Recommendation: The Secretary of Health and Human Services, in cooperation with the Secretary of Agriculture, should take steps to consult with respective sector partner(s), such as the sector coordinating council (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.[11]

Actions needed: HHS concurred with this recommendation. HHS is conferring with appropriate operating divisions and agencies to identify applicable methodologies for determining the level and type of framework adoption across the health care and public health (HPH) sector. To fully implement this recommendation, HHS should develop methods for determining the level and type of framework adoption by entities across their respective sector.

High-risk area: Ensuring the Cybersecurity of the Nation

Director: Nick Marinos, 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.: September 6, 2017.

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: HHS neither agreed nor disagreed with this recommendation. Until steps are taken to implement our recommendation, HHS may continue to lack the necessary progress

[11]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.

needed in order to establish an electronic public health situational awareness network capability mandated by PAHPRA. To 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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Electronic Health Record Programs: Participation Has Increased, but Action Needed to Achieve Goals, Including Improved Quality of Care, GAO-14-207. Washington, D.C.: March 6, 2014.

Recommendation: To ensure that CMS and the Office of the National Coordinator for Health Information Technology (ONC) can effectively monitor the effect of the electronic health record (EHR) programs and progress made toward goals, the Secretary of Health and Human Services should direct the agencies to develop performance measures to assess outcomes of the EHR programs—including any effects on health care quality, efficiency, and patient safety and other health care reform efforts that are intended to work toward similar outcomes.

Action Needed: HHS neither agreed nor disagreed with this recommendation. HHS provided a variety of publicly available reports, which the Department indicated showed how program participants were progressing in the EHR programs and the related impacts. However, in reviewing those materials, we did not see evidence that HHS had developed outcome-oriented performance measures that align with the intended outcomes of the EHR programs.

In 2018, CMS changed the name of these programs to the Promoting Interoperability programs to focus on improving interoperability and patients' access to health information, and officials noted that the agency is working to develop related outcome-based measures. To fully implement this recommendation, CMS needs to develop performance measures that enable the agency to assess whether the Promoting Interoperability programs are improving outcomes, such as health care quality, efficiency, and patient safety, as we recommended.

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Food and Drug Administration Oversight

Food Safety: Federal Efforts to Manage the Risk of Arsenic in Rice, GAO-18-199. Washington, D.C.: March 16, 2018.

Recommendation: The Commissioner of the Food and Drug Administration (FDA) should work with the U.S. Department of Agriculture (USDA) to develop a mechanism to coordinate the development of methods to detect contaminants in food, including arsenic in rice.

Actions needed: HHS concurred with this recommendation. To fully implement the recommendation, FDA and USDA should clearly describe what steps they will take to

proactively address joint research needs, in addition to sharing information on research the agencies have already approved.

High-risk area: Improving Federal Oversight of Food Safety

Director: Steve Morris, Natural Resources & Environment
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Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues, GAO-17-443. Washington, D.C.: September 15, 2017.

Recommendation: The Commissioner of 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: HHS concurred with this recommendation. To fully implement this recommendation, FDA should coordinate with USDA on (1) the development of testing methods that both agencies can use on seafood, including catfish, and on (2) maximum residue levels 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.: December 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 and stated 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. To close this recommendation, 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. FDA intends to conduct this assessment in fiscal year 2019. We will assess these actions once they have been completed.

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

Acting 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.: January 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: HHS concurred with this recommendation. To fully address this 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, and if warranted, report the results to Congress and recommend appropriate legislative changes.

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.: October 7, 2014.

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

Actions needed: HHS did not concur with this recommendation. HHS stated that, in its annual report, FDA discloses all pesticides tested for that were within the report's annual scope, as required by the Pesticide Monitoring Improvements Act of 1988. However, disclosing the pesticides that are not included in FDA's testing program would be consistent with Office of Management and Budget (OMB) best practices for reporting limitations relevant to analyzing and interpreting results from a data collection effort. To address this recommendation, 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

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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.: January 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 were underway 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. We will assess HHS's actions once completed.

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

Director: Jessica Farb, Health Care
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Indian Health Service: Actions Needed to Improve Oversight of Patient Wait Times, GAO-16-333. Washington, D.C.: March 29, 2016.

Recommendation: To help ensure that timely primary care is available and accessible to AI/AN people, the Secretary of HHS should direct the Director of IHS to monitor patient wait times in its federally operated facilities and ensure corrective actions are taken when standards are not met.

Actions needed: HHS concurred with this recommendation. IHS is updating its patient wait time policy to include emergency department wait times, and is working to automate and aggregate the reporting of patient wait time data for effective monitoring. Once the standards are fully developed and monitoring is underway, IHS will also need to ensure corrective actions are taken when standards are not met. We will assess HHS's actions once completed.

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

Director: Jessica Farb, Health Care
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Opioid Use Disorders

Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment, GAO-18-44. Washington, D.C.: October 31, 2017.

Recommendation: The Assistant Secretary for Planning and Evaluation should establish performance measures with targets related to expanding access to Medication-Assisted Treatment (MAT) for opioid use disorders.

Actions needed: HHS concurred with this recommendation. HHS stated that it will continue to work to develop robust performance measures, including measures related to MAT, as part of its overall Opioid Strategy. However, while HHS has established a goal to expand access to MAT, it has yet to establish performance measures to track the treatment capacity of medical practitioners who provide MAT. To fully implement this recommendation, HHS should establish these measures.

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Prescription Opioids: Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm, GAO-18-15. Washington, D.C.: October 6, 2017.

Recommendation: The Administrator of CMS should gather information over time on the number of beneficiaries at risk of harm from opioids, including those who receive high opioid morphine equivalent doses regardless of the number of pharmacies or providers, as part of assessing progress over time in reaching the agency's goals related to reducing opioid use.

Actions needed: HHS concurred with this recommendation. HHS stated that CMS tracks beneficiaries who meet these criteria through patient safety measures. However, while these patient safety measures are a potential source of this information, they currently do not include all at-risk beneficiaries, because the opioid use threshold they use is more lenient than indicated in Center for Disease Control (CDC) guidelines or in CMS's revised Overutilization Monitoring System criteria. In addition, while CMS uses the patient safety measures to assess plan sponsor performance, the data are relatively new, and CMS has not yet used them to report progress over time toward its goals. To fully implement this recommendation, HHS would need to demonstrate that it is tracking the complete number of at-risk beneficiaries over time to help determine progress toward its goals.

High-risk area: Medicare Program & Improper Payments

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Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome, GAO-18-32. Washington, D.C.: October 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 noted that its Behavioral Health Coordinating Council has taken steps to develop a plan for implementing the Strategy but has not yet finalized the plan. To close this recommendation, HHS would need to provide documentation that this plan includes priorities, time frames, clear roles and responsibilities, and methods for assessing progress.

High-risk area: Strengthening Medicaid Program Integrity

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Public Health Service Act Programs

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.

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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 Health and Human Services 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. 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.

Recommendation: To improve annual reporting on PTC improper payments, control activities related to eligibility determinations, and calculations of advance PTC, the Secretary of Health and Human Services should direct the Administrator of CMS to design and implement procedures for verifying compliance with applicable tax filing requirements—including the filing of the federal tax return and the Form 8962, Premium Tax Credit—necessary for individuals to continue to be eligible for advance PTC.

Actions needed: HHS concurred with this recommendation. HHS stated that the Internal Revenue Service (IRS) provides information to marketplaces on consumers who received advance PTC in the prior coverage year but have not taken the necessary steps to file a tax return and reconcile advance PTC. HHS officials stated that they have established a process for verifying compliance with applicable tax filing requirements; however, HHS has not provided documentation enabling GAO to validate that the verification process has taken place. We will assess HHS's actions once completed.

Recommendation: To improve annual reporting on PTC improper payments, control activities related to eligibility determinations, and calculations of advance PTC, the Secretary of Health and Human Services should direct the Administrator of CMS to design and implement procedures for verifying with IRS (1) household incomes, when attested income amounts significantly exceed income amounts reported by IRS or other third-party sources, and (2) family sizes.

Actions needed: HHS neither agreed nor disagreed with this recommendation. CMS conducted an analysis and determined it was feasible to verify household incomes but not family sizes. To fully implement this recommendation, HHS will need to design and implement procedures for verifying with IRS household incomes, when attested income amounts significantly exceed income amounts reported by IRS or other third-party sources.

High-risk area: Enforcement of Tax Laws

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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.: February 23, 2016.

Recommendation: As part of efforts to better oversee the efficacy of the Patient Protection and Affordable Care Act's (PPACA) 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 conduct a comprehensive feasibility study on actions that CMS can take to monitor and analyze, both quantitatively and qualitatively, the extent to which data hub queries provide requested or relevant applicant verification information, for the purpose of improving the data-

matching process and reducing the number of applicant inconsistencies; and for those actions identified as feasible, create a written plan and schedule for implementing them.

Actions needed: HHS concurred with this recommendation. HHS has noted steps the agency has taken to implement this recommendation but has not provided sufficient documentation to demonstrate full implementation. To demonstrate full implementation, HHS should conduct a comprehensive feasibility study and create a written plan and schedule for implementing appropriate actions based on the results of the study.

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 concurred with this recommendation. To demonstrate implementation, HHS must first show it has created the analytical capability to tally on an ongoing basis the value of advance premium tax credits that are terminated or adjusted for failure to resolve application inconsistencies.[12] Ideally, such information would be compiled at least annually on a plan-year basis since program inception, and then on a continuing basis. In doing so, HHS should take into account the statutorily provided inconsistency resolution period that follows application and approval of coverage. The emphasis of the analysis should be on subsidies improperly obtained; i.e., without sufficient support provided by applicants.

A key way of demonstrating fulfillment of this portion of the recommendation would be for CMS to present details of the creation of the analytical capability, plus comprehensive results of such an analysis. In addition, HHS must demonstrate that the results obtained from this analysis in turn become part of a management review process where the information is employed as part of regular assessments of program risk and performance.

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 inconsistencies where the Marketplace is unable to verify Social Security numbers or applicants do not provide them.

Actions needed: HHS concurred with this recommendation. HHS has noted steps the agency has taken to implement this recommendation but has not provided sufficient documentation to demonstrate full implementation. To fully implement this recommendation, HHS must show evidence of deployment of a system or procedures designed not simply to encourage applicants

[12]In October 2017, HHS announced it was discontinuing payments to issuers for CSRs due to the lack of an appropriation for the payments. We are in discussions with CMS officials regarding the impact of this decision on the implementation of the CSR portion of this recommendation.

to provide Social Security numbers, or to facilitate automatic verification attempts of numbers supplied, but instead to conclusively resolve Social Security number inconsistencies that remain when other avenues have been exhausted. Given the importance of Social Security numbers to the eligibility and enrollment process, this system or procedures should be designed to resolve a reasonable number of Social Security number inconsistencies after other methods fail to do so.

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 concurred with this recommendation. Under provisions of PPACA, incarcerated individuals are generally not eligible to enroll in marketplace health plans. In April 2016, HHS reported it considers this recommendation closed because in 2015 the agency determined that applicants would no longer be required to submit documentation regarding incarceration status. This decision, made before we issued our report, to no longer require documentation regarding incarceration status is insufficient, by itself, to implement the recommendation. Our recommendation called for a new evaluation of the use of PUPS, in the specific context of using PUPS for its intended purpose—as an indicator of further research—versus generally accepting all applicant attestations on incarceration status. To demonstrate implementation, HHS must provide evidence that it has conducted the re-evaluation we recommended, and then, based on that review, make the determination regarding PUPS data as we indicated.

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 concurred with this recommendation. HHS noted steps the agency has taken to implement this recommendation but has not provided sufficient documentation to demonstrate full implementation. To demonstrate full implementation, HHS should provide evidence that (1) call center representatives currently have on-demand, real-time access to up-to-date, application-level document status, including documentation showing development and implementation of this capability; or (2) HHS has a written plan and schedule for providing this capability as recommended.

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 concurred with this recommendation. HHS has noted steps the agency has taken to implement this recommendation but has not provided sufficient documentation to demonstrate full implementation. To demonstrate full implementation, HHS must provide evidence of formal adoption of a policy containing the elements specified in our recommendation.

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Oversight of Federal Awards and Research Grants

Single Audits: Improvements Needed in Selected Agencies' Oversight of Federal Awards, GAO-17-159. Washington, D.C.: Feb. 16, 2017.

Recommendation: The Secretary of Health and Human Services should direct the Assistant Secretary for Financial Resources to revise policies and procedures to reasonably assure that management decisions contain the required elements and are issued timely in accordance with OMB guidance.

Actions needed: HHS concurred with this recommendation. HHS has made progress in meeting the intent of our recommendation. However, HHS's recently updated Single Audit Resolution Standard Operating Procedure (SOP) lacked language identifying the control activities that help to ensure that analysts complete the management decision letters (MDL) with the required elements and issue the MDLs timely in accordance with OMB guidance. For example, the SOP does not identify steps such as reviews by management at the functional or activity levels to help reasonably assure that management decisions contain the required elements and are issued timely. To be effective, periodic reviews by management should be performed within a reasonable time frame that would allow HHS to take timely corrective actions that help to ensure that MDLs have the required elements and are issued timely. We will assess HHS's efforts once completed.

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Federal Research Grants: Opportunities Remain for Agencies to Streamline Administrative Requirements, GAO-16-573. Washington, D.C.: June 22, 2016.

Recommendation: To further standardize administrative research requirements, the Secretary of Energy, the National Aeronautics and Space Administration (NASA) Administrator, the

Secretary of HHS, and the Director of the National Science Foundation (NSF) should coordinate through the Office of Science and Technology Policy's (OSTP) Research Business Models working group to identify additional areas where they can standardize requirements and report on these efforts.

Actions needed: HHS concurred with this recommendation. In May 2018, the Research Business Models working group, which includes representatives from the Department of Energy, HHS, NASA, NSF, and other research-funding agencies, issued its first annual report under the American Innovation and Competitiveness Act. The report identified several potential areas for standardization or harmonization of requirements, such as the policy for what constitutes a financial conflict of interest. By continuing to coordinate through the working group to standardize administrative requirements for federal research grants, agencies could achieve reductions in universities' administrative workload and costs while maintaining accountability over grant funds. We will continue to monitor HHS's actions related to this recommendation.

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