

U.S. Department of Health and Human Services
Office of Inspector General

Semiannual Report to Congress

April 1, 2020–September 30, 2020



A Message From Christi A. Grimm, Principal Deputy Inspector General

I am pleased to submit this Semiannual Report to Congress summarizing the activities of the Department of Health and Human Services (HHS), Office of Inspector General (OIG), for the 6-month period ending on September 30, 2020.

During this reporting period, the COVID-19 public health emergency posed significant challenges for HHS programs and their capacity to ensure public health and safety. These challenges are many, thorny, and unprecedented. Government and the private sector are marshalling resources to respond to the pandemic and deliver needed health care services. Effective oversight is critical when public health, safety, and massive taxpayer investments are at stake.



Consequently, during this reporting period, COVID-19-related issues commanded much of OIG's attention. OIG's COVID-19 oversight strategic plan sets forth four goals: protecting people, protecting funds, protecting infrastructure, and promoting program effectiveness now and into the future. OIG accelerated efforts to initiate data-driven reviews examining the effectiveness of the public health response through an independent and objective lens. To date, we have announced 45 reviews, 35 of which we started during the reporting period. During the reporting period, OIG published work addressing hospital preparedness, state agency approaches to child care, and health care facility and community-level emergency response. OIG is also a leader in the fight against COVID-19-related fraud. We are aggressively pursuing those who seek to exploit the public health emergency, endanger people, and steal public funds. OIG mitigates the harm from these schemes by proactively alerting the public about potential scams and instructing people how to protect themselves. Consistent with Congress' call for transparency and robust oversight of the Federal COVID-19 response and funding, we are coordinating closely with the Pandemic Response Accountability Committee and other OIGs from multiple Departments responsible for the COVID-19 response.

Amid the COVID-19 pandemic, OIG continues its enterprisewide oversight of HHS's now \$2.4 trillion portfolio. OIG oversees approximately 22 percent of Federal spending in fiscal year 2020 and to achieve significant results we need to be both effective and efficient. To this end, we focus on key priority areas, harness data and technology, and cultivate public and private partnerships to conduct high-impact, evidence-based work. OIG's teams tackle problems by connecting the perspectives of multiple experts, including law enforcement agents, attorneys, auditors, analysts, data scientists, clinicians, and other specialists.

Using this approach, OIG produces outsized impact. During this reporting period, an OIG study identified \$2.6 billion per year of estimated Medicare Advantage risk-adjusted payments supported solely through health risk assessments. This means that Medicare paid plans extra money for claimed conditions, but beneficiaries may not have received services related to those conditions. This study raises concerns about the accuracy and completeness of payment data and the potential that some Medicare beneficiaries might not be receiving care they need. And in September, we targeted our enforcement efforts against illicit

“telefraud” and opioid schemes that lured unsuspecting beneficiaries through aggressive marketing tactics, resulting in the largest national health care fraud takedown in history, with more than \$6 billion in alleged fraud losses. The Semiannual Report more fully describes our portfolio of completed work during this time period.

Through the dedication and talent of OIG’s 1,600 dedicated public servants, we remain committed to executing our mission by conducting independent, relevant, and high-impact work. By focusing on consequential issues such as the pandemic response, cybersecurity, and the integrity of the Medicare and Medicaid programs, OIG will continue to maximize its resources to protect taxpayer dollars and promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve.

OIG appreciates the continued support of Congress and HHS for this important work.

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OIG’s Approach to Driving Positive Change

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS), Office of Inspector General (OIG), provides independent and objective oversight that promotes economy, efficiency, and effectiveness in HHS programs and operations. OIG’s program integrity and oversight activities are shaped by legislative and budgetary requirements and adhere to professional standards established by the Government Accountability Office (GAO), Department of Justice (DOJ), and Inspector General community. Through a nationwide network of audits, investigations, and evaluations OIG carries out its mission to protect the integrity of HHS programs and the health and welfare of the people served by those programs. OIG’s work is conducted by three operating components—the Office of Audit Services (OAS), the Office of Evaluation and Inspections (OEI), and the Office of Investigations (OI)—with assistance from the Office of Counsel to the Inspector General (OCIG) and Mission Support and Infrastructure (MSI).

OIG Organization

Office of Audit Services

OAS conducts audits of HHS programs and operations either through its own resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or of HHS's grantees and contractors in carrying out their respective responsibilities and provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote the economy, efficiency, and effectiveness of programs and operations throughout HHS.

Office of Evaluation and Inspections

OEI conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, and abuse and promoting economy, efficiency, and effectiveness in HHS programs. OEI reports also present practical recommendations for improving program operations.

Office of Investigations

OI conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in almost every State, the District of Columbia, and Puerto Rico, OI coordinates with DOJ and other Federal, State, and local law enforcement authorities. OI also coordinates with OAS and OEI when audits and evaluations uncover potential fraud. OI's investigative efforts often lead to criminal convictions, administrative sanctions, or civil monetary penalties (CMPs).

Office of Counsel to the Inspector General

OCIG provides legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including the False Claims Act, program exclusion, self-disclosure, and CMP cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements (CIAs). OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry about the anti-kickback statute and other OIG enforcement authorities.

Mission Support and Infrastructure

MSI is composed of the Immediate Office of the Inspector General and the Office of Management and Policy. MSI is responsible for coordinating OIG activities and providing mission support, including setting vision and direction for OIG's priorities and strategic planning; ensuring effective

management of budget, finance, human resource management, and other operations; and serving as a liaison with HHS, Congress, and other stakeholders. MSI plans, conducts, and participates in a variety of cooperative projects within HHS and with other Government agencies. MSI provides critical data analytics, data management, and information technology infrastructure that enable OIG components to conduct their work efficiently and effectively.

OIG Strategic Publications

HHS-OIG Strategic Publications



HHS-OIG Strategic Plan

OIG's [Strategic Plan](#) outlines the approach to protecting the integrity of HHS programs. The plan has three key goals: (1) to fight fraud, waste, and abuse; (2) to promote quality, safety, and value in HHS programs and for HHS beneficiaries; and (3) to advance excellence and innovation. These goals drive OIG's work planning for audits and evaluations as well as OIG's approach to enforcement. These goals also serve as a starting point for OIG's assessment of its own effectiveness.

OIG Work Plan

OIG's [Work Plan](#) sets forth projects that OIG plans to undertake during the fiscal year (FY) and beyond. Projects listed in the Work Plan span HHS's operating divisions (OpDivs), which include the Centers for Medicare & Medicaid Services (CMS); public health agencies such as the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH); and human services agencies such as the Administration for Children and Families (ACF) and the

Administration for Community Living (ACL). The Work Plan also includes oversight of State and local governments' use of Federal funds as well as the administration of HHS. Some of the projects described in the Work Plan are statutorily required.

OIG's Top Recommendations

OIG drives positive change by not only identifying risks, problems, abuses, and deficiencies, but also recommending solutions to address them. OIG maintains a list of recommendations it has made to address vulnerabilities detected in its reviews, and it keeps track of whether these recommendations have been implemented. OIG systematically follows up on its recommendations with the relevant HHS programs. From among the recommendations that have not been implemented, OIG identifies the top recommendations that, if implemented, are likely to garner significant savings and improvements in quality, efficiency, and effectiveness. OIG compiles these recommendations in the [Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs: OIG's Top Recommendations](#) (previously known as the Compendium of Unimplemented Recommendations).

Top Management and Performance Challenges Facing HHS

To focus HHS's attention on the most pressing issues, each year OIG identifies the [Top Management and Performance Challenges](#) facing HHS. These top challenges arise across HHS programs and cover critical HHS responsibilities, including delivering quality services and benefits, exercising sound fiscal management, safeguarding public health and safety, and enhancing cybersecurity.

OIG's Semiannual Report to Congress

OIG's [Semiannual Report\(s\) to Congress](#) (Semiannual Reports) describe OIG's work on identifying significant problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations that were disclosed during the reporting period. In the report below, we present OIG expected recoveries, criminal and civil actions, and other statistics as a result of our work for the semiannual reporting period April 1, 2020, through September 30, 2020. We also highlight some of our work completed during this semiannual reporting period.

Highlights of OIG Accomplishments

HHS-OIG'S SEMIANNUAL REPORT TO CONGRESS (Semiannual Report) describes OIG's work identifying significant risks, problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations that were disclosed during the semiannual reporting period April 1, 2020, through September 30, 2020. In this highlights section, we present data on OIG reports issued, expected recoveries, criminal and civil actions, and other statistics resulting from our work for both the semiannual reporting period and the entirety of FY 2020. We then highlight significant results from selected audits, evaluations, and enforcement activities completed during the reporting period.

At-a-Glance FY 2020 Highlights

Statistic	FY 2020 (10/1/2019–9/30/2020)
Audit Reports Issued	178
Evaluations Issued	44
Expected Audit Recoveries	\$942.06 million
Questioned Costs	\$733.93 million
Potential Savings	\$2.89 billion
New Audit and Evaluation Recommendations	689
Recommendations Implemented by HHS OpDivs	286
Expected Investigative Recoveries	\$3.14 billion
Criminal Actions	624
Civil Actions	791
Exclusions	2,148

Results for the Semiannual Reporting Period

During this semiannual reporting period (April 1, 2020, through September 30, 2020), we issued 97 audit reports and 27 evaluation reports. Our audit work identified \$337 million in expected recoveries, as well as \$446 million in questioned costs (costs questioned by OIG because of an alleged violation, costs not supported by adequate documentation, or the expenditure of funds where the intended purpose is unnecessary or unreasonable). Our audit work also identified \$2 billion in potential savings for HHS—funds that could be saved if HHS implemented all of OIG's audit recommendations. During this reporting period, OIG made 416 new audit and evaluation recommendations, which are crucial to encourage positive change in HHS programs. Meanwhile, HHS OpDivs implemented 156 prior recommendations, leading to positive impact for HHS programs and beneficiaries.

OIG also remains at the forefront of the Nation's efforts to fight fraud in HHS programs and hold wrongdoers accountable for their actions. Along with our partners DOJ, Medicaid Fraud Control Units (MFCUs or Units), and other Federal, State, and local law enforcement agencies, we detect, investigate, and prosecute fraud through a coordinated and data-driven approach. OIG's investigative work led to \$1.62 billion in expected investigative recoveries and 181 criminal actions during this reporting period. OIG also took civil actions, such as assessing monetary penalties, against 421 individuals and entities, and excluded 1,245 individuals and entities from Federal health care programs.

OIG continues to focus on the most significant and high-risk issues in health care and human services. Our mission is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve. Below we highlight results from selected OIG oversight and enforcement activities from the semiannual reporting period April 1, 2020, through September 30, 2020, organized by subject area. A comprehensive list of OIG work during the reporting period follows, and Appendices A–G provide data to meet the reporting requirements in the Inspector General Act of 1978.

Responding to the COVID-19 Pandemic

HHS continued to respond to the unprecedented challenges posed by COVID-19. HHS leads the Federal public health and medical response during public health emergencies. In May 2020, OIG published a [strategic plan](#) on the oversight of COVID-19 response and recovery. The plan sets forth the four goals that drive OIG's strategic planning and mission execution with respect to HHS's COVID-19 response and recovery. These goals are to: (1) protect people, (2) protect funds, (3) protect infrastructure, and (4) promote effectiveness of HHS programs.

OIG is using risk assessment and data analytics to identify, monitor, and target potential fraud, waste, and abuse affecting HHS programs and beneficiaries and to promote the effectiveness of HHS's COVID-19 response and recovery programs. OIG is coordinating our COVID-19 work with key oversight and law enforcement partners, including the Pandemic Response Accountability Committee; Federal, State, local, and Tribal entities; and GAO, among others, to ensure adequate oversight, avoid duplication, and share insights. OIG created a COVID-19 web page that alerts the public about emerging fraud schemes related to COVID-19. Additional information about OIG work related to COVID-19 is available on our website, [COVID-19 Portal](#). Significant OIG work during this semiannual reporting period related to COVID-19 includes the following:

OIG rapidly provided information about hospitals' experiences and perspectives in responding to COVID-19. In a pulse survey conducted in late March 2020 and described in an OIG report issued on April 3, 2020, hospitals nationwide described challenges, mitigation strategies, and the need for assistance in responding to COVID-19. Hospitals reported that their most significant challenges centered on testing and caring for patients with known or suspected COVID-19 and keeping staff safe. Hospitals also reported substantial challenges to maintaining or expanding their facilities' capacity to treat patients with COVID-19. (See report [OEI-06-20-00300](#).)

OIG issued guidance regarding the application of OIG’s administrative fraud enforcement authorities to support providers in delivering needed patient care during the public health emergency. In April 2020, OIG issued a Policy Statement in response to the Secretary’s January 31, 2020, declaration of a public health emergency. Under this Policy Statement, OIG will exercise its enforcement discretion to not impose administrative sanctions under the Federal anti-kickback statute for certain remuneration related to COVID-19 covered by the Blanket Waivers of Section 1877(g) of the Social Security Act (the Act) issue by the Secretary on March 30, 2020 (the Blanket Waivers), subject to certain conditions. Through this Policy Statement, OIG seeks to avoid the need for parties to undertake a separate legal review under the Federal anti-kickback statute for certain arrangements protected by the Blanket Waivers.

OIG issued guidance regarding physicians and other practitioners that reduce or waive amounts owed by Federal health care program beneficiaries for telehealth services during COVID-19. Ordinarily, routine reductions or waivers of costs owed by Federal health care program beneficiaries, including cost-sharing amounts such as coinsurance and deductibles, implicate the Federal anti-kickback statute, the civil monetary penalty and exclusion laws related to kickbacks, and the civil monetary penalty law prohibition on inducements to beneficiaries. However, in March 2020, in response to the public health emergency, OIG issued a Policy Statement notifying physicians and other practitioners that they will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations that a beneficiary may owe for telehealth services furnished consistent with the then-applicable coverage and payment rules during the public health emergency.

OIG briefed a congressional committee about OIG’s oversight related to COVID-19 response efforts. In May, Christi A. Grimm, Principal Deputy Inspector General, briefed members before the U.S. House Committee on Oversight and Reform. The briefing outlined OIG’s oversight of HHS’s COVID-19 programs and funding. (See [OIG congressional testimony](#).)

OIG issued two toolkits to aid current COVID-19 response efforts by leveraging past OIG work and offering action-oriented lessons learned for health care facilities and community leaders. The toolkits contain key insights and lessons learned from OIG reports published from 2002 to 2020 about health care facility emergency preparedness and response and community response and recovery. These resources leverage experiences during outbreaks of emerging infectious diseases (such as Ebola and H1N1 pandemic influenza) and natural disasters (such as Hurricane Katrina and Superstorm Sandy), as well as bioterrorism preparedness and response. (See toolkits [OEI-06-20-00470](#), [OEI-09-20-00440](#).)

Ensuring Health and Safety of Children Served by HHS

OIG has devoted substantial oversight efforts to protect children served by HHS programs such as the Unaccompanied Alien Children (UAC) Program and foster care.

OIG found that improvements are needed in the UAC Program to better protect children and ensure that relevant Federal funds are being used appropriately. The incident reporting system of ACF’s Office of

Refugee and Resettlement (ORR) is not effective at capturing information about significant incidents including, but not limited to, medical emergencies, self-harm, and incidents of a sexual nature to assist ORR's efforts to ensure the safety of minors in ORR's care. ACF concurred with OIG's recommendations to improve ORR's incident reporting system. (See report [OEI-09-18-00430](#).) In reviewing facility physical security inspection checklists from 40 UAC provider facilities, OIG also found that 39 facilities did not include all required physical security measures in their checklists. OIG provided recommendations to help ACF ensure that facilities are safe. (See report [OEI-05-19-00210](#).) Finally, OIG found that Southwest Key, a UAC Program grantee, claimed unallowable costs related to the UAC Program. In addition to recommending Southwest Key refund the unallowable costs to the Federal Government, OIG recommended that ORR provide guidance on allowable costs. (See report [A-06-17-07004](#).)

[OIG determined that Medicaid claim data can be used to identify incidents of potential child abuse or neglect.](#) Based on claim data and medical record review, OIG estimated that 29,260 of the 29,534 children enrolled in Medicaid in our sampling frame were involved with incidents of potential child abuse or neglect. CMS concurred with our recommendation that it issue guidance to inform States that performing data analysis to identify Medicaid claims containing diagnosis codes indicating potential child abuse or neglect could help identify incidents of potential child abuse or neglect and help ensure compliance with their mandatory reporting laws. (See report [A-01-19-00001](#).)

[OIG found that New Hampshire's criminal background check monitoring did not ensure provider compliance with State requirements.](#) By not ensuring that all current employees or household members who supervised or had routine unsupervised contact with children passed all criminal background checks, New Hampshire potentially jeopardized the safety of the children in the care of 21 or 30 selected child care providers. New Hampshire concurred with our recommendations to ensure all child care providers comply with criminal background check requirements. (See report [A-01-18-02504](#).)

[OIG found that Kansas and Ohio did not comply with State foster care requirements.](#) Kansas did not ensure that group homes for children in foster care complied with all State health and safety requirements in accordance with Federal laws and regulations. Kansas concurred with our recommendations. (See report [A-07-19-06087](#).) Ohio did not always comply with State requirements related to psychotropic and opioid medications prescribed for children in foster care. OIG found that, the medications listed in for 61 case records were not accurately documented in the Ohio Statewide Automated Child Welfare Information System. Ohio concurred with our recommendations. (See report [A-05-18-00007](#).)

Protecting Beneficiaries Receiving Long-Term Care Services

OIG conducts oversight to support a high-performing health care system to foster better health outcomes and identifying and combating potential abuse and neglect of beneficiaries.

[OIG found that individual nursing homes' daily staffing levels did not match their Staffing Star Ratings.](#) In 2018, nursing homes' reported staffing levels that often vary on a day-to-day basis, and staffing levels for 7 percent of nursing homes fell below required Federal standards for at least 30 total days. CMS's Star

Rating System ranks nursing homes on their average staffing levels each quarter; as a result, daily staffing variations are not transparent to consumers. CMS did not agree or disagree with our recommendations to enhance efforts to ensure that nursing homes meet daily staffing requirements. (See report [OEI-04-18-00450](#).)

OIG found that New Jersey did not ensure that its Managed Care Organizations complied with certain Federal and State requirements for beneficiaries enrolled in its Medicaid managed long-term services and supports program. Managed Care Organizations (MCOs) did not comply with the requirements to adequately assess and cover the associated beneficiaries' needs for long-term services and supports. Specifically, MCOs did not comply with requirements for providing adequate service planning and care management to the beneficiaries; conducting and documenting assessments; and developing, reviewing, and updating beneficiaries' care plans. New Jersey partially concurred with our recommendations to improve its monitoring and followup activities to ensure that its MCOs comply with Federal and State requirements detailed in its contracts with the MCOs. (See report [A-02-17-01018](#).)

Three former caregivers sentenced on civil rights and obstruction charges related to the death of a disabled resident. Three former caregivers in Missouri were sentenced for their roles in the death of a disabled resident at Second Chance Homes, an organization that provided housing and care for developmentally disabled persons through a Missouri Department of Mental Health initiative. The caregivers pleaded guilty to willfully failing to provide necessary medical care to the victim, resulting in injury to and the death of the victim.

Preventing and Treating Opioid Misuse

OIG continues to prioritize enforcement and oversight activities to protect beneficiaries from prescription drug abuse.

OIG found that most Part D beneficiaries at serious risk of opioid misuse or overdose in 2017 received high amounts of opioids the following year. Raising even more concern, 11 percent of beneficiaries at serious risk in 2017 had an overdose or an adverse effect from an opioid. About one-quarter of beneficiaries at serious risk in 2017 received a prescription for naloxone—an opioid-overdose reversal drug—through Part D. CMS concurred with our recommendation that it educate Part D beneficiaries and providers about access to medication-assisted treatment (MAT) drugs and naloxone. (See report [OEI-02-19-00130](#).)

OIG found, over the past several years, that opioid use has steadily declined in Medicare Part D and the use of drugs for MAT has increased. The changes in recent years in opioid use and MAT show progress from the efforts of HHS and others to address the opioid crisis. Nonetheless, it is critical to remain vigilant as the COVID-19 pandemic poses additional danger for at risk populations. Although the number of Part D beneficiaries who received opioids decreased in 2019, OIG determined that almost 34,000 beneficiaries remain at serious risk of opioid misuse or overdose. (See report [OEI-02-20-00320](#).) To help others identify certain patients who are at risk of opioid misuse or overdose, OIG published a toolkit during this reporting period that features detailed steps for using prescription drug claims data to analyze patients' opioid

levels. (See report [OEI-02-17-00561](#).) OIG encourages CMS to also closely monitor opioid use and access to treatment in 2020 and beyond.

OIG found that despite a significant increase in naloxone utilization under Medicaid, the program accounted for only a small proportion of all naloxone distributed in the United States in 2018. CMS and State Medicaid agencies can be encouraged by their progress to date in increasing access to naloxone while also continuing to look for ways to further expand naloxone availability under Medicaid. CMS did not explicitly concur with our recommendation to pursue strategies to increase the number of at-risk beneficiaries acquiring community-use versions of naloxone through Medicaid. (See report [OEI-BL-18-00360](#).)

An individual was sentenced to 108 months in Federal prison for leading a conspiracy to distribute powerful prescription opioids via sham medical clinics. Minas Matosyan and his co-conspirators controlled the sham clinics and hired corrupt doctors who allowed their names to be used on fraudulent prescriptions in exchange for kickbacks. Matosyan and his co-conspirators also stole the identities of other doctors and issued prescriptions in those doctors' names.

A pharmaceutical company entered into a \$300 million civil False Claims Act settlement in connection with the marketing and promotion of the opioid addiction treatment drug Suboxone. The total resolution relating to the company, Indivior, marketing of Suboxone is more than \$2 billion—the largest-ever resolution in a case brought by DOJ involving an opioid drug.

Ensuring Medicare Program Integrity

In 2019, Medicare spent \$796 billion, and provided health coverage to nearly 61.2 million beneficiaries. The Medicare program faces significant challenges with respect to solvency and spending.

In September 2020, the largest National takedown in DOJ history was carried out across 51 judicial districts. This national takedown resulted in charges against 345 individuals for submitting more than \$6 billion in false and fraudulent claims to Federal health care programs and private insurers, including more than \$4.5 billion connected to prescribing or ordering unnecessary medical items or services by leveraging aggressive marketing tactics and so-called telehealth services, more than \$845 million connected to substance abuse treatment facilities, or "sober homes," and more than \$806 million connected to other health care fraud and illegal opioid distribution schemes across the country.

OIG found that Medicare Advantage Organizations' encounter data continues to miss provider identifiers. Encounter data from Medicare Advantage Organizations (MAOs) continue to lack National Provider Identifiers (NPIs) for providers who order and/or refer durable medical equipment, prosthetics, orthotics, and supplies; clinical laboratory services; imaging services; and home health services. Yet, OIG found that almost all MAOs have data systems that are able to receive and store these NPIs when providers submit them. CMS concurred with our first recommendation and did not concur with our second recommendation. (See report [OEI-03-19-00430](#).)

A skilled nursing facilities provider entered in to a \$10 million settlement to resolve allegations that it violated the False Claims Act by knowingly causing certain facilities to submit false claims to Medicare for rehabilitation therapy. The settlement resolved allegations that the provider Saber Healthcare, Saber Healthcare Group LLC, and other Saber related entities submitted false claims for rehabilitation therapy by engaging in a systematic effort to increase Medicare billings for services that were not reasonable, necessary, or skilled. Saber entered into a 5-year CIA with OIG in connection with the settlement.

A pain clinic and two of their former executives agreed to pay a total of \$41 million to resolve alleged violations of the False Claims Act for billing Medicare, Medicaid, TRICARE, and other Federal health care programs for medically unnecessary urine drug tests (UDTs). The Government alleged that Logan Laboratories Inc., Tampa Pain Relief Centers Inc., and two of their former executives knowingly submitted or caused the submission of false claims to Federal health care programs for presumptive and definitive UDTs, in circumstances where such testing was not medically reasonable or necessary. The Government alleged that the defendants developed and implemented a policy and practice of automatically ordering both presumptive and definitive UDTs for all patients at every visit, without any physician making an individualized determination that either test was medically necessary for the patients for whom the tests were ordered.

A provider agreed to pay \$117 million to resolve alleged violations of the False Claims Act for billing medically unnecessary inpatient behavioral health services; failing to provide adequate and appropriate services; and paying illegal inducements to Federal health care beneficiaries. Specifically, the Government alleged that Universal Health Services (UHS) admitted Federal health care beneficiaries who were not eligible for inpatient or residential treatment because their conditions did not require that level of care, while also failing to properly discharge appropriately admitted beneficiaries when they no longer required inpatient care. The Government further alleged that UHS billed for services not rendered, billed for improper and excessive lengths of stay, failed to provide adequate staffing, training, and/or supervision of staff, and improperly used physical and chemical restraints and seclusion. In addition, UHS allegedly failed to develop and/or update individual assessments and treatment plans for patients, failed to provide adequate discharge planning, and failed to provide required individual and group therapy services in accordance with federal and state regulations. As a condition of the settlement, Universal Health Services entered into a CIA with OIG.

Maximizing Value by Ensuring Efficient Use of HHS Funds

OIG reviews of the HHS programs are critical to ensuring that taxpayer funds are used to deliver high-value services.

OIG found that billions of estimated Medicare Advantage (MA) risk-adjusted payments supported solely through health risk assessments (HRAs) raise concerns about the completeness of payment data. Diagnoses that MA organizations only reported on HRAs—and on no other encounter records in 2016—resulted in an estimated \$2.6 billion in risk-adjusted payments for 2017. In addition, in-home HRAs

generated 80 percent of these estimated payments. Most in-home HRAs were conducted by companies that partner with or are hired by MA organizations to conduct these assessments—and therefore are not likely conducted by the beneficiary's own primary care provider. Twenty MA organizations generated millions in payments from in-home HRAs for beneficiaries for whom there was not a single record of any other service being provided in 2016. CMS concurred with two of our five recommendations. (See report [OEI-03-17-00471](#).)

OIG found that total Medicare Part B spending for laboratory tests increased to \$7.6 billion in 2018, despite lower payment rates for most laboratory tests. Congress mandated that OIG monitor Medicare payments for laboratory tests and the implementation and effect of the new payment system for those tests. CMS neither concurred nor nonconcurred with our recommendation to seek legislative authority to establish a mechanism to control costs for automated chemistry tests. (See report [OEI-09-19-00100](#).)

OIG found that Medicare contractors were not consistent in how they reviewed extrapolated overpayments in the provider appeals process. OIG found that although Medicare administrative contractors (MACs) and qualified independent contractors (QICs) generally reviewed appealed extrapolated overpayments in a manner that conforms with existing CMS requirements, CMS did not always provide sufficient guidance and oversight to ensure that these reviews were performed in a consistent manner. In addition, CMS's ability to provide oversight over the extrapolation review process was limited because of data reliability issues in the Medicare Appeals System (MAS). Improving the accuracy of the information in the MAS would potentially assist CMS with ensuring that extrapolated overpayments are reviewed by the MACs and QICs in a consistent manner. CMS concurred with our recommendations. (See report [A-05-18-00024](#).)

A provider entered into a 5-year Recipient Compliance Agreement (RCA) with OIG. The RCA is OIG's first compliance agreement with an HHS grantee and contains a number of unique provisions, including requirements for the provider, Brooklyn Plaza Medical Center (BPMC) to hire an Independent Review Organization to conduct a random review of BPMC's drawdowns from the HHS Payment Management System. This review is to ensure that the drawdowns complied with HHS grant regulations and were based on allowable costs; that the provider hired a Compliance Expert to advise BPMC about its compliance program, financial management system, and internal controls; and that BPMC management make a number of annual certifications about BPMC's financial management system and internal controls.

Reducing Improper Payments for Health Care

OIG's oversight is paramount to ensuring that HHS beneficiaries and the American public get the true benefit of the substantial financial investment in HHS programs.

OIG found hospitals overbilled Medicare \$1 billion by incorrectly assigning severe malnutrition diagnosis codes to inpatient hospital claims. Hospitals correctly billed Medicare for severe malnutrition diagnosis codes for 27 of the 200 claims that we reviewed. However, hospitals did not correctly bill Medicare for the remaining 173 claims. CMS concurred with our recommendations. (See report [A-03-17-00010](#).)

OIG found that CMS could have saved \$192 million by targeting home health claims for review.

Specifically, we found that not all payments to home health agencies (HHAs) for home health services with five to seven visits in a payment episode complied with Medicare requirements. Based on our sample results, we estimated that Medicare overpaid HHAs nationwide \$192 million for our audit period. These improper payments occurred because the MACs did not analyze claim data or perform risk assessments to target claims with visits slightly above the Low Utilization Payment Adjustment threshold of four visits for additional review. CMS concurred with our recommendations. (See report [A-09-18-03031](#).)

OIG found that North Carolina and Iowa improperly claimed Medicaid health home expenditures and inadequately monitored its providers. North Carolina did not claim Federal Medicaid reimbursement for health home expenditures in accordance with Federal and State requirements. Instead, it improperly claimed \$124.6 million in Primary Care Case Management (PCCM) expenditures, which should have been reimbursed at the regular Federal medical assistance percentage. Iowa improperly claimed Federal Medicaid reimbursement for payments made to health home providers that did not comply with Federal and State requirements. These improper payments primarily involved deficiencies in documentation. Based on our sample results, we estimated that Iowa improperly claimed at least \$37.1 million in Federal Medicaid reimbursement for payments made to health home providers. North Carolina and concurred with our recommendations; Iowa concurred with the majority of our recommendations, with the exception of our recommendation that it refund \$37.1 million to the Federal Government. (See reports [A-04-18-00120](#), [A-07-18-04109](#).)

OIG found that inadequate edits and oversight caused Medicare to overpay more than \$267 million for hospital inpatient claims with post-acute-care transfers to home health services. Medicare improperly paid most inpatient claims subject to its transfer policy when beneficiaries resumed home health services within 3 days of discharge but hospitals failed to code the inpatient claim as a discharge to home with home health services or when the hospitals applied condition codes. Based on our sample results, we estimated that Medicare improperly paid \$267 million during a 2-year period for hospital services that should have been paid a graduated per diem payment. CMS concurred with our recommendations. (See report [A-04-18-04067](#).)

OIG found that Texas relied on impermissible provider-related donations to fund the State share of the Medicaid Delivery System Reform Incentive Payment Program (DSRIP). Of the \$189.3 million in funds that Texas used as the State share of DSRIP payments, \$146.6 million was funded through impermissible provider-related donations that did not meet Federal requirements. Those funds were derived from impermissible provider-related donations because the providers made donations that benefited the intergovernmental transfer (IGT) entity, the funds the IGT entity transferred resulted from those donations, and the providers' donations were part of a hold-harmless practice. Texas did not decrease its Medicaid expenditures by the \$146.6 million as required under Federal requirements. As a result, Texas inappropriately received \$83.8 million in Federal funds. Texas did not concur with two recommendations but concurred with our remaining recommendation. (See report [A-06-17-09002](#).)

OIG found that most Indian Health Service (IHS) Purchased/Referred Care (PRC) program claims were not reviewed, approved, and paid in accordance with Federal requirements. Through the PRC program, IHS pays for private providers to deliver health care services unavailable through the IHS network. Based on our sample results, we estimated that 658,025 of the 802,470 total claims were not paid in accordance with Federal requirements. IHS concurred with our recommendations. (See report [A-03-16-03002](#).)

Ensuring That HHS Programs and Patients Do Not Overpay for Prescription Drugs

OIG continues to prioritize efforts to lower drug spending for HHS programs and its beneficiaries.

OIG found that a loophole in a Part B drug payment rule continues to cost Medicare and beneficiaries hundreds of millions of dollars. As of December 2019, CMS continued to include noncovered, self-administered versions when calculating Part B payment amounts for Orencia and Cimzia, the same two drugs identified in an earlier OIG report from 2017. OIG determined that Part B spending for Orencia and Cimzia would have been reduced by \$497 million (22 percent of expenditures for the two drugs) in 2017 and 2018 if their payment amounts had been set using only the physician-administered versions. Consistent with its response to the earlier recommendation, CMS did not concur with our recommendation to seek a legislative change requiring that noncovered, self-administered versions be excluded in the calculation of Part B payment amounts. (See report [OEI-BL-20-00100](#).)

OIG found that Michigan did not fully comply with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to enrollees of Medicaid managed-care organizations. Michigan concurred with our recommendation that it bill for and collect manufacturers' rebates for pharmacy drugs and for single-source and top-20 multiple-source physician-administered drugs that we calculated to be at least \$30 million (Federal share) and to refund the Federal Government. (See report [A-05-17-00017](#).)

A pharmaceutical company entered into two settlements totaling \$642 million to resolve allegations that it violated the False Claims Act. The first settlement pertains to the company, Novartis Pharmaceuticals, alleged illegal use of three foundations as conduits to pay the copayments of Medicare patients taking two of Novartis's drugs. The second settlement resolves claims arising from the company's alleged payments of kickbacks to doctors.

Combating Cybersecurity Threats Within HHS and Health Care

OIG's oversight of HHS agencies' and programs' cybersecurity is vital in ensuring that HHS has necessary capabilities to protect and ensure the integrity of its systems and data assets.

OIG identified opportunities where HHS can strengthen its overall IT security program. OIG found that HHS made progress in improving its overall cybersecurity posture, but certain weaknesses persist and pose challenges. OIG found weaknesses in each of the following IG Federal Information Security Modernization Act of 2014 (FISMA) domains: risk management, configuration management, identity and access

management, data protection and privacy, security training, information security continuous monitoring, incident response, and contingency planning. HHS agreed with our recommendations to strengthen its cybersecurity program and enhance security controls at HHS. (See report [A-18-19-11200](#).)

[OIG identified cybersecurity vulnerabilities and possible compromise of HHS's systems and networks.](#)

Because of the current public health emergency and increased cyberactivity, we are only providing the title of our cybersecurity audits. (See reports [A-18-17-04002](#), [A-18-18-04005](#), [A-18-18-08400](#).)

Proposed Rule on Information Blocking and Grant Fraud

[OIG issued a notice of proposed rulemaking \(NPRM\) regarding its new authorities under the 21st Century Cures Act.](#) The NPRM discusses OIG's new authorities permitting the imposition of sanctions for fraudulent conduct related to HHS grants, contracts, or other agreements, and the investigation of information blocking. The NPRM also sets forth OIG's expected information blocking enforcement approach and priorities. The NPRM proposes modifying OIG's CMP regulations in accordance with the Bipartisan Budget Act of 2018. OIG will provide an update in a future SAR when OIG issues the Final Rule.

OIG Participation in Congressional Hearings

<i>Date</i>	<i>Witness</i>	<i>Testimony/Committee</i>
5/26/2020	Christi Grimm, Principal Deputy Inspector General, Office of Inspector General	<u>"Oversight Related to Coronavirus Response Efforts,"</u> U.S. House Committee on Oversight and Reform

Selected Acronyms and Abbreviations

ACA	Patient Protection and Affordable Care Act
ACF	Administration for Children and Families
ACL	Administration for Community Living
CDC	Centers for Disease Control and Prevention
CIA	corporate integrity agreement
CMP	civil monetary penalty
CMS	Centers for Medicare & Medicaid Services
CCDF	Child Care and Development Fund
DHS	Department of Homeland Security
DOJ	Department of Justice
DME	durable medical equipment
EMTALA	Emergency Medical Treatment and Labor Act
FDA	Food and Drug Administration
FY	fiscal year
GAO	Government Accountability Office
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
LIHEAP	Low-Income Home Energy Assistance Program
MCO	managed care organization
MFCU	Medicaid Fraud Control Unit
NIH	National Institutes of Health
OAS	Office of Audit Services
OCIG	Office of Counsel to the Inspector General
OEI	Office of Evaluation and Inspections
OI	Office of Investigations
OIG	Office of Inspector General
OMB	Office of Management and Budget
SAMHSA	Substance Abuse and Mental Health Services Administration
SNF	skilled nursing facility

Medicare and Medicaid Reports and Reviews

Medicare Program Reports and Reviews

Financial Management and Improper Payments

An Estimated 87 Percent of Inpatient Psychiatric Facility Claims With Outlier Payments Did Not Meet Medicare's Medical Necessity or Documentation Requirements (A-01-16-00508), April 2020

For our 160 sampled claims, we found that CMS paid 25 claims that did not meet Medicare medical necessity requirements for some or all days of the stay. Based on our sample results, we estimated that Medicare overpaid inpatient psychiatric facilities (IPFs) \$93 million for FYs 2014 and 2015 for stays that were noncovered or partially noncovered and resulted in outlier payments. In addition, 142 claims had missing or inadequate medical record elements, including physician certifications. We estimated that 87 percent of IPF claims for FYs 2014 and 2015 with outlier payments did not meet Medicare medical necessity or medical record requirements.

We identified three additional areas of concern: (1) outlier payments may have been made for stays that were not unusually costly, (2) beneficiaries used lifetime reserve days to help pay for days they no longer required inpatient hospitalization but for the unavailability of appropriate posthospitalization placements, and (3) CMS did not track patient falls or fall rates at IPFs.

CMS concurred with our recommendations to: (1) increase postpayment reviews to provide more feedback to IPFs, (2) promulgate regulations on the patient's right to make informed decisions regarding care, (3) study the accuracy of the outlier payment methodology, and (4) consider tracking patient falls or fall rates. CMS did not concur with our recommendations to: (1) research whether physician certification requirements are useful in preventing inappropriate payments, (2) require certifications to be in a specific format, and (3) study the lifetime reserve day issue.

Medicare Made \$11.7 Million in Overpayments for Nonphysician Outpatient Services Provided Shortly Before or During Inpatient Stays (A-01-17-00508), May 2020

Medicare made incorrect payments to outpatient providers for 40,984 nonphysician outpatient services provided nationwide within 3 days before the date of admission, on the date of admission, or during Inpatient Prospective Payment System stays (excluding date of discharge) that we reviewed. These incorrect payments occurred because the Common Working File (CWF) edits were not designed to identify all potentially incorrect claims.

As a result, Medicare made \$11.7 million in incorrect payments to hospital outpatient providers during 2016 and 2017. This includes claims beyond the 4-year reopening period. In addition,

beneficiaries incurred \$2.7 million in coinsurance and deductible liabilities related to these incorrect payments.

CMS concurred with our recommendation that it ensure that all necessary information is included in the CWF edits to accurately identify and prevent incorrect payments for nonphysician outpatient services. CMS also concurred with our recommendations that it direct the Medicare contractors to: (1) recover the portion of \$11.7 million in identified overpayments resulting from the incorrectly billed services; (2) instruct outpatient providers to refund the portion of the \$2.8 million in deductible and coinsurance amounts that may have been incorrectly collected; (3) notify providers so that they can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any of those returned overpayments as having been made; and (4) educate outpatient providers on how to correctly bill nonphysician outpatient services.

Hospitals Overbilled Medicare \$1 Billion by Incorrectly Assigning Severe Malnutrition Diagnosis Codes to Inpatient Hospital Claims (A-03-17-00010), July 2020

Hospitals correctly billed Medicare for severe malnutrition diagnosis codes for 27 of the 200 claims that we reviewed. However, hospitals did not correctly bill Medicare for the remaining 173 claims. For nine of these claims, the medical record documentation supported a secondary diagnosis code other than a severe malnutrition diagnosis code, but the error did not change the DRG or payment. For the remaining 164 claims, hospitals used severe malnutrition diagnosis codes when they should have used codes for other forms of malnutrition or no malnutrition diagnosis code at all, resulting in net overpayments of \$914,128. On the basis of our sample results, we estimated that hospitals received overpayments of \$1 billion for FYs 2016 and 2017.

CMS concurred with our recommendations, including that it collect the portion of the \$914,128 for the incorrectly billed hospital claims that are within the reopening period and, based on the results of this audit, notify appropriate providers so that the providers can exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule. To attempt recovery of the overpayment, which we estimate to be valued at \$1 billion, resulting from incorrectly billed hospital claims paid during our audit period and to ensure that claims made after our audit period are correct, we made additional recommendations. One of the additional recommendations includes reviewing all claims that were not part of our sample but were within the reopening period.

CMS Could Have Saved \$192 Million by Targeting Home Health Claims for Review With Visits Slightly Above the Threshold That Triggers a Higher Medicare Payment (A-09-18-03031), July 2020

Not all payments to home health agencies (HHAs) for home health services with five to seven visits in a payment episode complied with Medicare requirements. Of the 120 sampled claims we reviewed, 91 complied with requirements, and for 4 claims there was no documentation available

to make a compliance determination. However, the remaining 25 claims did not comply with requirements. As a result, Medicare improperly paid HHAs for a portion of the payment episode (14 claims) and for the full payment episode (11 claims), totaling \$41,613. These improper payments occurred because the Medicare administrative contractors (MACs) did not analyze claim data or perform risk assessments to target claims with visits slightly above the Low Utilization Payment Adjustment (LUPA) threshold of four visits for additional review. On the basis of our sample results, we estimated that Medicare overpaid HHAs nationwide \$191.8 million for our audit period.

CMS concurred with our recommendations that it: (1) direct the MACs to recover the \$41,613 in identified overpayments made to HHAs for the sampled claims, (2) require the MACs to perform data analysis and risk assessments of claims with visits slightly above the applicable LUPA threshold and target these claims for additional review, and (3) instruct the MACs to educate HHA providers on properly billing for home health services with visits slightly above the applicable LUPA threshold, which could have saved Medicare as much as \$191.8 million during our audit period.

Inadequate Edits and Oversight Caused Medicare To Overpay More Than \$267 Million for Hospital Inpatient Claims With Post-Acute-Care Transfers to Home Health Services (A-04-18-04067), August 2020

Medicare improperly paid most inpatient claims subject to its transfer policy when beneficiaries resumed home health services within 3 days of discharge, but hospitals failed to code the inpatient claim as a discharge to home with home health services or when the hospitals applied condition codes 42 (home health not related to inpatient stay) or 43 (home health not within 3 days of discharge). Based on our sample results, we estimated that Medicare improperly paid \$267 million during a 2-year period for hospital services that should have been paid a graduated per diem payment.

CMS concurred with our recommendations that it direct its Medicare contractors to: (1) recover a portion of the \$722,288 in overpayments identified in our sample, (2) reprocess the remaining inpatient claims in our sample with an incorrect patient discharge status code or condition code 43 to recover a portion of the estimated \$225.7 million in overpayments, and (3) analyze the remaining inpatient claims in our sample with condition code 42 and recover a portion of the estimated \$40.6 million in potential overpayments. Also, CMS agreed to correct its related system edits, improve its provider education regarding the Medicare transfer policy, and use data analytics to identify hospitals disproportionately using condition code 42. CMS did not concur with our recommendation that it consider taking the necessary actions to deem any home health service within 3 days of discharge to be “related.”

Medicare Laboratory Test Expenditures Increased in 2018, Despite New Rate Reductions (OEI-09-19-00100), August 2020

Total Medicare Part B spending for laboratory tests increased to \$7.6 billion in 2018, despite lower payment rates for most laboratory tests. The \$459 million spending increase was driven by: (1) increased spending on genetic tests, (2) the end of the discount for certain chemistry tests, and (3) the move to a single national fee schedule.

Congress mandated that the Office of Inspector General monitor Medicare payments for laboratory tests and the implementation and effect of the new payment system for those tests. This report also provides the fifth annual analysis of the top 25 laboratory tests by Medicare spending.

Our recommendation was for CMS to seek legislative authority to establish a mechanism to control costs for automated chemistry tests. CMS neither concurred nor nonconcurred with our recommendation.

Billions in Estimated Medicare Advantage Payments From Diagnoses Reported Only on Health Risk Assessments Raise Concerns (OEI-03-17-00471), September 2020

Billions of estimated Medicare Advantage (MA) risk-adjusted payments supported solely through health risk assessments (HRAs) raise concerns about the completeness of payment data submitted to CMS, the validity of diagnoses on HRAs, and the quality of care coordination for beneficiaries. Diagnoses that MA organizations reported only on HRAs—and on no other encounter records in 2016—resulted in an estimated \$2.6 billion in risk-adjusted payments for 2017. In addition, in-home HRAs generated 80 percent of these estimated payments. Most in-home HRAs were conducted by companies that partner with or are hired by MA organizations to conduct these assessments—and therefore are not likely conducted by the beneficiary's own primary care provider. Twenty MA organizations generated millions in payments from in-home HRAs for beneficiaries for whom there was not a single record of any other service being provided in 2016. CMS concurred with the second and third of our five recommendations, which were to:

- require MA organizations to implement best practices to ensure care coordination for HRAs,
- provide targeted oversight of the 10 parent organizations that drove most of the risk-adjusted payments resulting from in-home HRAs,
- provide targeted oversight of the 20 MA organizations that drove risk-adjusted payments resulting from in-home HRAs for beneficiaries who had no other service records in the 2016 encounter data,
- reassess the risks and benefits of allowing in-home HRAs to be used as sources of diagnoses for risk adjustment and reconsider excluding such diagnoses from risk adjustment, and
- require MA organizations to flag any MA organization-initiated HRAs in their MA encounter data.

Medicare-Allowed Charges for Noninvasive Ventilators Are Substantially Higher Than Payment Rates of Select Non-Medicare Payers (A-05-20-00008), September 2020

For calendar years (CYs) 2016 through 2018, we estimated that Medicare and beneficiaries could have saved \$86.6 million if Medicare-allowed charges were comparable with payment rates of select non-Medicare payers on Healthcare Common Procedure Coding System (HCPCS) code E0466. Of this payment difference, we estimated that Medicare paid \$69.3 million and that Medicare beneficiaries paid \$17.3 million. Generally, Medicare-allowed charges are higher than select non-Medicare payer payment rates because CMS does not routinely evaluate pricing trends for noninvasive ventilators or payment rates of select non-Medicare payers. In 2016, CMS was required to adjust certain fee schedule amounts for durable medical equipment, prosthetics, orthotics, and supplies using information from the competitive bidding program. But this change did not affect the noninvasive ventilator HCPCS code reviewed for this report.

We recommended that CMS review Medicare-allowed charges for noninvasive ventilators HCPCS code E0466, for which Medicare and beneficiaries could have potentially saved an estimated \$86.6 million in CYs 2016 through 2018, and add noninvasive ventilators HCPCS code E0466 to the competitive bidding program as soon as practicable. CMS confirmed that it had been evaluating noninvasive ventilators for potential inclusion in the competitive bidding program. CMS also confirmed that noninvasive ventilators had initially been included in Round 2021 of the program. However, the product category was removed because of the COVID-19 pandemic.

Incorrect Acute Stroke Diagnosis Codes Submitted by Traditional Medicare Providers Resulted in Millions of Dollars in Increased Payments to Medicare Advantage Organizations (A-07-17-01176), September 2020

Almost all of the selected acute stroke diagnosis codes that physicians submitted to CMS under traditional Medicare and that CMS later used to make payments to MA organizations for 2015 or 2016 on behalf of the 582 transferred enrollees did not comply with Federal requirements. For 580 of the transferred enrollees, the medical records did not support the acute stroke diagnosis codes. Thus, the Ischemic or Unspecified Stroke Hierarchical Condition Categories were not validated.

These errors originated from physicians submitting incorrect acute stroke diagnosis codes on claims billed under traditional Medicare. However, these errors were unnoticed and caused inaccurate payments in MA because CMS did not have policies and procedures to: (1) identify beneficiaries who transferred from traditional Medicare to MA and (2) evaluate whether the acute stroke diagnosis codes submitted under traditional Medicare on their behalf complied with Federal requirements. As a result, we estimated that CMS made inaccurate payments of just over \$14.4 million to MA organizations.

CMS concurred with our recommendations that it: (1) educate physicians on how to correctly submit acute stroke diagnosis codes and how these diagnosis codes may impact the MA program,

and (2) develop and implement policies and procedures to identify beneficiaries transferring from traditional Medicare to MA and evaluate whether the acute stroke diagnosis codes submitted under traditional Medicare comply with Federal requirements.

Quality of Care, Safety, and Access

States Continued To Fall Short in Meeting Required Timeframes for Investigating Nursing Home Complaints: 2016–2018 (OEI-01-19-00421), September 2020

Many States consistently fail to meet required timeframes for investigating the most serious nursing home complaints. Furthermore, nearly all States that fell short in a timely investigation of the most serious nursing home complaints from 2011 through 2015 continued to fall short from 2016 through 2018. Generally, we found that the States that we communicated with face challenges with receiving a high volume of complaints, triaging complaints, and having adequate human resources to investigate complaints. Our findings raise questions about some States' ability to address serious nursing home complaints and about the effectiveness of CMS's oversight of States. CMS concurred with both of our recommendations, which were to:

- ensure that all States receive training on CMS's updated triage guidance and
- identify new approaches to address those States that are consistently failing to meet required timeframes for investigating the most serious nursing home complaints.

Medicare Part D Beneficiaries at Serious Risk of Opioid Misuse or Overdose: A Closer Look (OEI-02-19-00130), May 2020

Most Part D beneficiaries at serious risk of opioid misuse or overdose in 2017 received high amounts of opioids the following year, while 11 percent had an overdose or adverse effect from an opioid in 2017 or 2018, and about half have been diagnosed with opioid use disorder or other conditions related to the misuse of opioids. Only 7 percent of those who were diagnosed with opioid use disorder received drugs for medication-assisted treatment (MAT drugs) through Part D, possibly because of challenges that beneficiaries have in accessing prescribers. Although opioids can be appropriate under certain circumstances, steps should be taken to mitigate the risk of misuse and overdose, especially when beneficiaries receive high amounts of opioids for long periods of time.

CMS concurred with our recommendation to educate Part D beneficiaries and providers about access to MAT drugs and naloxone.

Toolkit for Calculating Opioid Levels and Identifying Patients at Risk of Misuse or Overdose: R and SQL Programming Code (OEI-02-17-00561), May 2020

This toolkit provides detailed steps for using prescription drug claims data to analyze patients' opioid levels and identify certain patients who are at risk of opioid misuse or overdose. The toolkit includes R and Structured Query Language (SQL) programming code. It is a companion to the previously released Office of Inspector General (OIG) Toolkit: Using Data Analysis To Calculate Opioid Levels and Identify Patients at Risk of Misuse or Overdose, which includes SAS programming code. This toolkit is based on the methodology that OIG developed for its extensive work on opioid use in Medicare Part D. It is intended to assist our partners, such as Medicare Part D plan sponsors, private health plans, and State Medicaid Fraud Control Units, with analyzing their own prescription drug claims data to help combat the opioid crisis.

Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2020 ([OEI-05-20-00190](#)), June 2020

We found that overall, the rate at which Part D plan formularies include the drugs commonly used by dual eligibles (i.e., individuals who are eligible for both Medicare and Medicaid) is high, with some variation. The 448 unique formularies used by the 4,610 Part D plans include 97 percent of the 195 drugs most commonly used by dual eligibles and covered by Part D. In addition, 75 percent of the commonly used drugs are included by all Part D plan formularies. On average, formularies applied utilization management tools to 29 percent of the unique drugs we reviewed in 2020.

Because some variation exists in formularies' inclusion of these drugs and in their application of utilization management tools to the drugs, some dual eligibles may need to use alternative methods to access the drugs they take. This report did not make recommendations.

Some Nursing Homes' Reported Staffing Levels in 2018 Raise Concerns; Consumer Transparency Could Be Increased ([OEI-04-18-00450](#)), August 2020

Nursing homes' reported staffing levels often vary on a day-to-day basis, and 7 percent fell below required Federal staffing levels on at least 30 total days in 2018. CMS's Star Rating System ranks nursing homes on their average staffing levels each quarter; as a result, daily staffing variations are not transparent to consumers. This review, initiated before the COVID-19 pandemic emerged, focuses on staffing data from 2018. However, the 2020 pandemic reinforces the importance of adequate staffing for nursing homes, as inadequate staffing can make it more difficult for nursing homes to respond to infectious disease outbreaks like COVID-19.

Our recommendations were that CMS should:

- enhance efforts to ensure that nursing homes meet daily staffing requirements and
- explore ways to provide consumers with additional information on nursing homes' daily staffing levels and variability.

CMS did not agree or disagree with either of our recommendations.

Opioid Use in Medicare Part D Continued To Decline in 2019, but Vigilance Is Needed as COVID-19 Raises New Concerns (OEI-02-20-00320), August 2020

Medicare Part D has seen a steady decline in opioid use over the past several years and an increased use of MAT drugs. About one in four Part D beneficiaries received opioids in 2019, a decrease from the prior 3 years. At the same time, the number of beneficiaries receiving MAT drugs for opioid use disorder increased to 209,000 in 2019. Also, the number of beneficiaries receiving through Part D prescriptions for naloxone has continued to grow. Nearly 267,000 beneficiaries received high amounts of opioids in 2019, with almost 34,000 beneficiaries at serious risk of opioid misuse or overdose. About 140 prescribers ordered opioids for large numbers beneficiaries at serious risk.

The changes in recent years in opioid use and MAT show progress from the efforts of HHS and others to address the opioid crisis. Nonetheless, it is critical to remain vigilant. The COVID-19 pandemic poses additional danger for this population.

OIG is committed to continuing our work on opioid use and access to treatment. Likewise, we encourage CMS to also closely monitor opioid use and access to treatment.

CMS's Monitoring Activities for Ensuring That Medicare Accountable Care Organizations Report Complete and Accurate Data on Quality Measures Were Generally Effective, but There Were Weaknesses That Could Be Improved (A-09-18-03033), September 2020

CMS's monitoring activities were generally effective for ensuring that Medicare Accountable Care Organizations (ACOs) report complete and accurate data on quality measures through claim and administrative data and the CMS web portal. However, we identified weaknesses in CMS's monitoring activities that could lead to ACOs reporting incomplete or inaccurate data through the patient survey. Specifically, CMS did not ensure that its contractor: (1) verified survey vendors' correction of identified issues even though the issues were directly related to the collection or reporting of data and (2) provided feedback reports in time for survey vendors to include in their Quality Assurance Plans all of the changes implemented to address identified issues. In addition, CMS did not ensure that its contractor reviewed survey instruments (e.g., mail survey packages) translated into other languages. As a result of these weaknesses, ACOs may not report complete and accurate data on quality measures, which could affect the ACOs' overall quality performance scores and ultimately the shared savings payments.

To improve its monitoring activities for ensuring that ACOs report complete and accurate data on quality measures, we recommend that CMS update the Statement of Work to require its contractor to: (1) verify that survey vendors have corrected identified issues that directly relate to the collection or reporting of data; (2) confirm that all implemented changes to address the identified issues are

included in Quality Assurance Plans before they are approved; and (3) review the translated survey templates, mail survey packages, and telephone survey scripts to ensure that they are consistent with the English versions. CMS concurred with our recommendations.

Program Integrity

2019 Performance Data for the Senior Medicare Patrol Projects (OEI-02-20-00150), June 2020

The Senior Medicare Patrol (SMP) projects receive grants from the Administration for Community Living to recruit and train retired professionals and other older adults and community members to prevent, recognize, and report health care fraud, errors, and abuse. In 2019, the 54 SMP projects had a total of 6,875 total active team members who conducted a total of 28,146 group outreach and education events, reaching an estimated 1.6 million people. In addition, the projects had 320,590 individual interactions with, or on the behalf of, a Medicare beneficiary. The projects reported \$2.4 million in expected Medicare recoveries. Cost avoidance totaled \$60,971, while savings to beneficiaries and others totaled \$20,150.

CMS's Encounter Data Lacks Essential Information That Medicare Advantage Organizations Have the Ability to Collect (OEI-03-19-00430), August 2020

Encounter data from Medicare Advantage Organizations (MAOs) continue to lack NPIs for providers who order and/or refer durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); clinical laboratory services; imaging services; and home health services. However, almost all MAOs have data systems that are able to receive and store these NPIs when providers submit them. Additionally, a substantial portion of MAOs reported that providers are already submitting the ordering provider NPIs on claims or encounter records for DMEPOS, laboratory services, and imaging services. Further, a majority of MAOs require NPIs to be submitted for their other lines of business. Finally, almost half of MAOs believe that NPIs for ordering providers are critical for combating fraud.

CMS concurred with our first recommendation but did not concur with our second recommendation. Our recommendations were to:

- require MAOs to submit the ordering provider NPI on encounter records for DMEPOS and for laboratory, imaging, and home health services; and
- establish and implement “reject edits” that: (1) reject encounter records in which the ordering provider NPI is not present when required and (2) reject encounter records that contain an ordering provider NPI that is not a valid and active NPI in the National Plan and Provider Enumeration System registry.

CMS Generally Met Requirements for the DMEPOS Competitive Bidding Program Round 1 Recompete (A-05-16-00051), August 2020

We reviewed the process used by CMS to conduct the competitive bidding and subsequent pricing determinations that are the basis for bid amounts and single-payment amounts (SPAs) of the Round 1 Recompete phase of the DMEPOS Competitive Bidding Program (the Program).

CMS consistently followed its established Program procedures and applicable Federal requirements for 219 of the 225 winning suppliers associated with the sampled SPAs reviewed. Although the overall effect on Medicare payments to suppliers was relatively small, CMS did not consistently follow its established procedures and applicable Federal requirements for selecting suppliers during the bid process for 6 of the 225 winning suppliers. Additionally, CMS did not monitor suppliers in accordance with established procedures and Federal requirements for another seven suppliers that did not maintain the applicable license, as required by their contracts, for the first 6 months of 2014.

On the basis of our sample, we estimated that CMS paid suppliers \$24,054 more than they would have received without any errors, or less than 0.03 percent of the \$73 million paid under the Round 1 Recompete during the first 6 months of 2014.

CMS concurred with our recommendations that it: (1) follow its established Program procedures and applicable Federal requirements consistently in evaluating the financial documents of all suppliers; (2) ensure that suppliers have the applicable licenses for the specific competitions in which they are submitting a bid by continuing to work with State licensing boards, as recommended in our previous report; and (3) ensure that it has a system to monitor supplier licensure requirements and identify potentially unlicensed suppliers.

Medicare Contractors Were Not Consistent in How They Reviewed Extrapolated Overpayments in the Provider Appeals Process (A-05-18-00024), August 2020

Although MACs and qualified independent contractors (QICs) generally reviewed appealed extrapolated overpayments in a manner that conforms with existing CMS requirements, CMS did not always provide sufficient guidance and oversight to ensure that these reviews were performed in a consistent manner. In addition, CMS's ability to provide oversight over the extrapolation review process was limited because of data reliability issues in the Medicare Appeals System (MAS). Improving the accuracy of the information in the MAS would potentially assist CMS with ensuring that extrapolated overpayments are reviewed by the MACs and QICs in a consistent manner.

CMS concurred with our recommendations that it: (1) provide additional guidance to contractors to ensure reasonable consistency in procedures used to review extrapolated overpayments during the first two levels of the Medicare Parts A and B appeals process; (2) take steps to identify and resolve discrepancies in the procedures contractors use to review extrapolations during the appeals

process; (3) provide guidance regarding the organization of extrapolation-related files that must be submitted in response to a provider appeal; (4) improve system controls to reduce the risk of contractors incorrectly marking the extrapolation flag field in the MAS; and (5) update the information in the MAS to accurately reflect extrapolation amounts challenged as part of an appeal, whether the extrapolation was reviewed by a contractor, and the outcome of any extrapolation review.

Drug Pricing and Reimbursement

Loophole in Drug Payment Rule Continues To Cost Medicare and Beneficiaries Hundreds of Millions of Dollars ([OEI-BL-20-00100](#)), July 2020

As of December 2019, CMS continued to include noncovered, self-administered versions when calculating Part B payment amounts for Orencia and Cimzia, the same two drugs identified in an earlier OIG report from 2017. Part B spending for Orencia and Cimzia would have been reduced by \$497 million (22 percent of expenditures for the two drugs) in 2017 and 2018 if their payment amounts had been set using only the physician-administered versions (i.e., if the self-administered versions had not been used in determining payment). Twenty percent (\$99.5 million) of the total savings would have come directly through reduced coinsurance owed by Medicare beneficiaries. Further, OIG found that physicians almost never administered the self-injected versions of Orencia to patients in their offices, and that the payment loophole may give physicians substantial incentives to administer Orencia and Cimzia instead of other drugs for the same conditions. As recommended in our previous study, OIG continues to believe that CMS should seek a legislative change requiring that noncovered, self-administered versions be excluded in the calculation of Part B payment amounts. Consistent with its response to the earlier recommendation, CMS did not concur.

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2018 Average Sales Prices ([OEI-03-20-00130](#)), August 2020

On the basis of 2018 data, CMS lowered Medicare Part B reimbursement for 16 drugs, saving Medicare and its beneficiaries \$4.4 million over 1 year. This finding highlights the success of OIG's mandated quarterly comparisons of average sales prices (ASPs) with average manufacturer prices (AMPs) and implementation of CMS's current price-substitution policy. If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage—currently 5 percent—the ASP-based payment amount is substituted with a lower calculated rate. This serves as a mechanism for monitoring market prices and limiting potentially excessive payment amounts. OIG continues to recommend that CMS expand the price-substitution criteria. CMS did not concur with this recommendation and stated that more experience with the price substitution policy is needed before it can be expanded.

Some Drug Manufacturers Reported Inaccurate Product Data to CMS (OEI-03-19-00200), September 2020

Manufacturers reported inaccurate drug product data for 14 percent of the national drug codes we reviewed that were associated with Medicare Part B-covered drugs. (Such drugs are generally those that are injected or infused in physicians' offices or hospital outpatient settings.) If manufacturer-reported product data are incorrect, Medicare may make inaccurate payments for drugs and Medicaid may collect inaccurate rebates from manufacturers. CMS did not explicitly state whether it concurred or nonconcurred with our recommendation that it should work with manufacturers associated with errors to correct and resubmit accurate product data.

Medicaid Program Reports and Reviews

Financial Management and Improper Payments

North Carolina Received \$30 Million in Excess Federal Funds Related to Improperly Claimed Health Home Expenditures (A-04-18-00120), April 2020

North Carolina did not claim Federal Medicaid reimbursement for health home expenditures in accordance with Federal and State requirements. Instead, it improperly claimed \$124.6 million in Primary Care Case Management (PCCM) expenditures, which should have been reimbursed at the regular Federal medical assistance percentage (FMAP) (\$81.5 million Federal share), as health home expenditures, which were reimbursed at the enhanced FMAP (\$112.2 million Federal share). North Carolina did not claim any health home expenditures before or after the enhanced FMAP period for Federal FYs 2012 and 2013. Of the 2,999 payments associated with 100 beneficiaries in our stratified random sample, none met all of the requirements for payment identified in North Carolina's approved State plan amendment for health home services. North Carolina claimed PCCM expenditures as health home expenditures because it did not take certain steps to ensure implementation of the health home option and did not implement internal controls needed to ensure compliance. As a result, North Carolina received \$30.7 million in excess Federal funds.

North Carolina concurred with our recommendations that it reclassify \$124.6 million (\$112.2 million Federal share) from health home expenditures to PCCM expenditures and refund \$30.7 million in excess Federal funds to the Federal Government.

Iowa Inadequately Monitored Its Medicaid Health Home Providers, Resulting in Tens of Millions in Improperly Claimed Reimbursement (A-07-18-04109), April 2020

Iowa improperly claimed Federal Medicaid reimbursement for 62 of the 130 payments made to health home providers that did not comply with Federal and State requirements. These improper payments primarily involved deficiencies in documentation. Specifically, Iowa's health home providers did not document core services, integrated health home outreach services, diagnoses,

and enrollment with providers. In addition, Iowa's providers did not maintain documentation to support higher payments for intense integrated health home services and did not ensure that beneficiaries had full Medicaid benefits.

The improper payments occurred because Iowa did not adequately monitor providers for compliance with certain Federal and State requirements. Based on our sample results, we estimated that Iowa improperly claimed at least \$37.1 million in Federal Medicaid reimbursement for payments made to health home providers.

Iowa did not concur with our recommendation that it refund \$37.1 million to the Federal Government. Iowa concurred with our recommendations that it improve its monitoring of the health home program to ensure that health home providers comply with Federal and State requirements for documenting services, revise its State Medicaid plan to define documentation requirements, and educate providers on these requirements.

New Jersey Did Not Ensure That Its Managed Care Organizations Adequately Assessed and Covered Medicaid Beneficiaries' Needs for Long-Term Services and Supports (A-02-17-01018), May 2020

New Jersey did not ensure that its MCOs complied with certain Federal and State requirements for beneficiaries enrolled in its Medicaid managed long-term services and supports (MLTSS) program. For 68 of the 100 monthly capitation payments in our random sample, MCOs did not comply with the requirements to adequately assess and cover the associated beneficiaries' needs for long-term services and supports. Specifically, MCOs did not comply with requirements for: (1) providing adequate service planning and care management to the beneficiaries; (2) conducting and documenting assessments; and (3) developing, reviewing, and updating beneficiaries' care plans.

These deficiencies occurred because New Jersey did not adequately monitor MCOs for compliance with certain Federal and State requirements. On the basis of our sample results, we estimated that New Jersey made monthly payments totaling approximately \$386 million (Federal share) to MCOs that did not comply with certain Federal and State requirements.

New Jersey partially concurred with our recommendations that it improve its monitoring and followup activities to ensure that its MCOs comply with Federal and State requirements detailed in its contracts with the MCOs; and take actions, including imposing corrective action plans, fines, or other financial disincentives on MCOs, to address the MCOs' noncompliance affecting \$721 million (\$386 million Federal share) in capitation payments in CY 2016 and ensure future compliance with contract requirements.

The New York State Medicaid Agency Made Capitation Payments to Managed Care Organizations After Beneficiaries' Deaths (A-04-19-06223), July 2020

New York made capitation payments after beneficiaries' deaths. Based on New York and Social Security Administration data available to us, we could not fully confirm that 2 beneficiaries associated with 4 of the 100 capitation payments were deceased. In addition, New York adjusted 12 capitation payments before our audit. For the remaining 84 payments, New York made unallowable payments totaling \$269,473 (\$143,643 Federal share).

The unallowable payments occurred because New York did not: (1) have system edits to identify errors in the automated process that terminates beneficiaries' eligibility after dates of death; (2) update the eligibility and payment systems with correct dates of death; (3) identify as deceased and disenroll beneficiaries that had a date of death in one of its data sources; or (4) use additional sources of death information and alternative procedures similar to those that we used in our audit to identify, verify, or determine dates of death.

On the basis of our sample results, we estimated that New York made payments to MCOs on behalf of deceased beneficiaries totaling at least \$23.3 million (\$13.7 million Federal share) during our audit period.

New York did not specifically indicate that it concurred with our recommendations that it: (1) refund the \$13.7 million to the Federal Government and (2) identify and recover unallowable payments made to MCOs during our audit period on behalf of deceased beneficiaries. We also made other procedural and administrative recommendations.

Nebraska Claimed Unallowable School-Based Administrative Costs Because of Improper Coding of Random Moment Timestudy Responses (A-07-19-03234), August 2020

Not all of the school-based administrative (SBA) costs that Nebraska claimed for Medicaid reimbursement for September 1, 2014, through August 31, 2017, were reasonable, allowable, and adequately supported in accordance with the terms of the State Medicaid plan and applicable Federal and State requirements. Specifically, Nebraska did not correctly calculate and claim SBA costs for Medicaid reimbursement because the contractors incorrectly coded some random moment timestudy (RMTS) responses. Additionally, one contractor incorrectly assigned some participants to the RMTSs. Nebraska claimed and received Federal reimbursement totaling \$25.3 million; however, we determined that the allowable SBA costs were \$12.1 million. Therefore, Nebraska claimed and received \$13.2 million in unallowable SBA costs.

Nebraska claimed these unallowable costs because it did not exercise proper oversight to ensure that contractors followed State requirements when coding RMTS responses and when assigning participants to the RMTSs.

Nebraska did not concur with our recommendations that it refund the \$13.2 million to the Federal Government, review SBA costs claimed after our audit period and refund unallowable amounts, and strengthen oversight of its contractors to ensure that they follow State requirements when coding RMTS responses and assigning participants to the RMTSs.

Texas Relied on Impermissible Provider-Related Donations To Fund the State Share of the Medicaid Delivery System Reform Incentive Payment Program (A-06-17-09002), August 2020

Of the \$189.3 million in funds that Texas used as the State share of Delivery System Reform Incentive Payment (DSRIP) Program payments, \$146.6 million was funded through impermissible provider-related donations that did not meet Federal requirements. Those funds were derived from impermissible provider-related donations because the providers made donations that benefited the intergovernmental transfer (IGT) entity, the funds the IGT entity transferred resulted from those donations, and the providers' donations were part of a hold-harmless practice.

Texas did not decrease its Medicaid expenditures by the \$146.6 million as required under Federal requirements. As a result, Texas inappropriately received \$83.8 million in Federal funds.

Texas did not concur with our recommendations to: (1) refund the \$83.8 million it inappropriately received because it used IGTs derived from impermissible provider-related donations as the State share of DSRIP Program payments and (2) provide its IGT entities with guidance about arrangements that may result in impermissible provider-related donations. Texas concurred with our recommendation to request that its IGT entities disclose whether similar arrangements exist and provide Texas with action plans on ending the arrangements.

Connecticut Did Not Meet Federal and State Requirements for Claiming Medicaid School-Based Child Health Services for Hartford Public Schools (A-01-19-00003), September 2020

Connecticut did not claim Federal Medicaid reimbursement for school-based health services submitted by Hartford Public Schools (HPS) in accordance with Federal and State requirements. Of the 100 student-months selected in our sample, 32 student-months were allowable. However, 68 student-months had 1 or more school-based health services, totaling \$11,928 (\$5,964 Federal share), that were not allowable. These errors occurred because Connecticut did not adequately monitor School Based Child Health (SBCH) claims for school-based health services submitted by HPS. On the basis of our sample results, we estimated that Connecticut improperly claimed at least \$1,522,359 (\$761,179 Federal share) for Medicaid payments made to HPS.

Connecticut agreed with our recommendations that it: (1) refund \$761,179 to the Federal Government, (2) work with CMS to review Medicaid payments made to HPS after our audit period and refund any overpayments, and (3) strengthen its oversight of the SBCH program by working with the Connecticut Department of Administrative Services to develop a detailed review process

for claims submitted by the Local Education Agencies to ensure that all claims meet Federal and State requirements.

Colorado Claimed Unsupported and Incorrect Federal Medicaid Reimbursement for Beneficiaries Enrolled in the New Adult Group (A-07-19-02822), September 2020

Colorado did not always comply with Federal and State requirements when claiming Federal Medicaid reimbursement for Medicaid services provided to beneficiaries enrolled in the new adult group (nondisabled, low-income adults without dependent children). Specifically, Colorado claimed Medicaid payments at the newly eligible FMAP on behalf of 33,036 beneficiaries, but it did not have adequate supporting documentation to substantiate that these beneficiaries were eligible for the new adult group. Therefore, Colorado may have incorrectly claimed \$4.1 million on behalf of these beneficiaries. In addition, Colorado claimed the incorrect FMAP for beneficiaries whom it enrolled in the new adult group but who were eligible for the Transitional Medicaid eligibility group. As a result, Colorado incorrectly received an additional \$1.8 million for services that it claimed on behalf of these beneficiaries.

Colorado did not have adequate system controls to ensure that its claims for Federal Medicaid reimbursement were adequately supported and were claimed at the correct FMAP.

Colorado agreed with our recommendations that it: (1) update its eligibility determination system by implementing an automatically accessible eligibility history to eliminate the need for manual interventions to identify eligibility changes in eligibility status, (2) ensure that the Medicaid Management Information System (MMIS) retains all beneficiary eligibility changes and reconcile the data in the MMIS to the data in its eligibility determination system to determine whether discrepancies in eligibility groups are occurring, and (3) ensure that its systems have automated edits to enroll Transitional Medicaid beneficiaries in the correct eligibility group.

North Carolina Made Capitation Payments to Managed Care Entities After Beneficiaries' Deaths (A-04-16-00112), September 2020

North Carolina made unallowable capitation payments to certain managed care entities on behalf of deceased beneficiaries. Of the 37,434 capitation payments reviewed, North Carolina paid 3,912 before the beneficiaries' deaths or recovered the payments. However, the remaining 33,522 payments were for monthly coverage after the beneficiaries' deaths, were unrecovered, and were therefore unallowable. Although North Carolina identified and recovered some unallowable payments, it did not always identify and process death information in its eligibility system and MMIS. As a result, North Carolina made \$2.9 million (\$1.9 million Federal share) in unallowable payments to certain managed care entities for the audit period.

North Carolina agreed with our recommendations that it refund \$1.9 million to the Federal Government, identify capitation payments made to managed care entities on behalf of deceased

beneficiaries before and after our audit period and refund the Federal share of amounts recovered, and improve the accuracy of eligibility system date of death information and apply MMIS edits as necessary to identify all deceased beneficiaries, prevent all capitation payments for monthly coverage after death, and recover such unallowable payments.

96 Percent of South Carolina's Medicaid Fee-for-Service Telemedicine Payments Were Insufficiently Documented or Otherwise Unallowable (A-04-18-00122), April 2020,

Texas Telemedicine Services Were Provided in Accordance With State Requirements (A-06-18-05001), June 2020, and

Illinois Claimed Unallowable Telemedicine Payments (A-05-18-00028), August 2020

South Carolina made telemedicine payments that were not in accordance with Federal and State requirements and were therefore unallowable. On the basis of our sample results, we estimated that 96 percent of South Carolina's Medicaid fee-for service telemedicine payments were unallowable. We also estimated that unallowable payments totaled at least \$2.1 million (\$1.5 million Federal share) during our audit period.

South Carolina concurred with our recommendations that it refund \$1.5 million to the Federal Government, give providers formal training on telemedicine documentation requirements, and enhance the monitoring of provider compliance by conducting periodic reviews of telemedicine payments for compliance with documentation requirements.

We determined that 39 of the 40 client dates of service we reviewed were allowable in accordance with the Texas Medicaid requirements. The remaining incorrect billing did not affect the Medicaid payment amount that the provider received. This report contains no recommendations.

Illinois made telemedicine payments that were not in accordance with Federal and State requirements and were therefore unallowable. Based on our testing, we determined that Illinois made unallowable payments of \$198,124 (\$124,812 Federal share) during our audit period.

Illinois concurred with our recommendations that it refund \$124,812 to the Federal Government, give providers formal training on telemedicine billing requirements, and enhance the monitoring of provider compliance by conducting periodic reviews of telemedicine payments for compliance with billing requirements.

Quality of Care, Safety, and Access

CMS Should Pursue Strategies To Increase the Number of At-Risk Beneficiaries Acquiring Naloxone Through Medicaid (OEI-BL-18-00360), September 2020

CMS and State Medicaid agencies can be encouraged by their progress to date in increasing access to naloxone—a drug that reverses opioid overdoses—while also continuing to look for ways to further expand naloxone availability under Medicaid. We recommend that CMS pursue strategies to increase the number of at-risk beneficiaries acquiring community-use versions of naloxone (i.e., that versions that can be appropriately administered in emergency situations by those with minimal to no training) through Medicaid. CMS did not explicitly concur with our recommendation but stated that it is already pursuing multiple strategies to increase the number of at-risk beneficiaries acquiring community-use versions of naloxone through Medicaid and will continue to do so.

National Background Check Program for Long-Term-Care Providers: Assessment of State Programs Concluded in 2019 (OEI-07-20-00180), September 2019

States participating in the National Background Check Program (Program) for long-term-care providers had varying degrees of State-level legal requirements and practical infrastructure for conducting background checks. This affected their ability to implement select Program requirements and to consistently report quality data. Our findings can help CMS identify ways to strengthen its support of the Program.

CMS concurred with both of our recommendations to assist participating States to address the challenge of coordinating between State-level departments and require participating States to consistently submit data that allow for CMS and each State to calculate determinations of ineligibility.

Texas Did Not Fully Comply With Federal and State Requirements for Reporting and Monitoring Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities (A-06-17-04003), July 2020

Texas did not ensure that all beneficiary deaths were reported and reviewed; that all complaints not closed within 10 days were tracked; and that all allegations of abuse, neglect, and exploitation were entered into the Human Services Enterprise Administration Reporting and Tracking (HEART) system. Although Texas had a procedure in place to detect unreported deaths, it did not follow it, did not have a system in place to track complaints not closed within 10 days, and did not have procedures to ensure that allegations were entered into the HEART system.

Texas concurred with our recommendations that it: (1) ensure that procedures are followed to detect unreported deaths; (2) implement a system to ensure that it can track complaints not closed within 10 days; and (3) implement procedures to ensure that investigations of abuse, neglect, and exploitation are entered in the HEART system. Texas also described actions that it has taken or plans to take to address our recommendations. These actions include increasing the frequency of comparing deaths reported by the provider to death reports from the Client Assignment and

Registration system, implementing a new system to monitor unreported deaths, and issuing violations and administrative penalties for failure to report deaths.

North Carolina Did Not Ensure That Nursing Facilities Always Reported Allegations of Potential Abuse and Neglect of Medicaid Beneficiaries and Did Not Always Prioritize Allegations Timely (A-04-17-04063), July 2020

North Carolina did not ensure that nursing facilities always reported potential abuse or neglect of Medicaid beneficiaries transferred from nursing facilities to hospital emergency departments. In addition, it did not always fully comply with Federal requirements for assigning a priority level to reported allegations of potential abuse and neglect or for correctly recording the associated dates. Finally, North Carolina's complaint and incident report program may not have been effective in promoting and protecting the health, safety, and welfare of residents, patients, and other clients receiving health care services.

North Carolina generally concurred with our recommendations that it continue working with CMS to provide clear guidance to nursing facilities regarding what constitutes a reportable incident and when to report and revise its policies and procedures to require that it: (1) assign a priority level to incident reports even if the nursing facilities' investigations are not complete, (2) enter into CMS's automated tracking system the date that North Carolina first receives incident reports, and (3) manage employee absences to better prevent them from interfering with assigning priority levels to allegations within appropriate timeframes. We also made procedural recommendations, including recommendations to address our concerns with the effectiveness of North Carolina's complaint and incident report program.

Medicaid Data Can Be Used To Identify Instances of Potential Child Abuse or Neglect (A-01-19-00001), July 2020

We determined that Medicaid claim data can be used to identify incidents of potential child abuse or neglect and, using that data, estimated that 29,260 of the 29,534 Medicaid beneficiaries in our sampling frame were involved with incidents of potential child abuse or neglect that were supported by Medicaid claim data and evidence contained in medical records. We further estimated that of the beneficiaries in our population associated with incidents of potential child abuse or neglect, 3,928 were involved with incidents that were not reported to child protective services. We also determined that most incidents of potential child abuse or neglect identified in our sample occurred in familiar settings by perpetrators known to the victims. CMS did not identify similar incidents of potential child abuse or neglect during our audit period or encourage the States to identify the incidents.

CMS concurred with our recommendation that it issue guidance to inform States that performing a data analysis to identify Medicaid claims containing diagnosis codes indicating potential child abuse or neglect could help identify incidents of potential child abuse or neglect and help ensure

compliance with their mandatory reporting laws. CMS did not concur with our recommendation that it assess the sufficiency of existing Federal requirements to report suspected child abuse and neglect of Medicaid beneficiaries to determine whether CMS should strengthen those requirements or seek additional authorities to provide oversight over the reporting of suspected child abuse and neglect of Medicaid beneficiaries.

New Jersey Did Not Ensure That Incidents of Potential Abuse or Neglect of Medicaid Beneficiaries Residing in Nursing Facilities Were Always Properly Investigated and Reported (A-02-18-01006), August 2020

New Jersey did not ensure that nursing facilities always investigated and reported incidents of potential abuse or neglect to the State in accordance with Federal and State requirements. Of the 103 claims in our sample, 79 claims were not the result of potential abuse or neglect; therefore, nursing facilities were not required to report the incident to the State. Of the remaining 24 claims, 10 claims were the result of potential abuse or neglect that should have been reported to the State. However, 5 of the 10 claims were not properly investigated and reported to the State. For the other 14 claims, nursing facilities did not provide documentation, or their records did not contain sufficient documentation for State officials to determine whether the incident should have been investigated and reported. These deficiencies occurred because nursing facility staff did not follow requirements for investigating and reporting potential incidents of abuse or neglect. In addition, New Jersey did not have adequate survey procedures for ensuring that nursing facilities documented all such incidents.

New Jersey did not indicate concurrence or nonconcurrence with our recommendations that it: (1) reinforce guidance to nursing facilities for ensuring potential incidents of abuse or neglect are reported in accordance with Federal and State requirements and (2) develop additional procedures for its survey site visits, including reviewing nursing facilities' records related to hospital transfers for certain beneficiary injuries or conditions that could be the result of potential abuse or neglect.

Oregon's Oversight Did Not Ensure That Four Coordinated-Care Organizations Complied With Selected Medicaid Requirements Related to Access to Care and Quality of Care (A-09-18-03035), September 2020

Oregon's coordinated-care organizations (CCOs) generally complied with Federal and State requirements related to time and distance standards and timely access standards, as well as requirements related to assignment of primary care providers. However, the CCOs did not comply with requirements related to provider credentialing and beneficiary grievances and appeals. In addition, CCOs did not resolve or review beneficiary grievances appropriately and did not adjudicate appeals in compliance with their contracts with Oregon. Also, CCOs submitted inaccurate or incomplete data on grievances and appeals, which Oregon used for oversight.

These issues occurred because: (1) Oregon provided insufficient oversight of, and guidance to, the CCOs and (2) the CCOs provided insufficient oversight of, and guidance to, their subcontractors. Because not all providers were appropriately credentialed, there was an increased risk of poor quality of care. In addition, the mishandling of grievances and appeals may have reduced beneficiaries' access to care and the quality of care.

Oregon concurred with our recommendations that it provide additional guidance to CCOs on: (1) the processes for provider credentialing and for beneficiary grievances and appeals and (2) monitoring subcontractors, that Oregon take actions to ensure that CCOs do not subcontract the adjudication of final appeals, and that the data that CCOs submit on grievances and appeals are accurate and complete.

Illinois Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety and Emergency Preparedness (A-05-18-00037), September 2020

Illinois did not ensure that selected nursing homes in the State that participated in the Medicare or Medicaid programs complied with CMS requirements for life safety and emergency preparedness. During our site visits, we identified deficiencies in areas related to life safety and emergency preparedness at all 15 nursing homes that we reviewed. Specifically, we found 53 instances of noncompliance with life safety requirements and 184 instances of noncompliance with emergency preparedness requirements. As a result, residents at the 15 nursing homes were at increased risk of injury or death during a fire or other emergency.

The identified deficiencies occurred because the existing life safety training program for nursing home management could not educate all Illinois nursing home management in a timely manner, and the State did not offer an emergency preparedness training program for nursing home management.

Illinois generally agreed with our recommendations that it: (1) follow up with the 15 nursing homes to verify that corrective actions have been taken regarding the deficiencies that we identified, (2) conduct more thorough emergency preparedness reviews for the safety and protection of nursing home residents and staff, (3) work with CMS to develop emergency preparedness training and expand life safety training sessions to accommodate all nursing home management, (4) consider increasing staffing levels to address caseload thresholds for State surveyors, and (5) consider modifying its survey procedures to check for carbon monoxide alarms required by Illinois law.

Drug Pricing and Reimbursement

New York Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-02-18-01016), April 2020, and

Michigan Did Not Bill Manufacturers for Some Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-05-17-00017), August 2020

New York and Michigan did not fully comply with Federal Medicaid requirements for billing manufacturers for rebates for drugs dispensed to managed care organization enrollees. Specifically, New York did not bill for and collect from manufacturers estimated rebates of more than \$10.8 million (Federal share) for pharmacy and physician-administered drugs that were eligible or may have been eligible for rebates for our audit period. Although its policies and procedures require the collection of drug utilization data necessary to invoice for rebates on all claims, New York's internal controls did not always ensure that the data were used to invoice manufacturers to secure rebates.

Michigan did not bill for and collect manufacturers' rebates that we calculated to be at least \$31.5 million (Federal share). Michigan did not always bill for and collect manufacturers' rebates because Michigan and its contractor did not identify all of the rebate-eligible drugs in the utilization data submitted by the MCOs.

New York partially agreed with our recommendation that it bill for and collect from manufacturers rebates for single-source and top-20 multiple-source pharmacy and physician-administered drugs and refund the estimated \$7.8 million (Federal share), and it agreed with our recommendations that it work with CMS to determine whether the other pharmacy and physician-administered drugs were eligible for rebates and, if so, upon receipt of the rebates, refund up to an estimated \$3 million (Federal share) of rebates collected; and strengthen its internal controls to ensure that all pharmacy and physician-administered drugs eligible for rebates are invoiced.

Michigan concurred with our recommendation that it bill for and collect manufacturers' rebates for pharmacy drugs and for single-source and top-20 multiple-source physician-administered drugs that we calculated to be at least \$30 million (Federal share) and refund the Federal Government. Michigan described actions that it has taken or plans to take to address our remaining recommendations. We recognize the corrective actions Michigan has implemented or plans to implement to address our recommendations.

Legal and Investigative Activities Related to Medicare and Medicaid

OIG investigates allegations of fraud, waste, and abuse in all HHS programs. Our largest body of work involves investigating matters related to the Medicare and Medicaid programs, such as patient harm; billing for services not rendered, medically unnecessary services, or upcoded services (i.e., services billed for at a level higher than warranted); illegal billing, sale, and diversion of prescription drugs; marketing of off-label uses for prescription drugs; and solicitation and receipt of kickbacks, including illegal payments to patients for involvement in fraud schemes and illegal referral arrangements between physicians and medical companies.

OIG also conducts investigations regarding organized criminal activity, including medical identity theft and fraudulent medical schemes established for the sole purpose of stealing Medicare dollars. Investigators are opening an increasing number of cases against health care providers who engage in these health care fraud schemes. Those who participate in the schemes may face heavy fines, jail time, and exclusion from participation in Federal health care programs.

One of the most common types of fraud perpetrated against Medicare, Medicaid, and other Federal health care programs involves filing false claims for reimbursement. False claims may be pursued under Federal and State criminal statutes and, when appropriate, under the False Claims Act. Depending on the types of fraud or other violations involved, OIG investigations may culminate in criminal or civil court judgments and decisions, administrative sanctions and decisions, and/or negotiated settlement agreements. Investigative outcomes take many forms, including incarceration, restitution, fines, penalties, forfeitures, assessments, and exclusion of individuals or entities from participation in all Federal health care programs. Frequently used exclusion and penalty authorities are described on our website at <http://oig.hhs.gov/fraud/enforcement/cmp/>.

During this semiannual reporting period, we reported 166 criminal and 414 civil actions against individuals or entities that engaged in offenses related to health care. We also reported over \$1.24 billion in investigative receivables due to HHS and more than \$363.2 million in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare, Medicaid, and other Federal, State, and private health care programs.

Criminal and Civil Enforcement Activities Related to Medicare and Medicaid

The following recently completed actions and settlements are organized by the type of provider or entity involved. Additional cases appear in the Medicare Fraud Strike Force Activities section below.

Ambulance Transportation Company

The following case example involves an ambulance company:

Guam—On June 30, 2020, the two owners of Guam Medical Transport (GMT), Clifford P. Shoemake and Kimberly Clyde Conner, were sentenced to serve 71 and 63 months, respectively, in Federal prison in connection with their October 29, 2019, guilty pleas to one count of conspiracy to commit health care fraud and one count of conspiracy to engage in monetary transactions with the proceeds of specified unlawful activity. Shoemake and Conner were also ordered to pay \$10,884,964 in restitution. According to their admissions at the plea hearing, the defendants engaged in a conspiracy to defraud Medicare and TRICARE by submitting claims for reimbursement for medically unnecessary ambulance services that GMT provided to patients with end-stage renal disease from approximately March 11, 2010, to approximately March 21, 2014. The defendants admitted they were aware that GMT was transporting patients who did not qualify for ambulance transportation under applicable Medicare and TRICARE regulations and guidelines, with which they had failed to familiarize themselves. Specifically, the defendants admitted they were aware that many of GMT's patients were not bed-confined and did not have acute medical conditions that would otherwise qualify them for ambulance transportation. As part of the scheme, the defendants directed GMT employees to remove from internal documents references to GMT patients' ability to walk because they knew that Medicare and TRICARE would not provide reimbursement for the patients. The defendants further admitted they were aware of, but failed to address, concerns about GMT's Medicare and TRICARE billing practices raised by other GMT employees. According to court documents, GMT submitted claims to Medicare totaling approximately \$32 million during the scheme. The conspiracy resulted in improper payments to GMT of approximately \$10.8 million.

Patient Harm

The following example involves patient harm:

Missouri—On September 1, 2020, Sherry Paulo and Anthony Flores were sentenced to serve 210 months and 188 months, respectively, in Federal prison for their roles in the death of a disabled resident at Second Chance Homes (SCH), an organization that provided housing and care for developmentally disabled persons through a Missouri Department of Mental Health initiative. In addition, the couple's son, Anthony (R.K.) Flores, was sentenced to 3 years of probation for falsifying a document. Paulo and Flores pleaded guilty in Federal court to one count of willfully failing to provide necessary medical care to the victim, resulting in injury to and the death of the victim. Paulo also pleaded guilty to one count of health care fraud arising from her efforts to hide the victim's death. On February 12, 2020, R.K. Flores pleaded guilty to one count of knowingly falsifying a document with the intent to impede, obstruct, and influence a Federal investigation related to the death of

the victim. According to court documents, Flores, Paulo, and R.K. Flores all worked at SCH. Flores and Paulo admitted that, beginning in 2014, they observed victim's weight decline and his health deteriorate. However, Paulo stopped following victims' prescribed health regimen and stopped taking him to his doctors' appointments. As the victim's health deteriorated, Paulo occasionally took him out of his designated SCH residence and put him in the basement of the home she shared with Flores. The basement was small and dark without access to sunlight or running water. In approximately September 2016, the victim suffered an acute medical emergency while in the basement room of Paulo and Flores's home. Paulo and Flores chose not to seek medical care for victim, and he died in their home while they watched. Paulo and Flores admitted that, after victim's death, Paulo placed his body in a trashcan and put the trashcan in a wooden crate that they filled with cement. Paulo, Flores, and R.K. Flores then placed the crate in Paulo's storage unit. Paulo also admitted that after the victim died, she submitted, or caused to be submitted, false Medicaid claims for services purportedly rendered to the victim when, as Paulo knew, he was deceased. The amount wrongfully paid by Medicaid between approximately September 2016 and April 2017 was \$106,795.

Pharmaceutical Companies

The following case example involves a pharmaceutical company:

New York—On July 1, 2020, Novartis Pharmaceuticals Corporation (Novartis) entered into two settlements totaling \$642 million to resolve allegations that it had violated the False Claims Act. The first settlement pertains to the company's alleged illegal use of three foundations as conduits to pay the copayments of Medicare patients taking two of Novartis's drugs. The second settlement resolves claims arising from the company's alleged payments of kickbacks to doctors. In the first settlement, Novartis agreed to pay \$51.3 million to resolve allegations that it illegally paid the copay obligations for patients taking its drugs. From January 1, 2010, through December 31, 2014, Novartis used The Assistance Fund as a conduit to pay kickbacks to Medicare patients taking a Novartis drug for multiple sclerosis; and used the National Organization for Rare Disorders and Chronic Disease Fund (CDF) as conduits to pay kickbacks to Medicare patients taking Afinitor, a Novartis drug for renal cell carcinoma and progressive neuroendocrine tumors of pancreatic origin. In the second matter, Novartis agreed to pay \$591,442,008 to resolve claims that it had paid kickbacks to doctors to induce them to prescribe the Novartis drugs Lotrel, Valtorna, Starlix, Tektorna, Tektorna HCT, Tekamlo, Diovan, Diovan HCT, Exforge, and Exforge HCT. In addition, Novartis agreed to forfeit \$38.4 million under the Civil Asset Forfeiture Statute. Novartis also made extensive factual admissions in the settlement and agreed to strict limitations on any future speaker programs, including reductions to the amount it may spend on such programs. Novartis entered into a 5-year CIA with OIG as part of this settlement.

Nursing Home

The following case example involves a nursing home:

Virginia—On April 14, 2020, Saber Healthcare, Saber Healthcare Group LLC, and related entities, (Saber) entered in to a \$10 million settlement to resolve allegations that Saber violated the False Claims Act by knowingly causing certain of its skilled nursing facilities (SNFs) to submit false claims to Medicare for rehabilitation therapy services that were not reasonable, necessary, or skilled. This settlement resolved allegations that Saber submitted false claims for rehabilitation therapy by engaging in a systematic effort to increase Medicare billings. Medicare reimburses SNFs at a daily rate that reflects the skilled therapy and nursing needs of qualifying patients. The greater the patient’s needs, the higher the level of Medicare reimbursement. The highest level of Medicare reimbursement for SNFs is for “Ultra High” patients, who require a minimum of 720 minutes of skilled therapy from two therapy disciplines (e.g., physical, occupational, speech), one of which has to be provided 5 days a week. The United States alleged that Saber improperly established general goals that all patients should be provided with the Ultra High level of therapy, regardless of the patients’ individual therapeutic needs, and enforced that expectation by pressuring therapists to provide Ultra High therapy to each patient at nine facilities. The United States further contended that Saber established uniform expectations for Ultra High therapy in facility budgets; pressured facility directors in weekly or daily calls to ensure that therapists provided the Ultra High therapy to each patient; prevented therapists from providing lower levels of therapy minutes if, in the therapists’ clinical judgment, a lower amount was warranted; caused therapists to report time spent on initial evaluations as therapy time in violation of Medicare policy; and caused therapists to report time spent providing unskilled services as time spent on skilled therapy. Saber entered into a 5-year CIA with OIG in connection with the settlement.

DME Companies

The following case examples involve durable medical equipment companies:

Nebraska—On June 23, 2020, Nereus Sutko was sentenced to 46 months imprisonment and ordered to pay \$809,561 in restitution. The investigation showed that between 2010 and 2019, Sutko operated Better Lives, LLC, an Omaha-based business purporting to sell durable medical equipment to Medicare and Medicaid beneficiaries. Sutko hosted pizza parties and other gatherings at senior living residences and low-income housing facilities and obtained health care program beneficiaries’ personal and insurance information under the guise of providing free items such as heating pads or shoe inserts. Sutko offered gift cards and other rewards to people who referred health care beneficiaries to him or provided him with the names and insurance information of beneficiaries. Sutko then billed health care programs, including Medicare, Nebraska Medicaid, and Iowa Medicaid for fitted

braces and other durable medical equipment that was never prescribed for, or provided to, the beneficiaries. Sutko primarily targeted beneficiaries in the Lincoln and Omaha, Nebraska, and Des Moines, Iowa areas. Between 2010 and 2019, Sutko was paid more than \$1.8 million by Medicare, Nebraska Medicaid, and Iowa Medicaid.

Tennessee—On July 9, 2020, John Davis the former CEO of Comprehensive Pain Specialists (CPS) was sentenced to 42 months in prison and ordered to forfeit \$770,036 after being convicted of one count of conspiracy to defraud the United States and violate the anti-kickback statute as well as seven counts of violating the anti-kickback statute. According to evidence presented at trial, Davis abused his position as CEO of CPS to arrange for referrals of Medicare durable medical equipment (DME) orders to his co-conspirator, Brenda Montgomery, and her company, CCC Medical. Evidence showed that Davis operated a shell company called ProMed Solutions (ProMed), which he had registered in the name of his wife. Davis received over \$770,000 in illegal kickbacks disguised as payments to his wife and ProMed. Together, Davis and Montgomery collected over \$2.9 million dollars in improper reimbursements from Medicare. Davis used company funds from CPS to pay bonuses to providers who ordered DME for Medicare beneficiaries and referred those orders to CCC Medical. Davis received 60 percent of the Medicare profit from these referrals, while the company he ran lost the opportunity to bill for these services.

Pharmacies

The following case example involves a pharmacy:

Georgia—On June 26, 2020, Ray Ashley Dixon, a pharmacist who owned and operated Fulghum Pharmacy, was sentenced to 48 months in Federal prison after pleading guilty to a conspiracy that involved health care fraud and illegal distribution of opioids. According to court documents and information presented during the sentencing hearing, Dixon distributed opioids, including oxycodone and hydrocodone, to several individuals without a legitimate prescription issued by a physician in the usual course of professional practice. Dixon, through his pharmacy, was also a major source of opioids for patients of notorious convicted pill-mill operator Dr. Frank Bynes, Jr., distributing in excess of 110,000 units of opioids and other controlled substances during a 15-month period. In addition to his drug distribution, Dixon created fake prescriptions for expensive medication and then billed insurance programs, including Medicare Part D plans and Medicaid, even though the medication was neither prescribed nor dispensed. According to information presented during the sentencing hearing, Ray Dixon's fraud amounted to more than \$1.8 million over 4 years.

Prescription Drugs

The following case example involves prescription drugs:

California—On May 21, 2020, Minas Matosyan (a.k.a. “Maserati Mike”) was sentenced to 108 months in Federal prison for leading a conspiracy to distribute powerful prescription opioids via sham medical clinics that hired corrupt doctors who wrote fraudulent prescriptions to black market customers. Matosyan was arrested in August 2017 after a Federal grand jury indicted him, charging him and 12 other defendants with scheming to divert at least 2 million controlled prescription pills for sale on the black market. According to his plea agreement, Matosyan and his co-conspirators controlled the sham clinics and hired corrupt doctors who allowed their names to be used on fraudulent prescriptions in exchange for kickbacks. Matosyan also admitted that he and his co-conspirators either personally acquired prescription pads in the doctors’ names or arranged for other co-conspirators to do so. As part of the scheme, Matosyan staffed receptionists at the clinics who would falsely verify the false prescriptions to pharmacists who called to check on their veracity. Matosyan sold narcotic prescriptions to black market customers—either directly or through couriers—and also sold bulk quantities of hydrocodone and oxycodone that he had acquired from false prescriptions filled at pharmacies by other customers. In May 2016, Matosyan offered a doctor a “very lucrative position” where the doctor would “sit home making \$20,000 a month doing nothing,” according to Matosyan’s plea agreement. After the doctor declined the offer, Matosyan stole the doctor’s identity, sending a co-conspirator a text message containing the doctor’s full name, medical license number, and national provider identifier number that the co-conspirator used to order prescription pads in the doctor’s name. Over the next 2 months, Matosyan and his co-conspirators sold fraudulent prescriptions, purportedly issued by the victim doctor, for at least 9,450 pills of oxycodone and 990 pills of hydrocodone.

Kickbacks

The following case example involves kickbacks:

Pennsylvania—On May 22, 2020, Branden Coluccio was sentenced to 37 months in prison for conspiracy to commit health care fraud. As part of his sentence, he was also ordered to pay restitution in the amount of \$3,070,157, and to forfeit \$110,000, with an additional \$15,000 fine. This scheme involved Liberation Way, a drug and alcohol rehabilitation organization that had treatment centers in Yardley, Bala Cynwyd, and Fort Washington, Pennsylvania. The investigation exposed an array of health care fraud schemes committed by individuals associated with Liberation Way, including an overbilling scheme connected to the facility’s medical director, as well as an elaborate kickback scheme involving thousands of medically unnecessary urine tests which were sent to Florida-based laboratories for analysis. Coluccio, a co-founder of Liberation Way, participated in yet another scheme by fraudulently purchasing premium insurance policies for prospective patients on their behalf, which then allowed Liberation Way to bill insurance companies for expensive “treatment” purportedly provided to these patients. Liberation Way represented

that the patients were buying and paying for these policies, when in reality Liberation Way was paying the premiums, which is illegal.

Electronic Health Records

The following case example involves electronic health records:

Ohio—On April 21, 2020, KPMD, Inc., a California based technology company, was ordered by the U.S. District Court to pay nearly \$1.7 million in restitution to the Medicare and Medicaid programs. According to court documents, KPMD, Inc. defrauded a Medicaid program that was established as part of the 2009 American Recovery and Reinvestment Act through its contract with the Southwest Regional Medical Center in Georgetown, Ohio. In September 2011, KPMD entered into a contract with Southwest Regional Medical Center and agreed to implement the KPMD software program for electronic health records. In exchange, the hospital assigned its Government incentive payments to KPMD. KPMD's CEO later purchased the hospital. Thereafter, KPMD falsely attested to the Federal and State medical incentive programs that Southwest Regional Medical Center emergency room had met the criteria for incentive payments, even as the hospital was in the process of closing down. As a result, payments totaling nearly \$1.7 million were wired to KPMD.

Hospital

The following case example involves a hospital:

Georgia—On June 25, 2020, Piedmont Healthcare, Inc., an Atlanta-based hospital system, agreed to pay \$16 million to settle allegations that it violated the False Claims Act by billing Medicare and Medicaid for procedures at the more expensive inpatient level of care instead of the less costly outpatient or observation level of care. The settlement also resolved allegations that Piedmont paid a commercially unreasonable and above fair market value to acquire Atlanta Cardiology Group in 2007 in violation of the Federal anti-kickback statute. The settlement resolves two separate False Claims Act allegations. First, between 2009 and 2013, Piedmont's case managers allegedly overturned the judgment of its treating physicians on numerous occasions and billed Medicare and Medicaid at the more expensive inpatient level of care, even though the treating physicians recommended performing the procedures at the less expensive outpatient or observation level of care. Second, in 2007 Piedmont allegedly acquired the Atlanta Cardiology Group, a physician practice group, in violation of the Federal anti-kickback statute by paying a commercially unreasonable and above fair market value for a catheterization laboratory partly owned by the practice group. This case was initiated based on a qui tam complaint filed in the U.S. Attorney's Office for the Northern District of Georgia.

Laboratories

The following case example involves laboratory:

Florida—On April 15, 2020, Logan Laboratories Inc. (Logan Labs), a reference laboratory in Tampa, Florida; Tampa Pain Relief Centers Inc. (Tampa Pain), a pain clinic also based in Tampa Florida; and two of their former executives, Michael T. Doyle and Christopher Utz Toepke (collectively, Defendants), agreed to pay a total of \$41 million to resolve alleged violations of the False Claims Act for billing Medicare, Medicaid, TRICARE, and other Federal health care programs for medically unnecessary UDTs. Both Logan Labs and Tampa Pain are subsidiaries of Surgery Partners Inc. Doyle is the former CEO of Surgery Partners and Logan Labs. Toepke is the former Group President for Ancillary Services at Surgery Partners, with oversight of Logan Labs, and a former Vice President at Tampa Pain. The Government alleged that the Defendants knowingly submitted or caused the submission of false claims to Federal health care programs for presumptive and definitive UDTs, in circumstances where such testing was not medically reasonable or necessary. Presumptive UDTs are tests that screen for the *presence* of drugs, and definitive UDTs are tests that *identify* the amounts of those drugs in a patient’s system. The Government alleged that the Defendants developed and implemented a policy and practice of automatically ordering both presumptive and definitive UDTs for all patients at every visit, without any physician making an individualized determination that either test was medically necessary for the patients for whom the tests were ordered. According to the Government’s allegations, the medically unreasonable and unnecessary definitive UDTs were performed at Logan Labs, the medically unreasonable and unnecessary presumptive UDTs were performed at Tampa Pain, and the resulting false claims were submitted by both Tampa Pain and Logan Labs to Federal health care programs, from January 1, 2010, through December 31, 2017.

Medicare Fraud Strike Force Activities

In 2007, Medicare Fraud Strike Force teams began an effort to combine resources of Federal, State, and local law enforcement entities to prevent and combat health care fraud, waste, and abuse. These partnerships among OIG and HHS, DOJ, U.S. Attorneys’ Offices, the Federal Bureau of Investigation (FBI), and State and local law enforcement have a common goal: to analyze health care fraud data and investigative intelligence to quickly identify fraud and bring prosecutions. Strike Force teams operate in 11 areas: Miami and Tampa/Orlando, Florida; Dallas and Houston, Texas; Los Angeles, California; Detroit, Michigan; Brooklyn, New York; Baton Rouge and New Orleans, Louisiana; Chicago, Illinois; and Newark, New Jersey/Philadelphia, Pennsylvania; along with a Corporate Strike Force located in Washington, DC. During this semiannual reporting period, Strike Force efforts resulted in the filing of charges against 56 individuals or entities, 21 criminal actions, and more than \$32.2 million in investigative receivables.

In October 2018, DOJ announced the creation of a new initiative to combat the nation's opioid epidemic. The Appalachian Regional Prescription Opioid Strike Force covers 10 Federal judicial districts in Alabama, Kentucky, Ohio, Tennessee, Virginia, and West Virginia. OIG's Office of Investigations is working closely with its law enforcement partners at the Drug Enforcement Administration (DEA), FBI, and the Medicaid Fraud Control Units (MFCUs) to provide investigative support. Cases involve physicians and pharmacies that are responsible for medically unnecessary opioid prescriptions and dangerous drug combinations that are being paid for by Medicare and Medicaid. In many instances, there are other allegations of wrongdoing relating to kickbacks, health care fraud, and quality of care, including patient overdoses and deaths.

The following case example involves Strike Force case:

Alabama—On June 11, 2020, Celia Lloyd-Turney was sentenced to 60 months of probation, with the special condition of 24 months of home confinement, for the unlawful distribution of controlled substances. At trial, evidence showed that from 2015 to 2017, Lloyd-Turney wrote multiple prescriptions for controlled substances to purported patients who were actively abusing other drugs, suffering from addiction, and selling the pills. This case was investigated by HHS-OIG and DEA as part of the Appalachian Regional Prescription Opioid (ARPO) Strike Force.

Compliance Trainings

Health Care Provider Compliance Training

OIG provides free training on our website for health care providers, compliance professionals, and attorneys. OIG's Provider Compliance Training was an initiative developed in 2011 that continues to reach the health care community with OIG's message of compliance and prevention via free downloadable comprehensive training materials and podcasts. OIG's provider compliance training resources are available at <https://oig.hhs.gov/compliance/compliance-guidance/index.asp>.

Indian Health and Human Services Compliance Training

In addition to the May 2018 compliance and quality training held in Oklahoma for more than 200 individuals representing IHS, Tribes, and Tribal health care and human services organizations, OIG participated throughout this semiannual reporting period in various HHS-sponsored conferences, providing training on fraud prevention, internal controls, and compliance. OIG Indian health and human services compliance training resources are available at <https://oig.hhs.gov/AIAN>.

Most Wanted Fugitives List

The OIG Most Wanted Fugitives website continues to garner national and international attention and has greatly assisted in helping to capture fugitives charged with defrauding Federal health care programs and

stealing millions of taxpayer dollars. The Most Wanted Fugitives website is continually updated and features a profile for each fugitive as well as an online tip form and a hotline number for individuals to report fugitive-related information to OIG, in English or Spanish, 24 hours a day, 365 days a year. The Most Wanted Fugitives list is available at <https://oig.hhs.gov/fraud/fugitives/>.

HHS-OIG Hotline

As part of OIG’s Office of Investigations, the hotline is the public-facing division for OIG’s intake and evaluation of fraud tips. The mission of the HHS-OIG Hotline is to support OIG’s oversight responsibilities in safeguarding the integrity of all programs and personnel under HHS’s purview and protecting them from fraud, waste, and abuse. The hotline achieves its mission through its staff’s dedication to timely intake and analysis of information received from various sources, such as the “Submit a Complaint” link on the HHS-OIG website. During this semiannual reporting period, the OIG Hotline reported expected recoveries of \$14.9 million as a direct result of cases originating from hotline complaints.

OIG Hotline Activity (4/1/20–9/30/20)

Contacts to 1-800-HHS-TIPS phone line, including callers seeking information	53,048
Total tips evaluated	16,707
Tips referred for action	5,995
Closed; no basis provided for further action	6,103
Closed; no HHS violation ¹	222

Sources of tips referred for action

Phone	2,309
OIG website	3,242
Letters or faxes	437
Other	115

¹ Some of the closed complaints in this reporting period may have been evaluated or referred for action in a previous reporting period.

Medicaid Fraud Control Units

OIG Oversight of Medicaid Fraud Control Units

MFCUs are key partners with OIG in the fight against fraud, waste, and abuse in State Medicaid programs. OIG has oversight responsibility for MFCUs and administers grants that provide Federal funding for their operations. Currently, all 50 States, the District of Columbia, Puerto Rico, and the U.S. Virgin Islands operate MFCUs. The Federal Government reimburses 90 percent of a MFCU's total expenditures during the first 3 years of operation and 75 percent thereafter. MFCUs investigate and prosecute Medicaid provider fraud as well as patient abuse and neglect in health care facilities and board and care facilities.

OIG Onsite Reviews of MFCUs

In addition to an annual recertification review of each MFCU, OIG conducts reviews of a sample of MFCUs. OIG evaluates MFCU operations based on 12 performance standards and assesses compliance with laws, regulations, and OIG policy guidance. During the reporting period, OIG issued reports of onsite reviews of the following MFCUs:

Hawaii Medicaid Fraud Control Unit: 2019 Onsite Review ([OEI-06-19-00110](#)), June 2020, and

Arkansas Medicaid Fraud Control Unit: 2019 Onsite Inspection ([OEI-12-19-00450](#)), September 2020.

OIG Joint Casework With MFCUs

The following case example(s) involve(s) OIG's joint efforts with MFCUs:

Oklahoma—On May 21, 2020, Jeffrey Scott Terry was sentenced to 37 months in Federal prison and ordered to pay over \$1 million to Medicare and Medicaid for his role in a health care fraud scheme. According to an indictment filed in March 2019, Terry was a licensed pharmacist who began operating Bratton Drug in August 2015. Both the Oklahoma Health Care Authority—which administers Medicaid under the name SoonerCare—and Medicare reimbursed Bratton Drug for prescription drugs that it dispensed. The indictment alleged that from August 2015 through September 2018, Terry submitted false claims to SoonerCare and Medicare Part D for drugs that had not actually been prescribed or dispensed to patients. Separately, the United States filed a civil action pursuant to the Anti-Fraud Injunction Statute and obtained an injunction to prohibit Terry from dissipating or disposing assets he accumulated as a result of the false claims. On August 12, 2019, Terry entered a guilty plea before Judge Palk to one count relating to Medicaid and one count relating to Medicare. OIG investigated this case with the Oklahoma MFCU.

Advisory Opinions and Other Industry Guidance

Advisory opinions, which are developed in consultation with DOJ, are issued to requesting parties regarding the interpretation and applicability of certain statutes relating to Federal health care programs. The Health Insurance Portability and Accountability Act of 1996 (HIPAA), § 205, allows OIG to provide case-specific formal guidance on the application of the anti-kickback statute and safe harbor provisions and other OIG health care fraud and abuse sanctions. During this semiannual reporting period, OIG received seven requests for advisory opinions and issued three advisory opinions.

Sanction Authorities and Other Administrative Actions

Various Federal laws provide authorities the ability to impose administrative sanctions for fraud and abuse as well as other activities that pose a risk to Federal health care programs and their beneficiaries. Sanctions include the exclusion of individuals and entities from Federal health care programs and the imposition of CMPs for submitting false and fraudulent claims to a Federal health care program or for violating the anti-kickback statute, the physician self-referral law (commonly referred to as the “Stark Law”), or the Emergency Medical Treatment and Labor Act (EMTALA), also known as the “patient dumping statute.” Sanctions also include referrals for suspension and debarment in cases of grant and contract fraud.

During this semiannual reporting period, OIG imposed 1,323 administrative sanctions in the form of program exclusions or administrative actions for alleged fraud or abuse or other activities that posed a risk to Federal health care programs and their beneficiaries.

Exclusion and penalty authorities are described in Appendix C and on our website at <http://oig.hhs.gov/fraud/enforcement/cmp/index.asp>.

Program Exclusions

During this semiannual reporting period, OIG excluded 1,245 individuals and entities from Medicare, Medicaid, and other Federal health care programs. Most of the exclusions resulted from convictions for crimes relating to Medicare or Medicaid, patient abuse or neglect, financial misconduct, controlled substances, or as a result of license revocation. OIG completed the deployment of a new service for MFCUs to report convictions through a central web-based portal for exclusions. OIG is also responsible for reinstating providers who apply and have met the requirements of their exclusions. For a list of excluded individuals and entities, see <https://exclusions.oig.hhs.gov/>.

The following are case examples of program exclusions:

Mississippi—Thomas Spell, a pharmacy owner, was excluded for a minimum period of 75 years based on his conviction for conspiracy to commit health care fraud. From about

December 2014 to about January 2016, Mr. Spell participated in a scheme to defraud Tricare by formulating compounded medications that did not fit the individualized needs of patients but instead were formulated to obtain maximum reimbursement from Tricare. In addition, Spell and his co-conspirators arranged for their employees to purchase prepaid debit cards to make copayments for beneficiaries. The court ordered this individual to pay approximately \$243.5 million in restitution and serve 120 months of incarceration. The Mississippi Board of Pharmacy also revoked his license to practice as a pharmacist.

Michigan—Salman Ali, the owner of a home health agency was excluded for a minimum period of 20 years based on his conviction of health care fraud conspiracy. From about October 2005 to about March 2013, Ali and his wife controlled and operated home health agencies that billed Medicare for services that were not medically necessary or were not provided. In addition, the individual created false physical therapy files and claimed that physical therapy services had been provided, when in fact, no such services had been provided. The court sentenced him to serve 32 months of incarceration and repay approximately \$12.1 million in restitution.

Suspensions and Debarments

Suspensions and debarments are administrative tools used by HHS and other Federal agencies to protect the Government from individuals and entities that have engaged in contract fraud, have misused grant funds, or are otherwise not presently responsible. Because these are Governmentwide sanctions, an individual or entity that has been suspended or debarred by HHS or any other agency is ineligible to participate in any future funding opportunities across the Federal Government for a specified period of time.

OIG refers individuals and entities that have potentially engaged in grant or contract fraud or misconduct to the HHS Suspension and Debarment Official, who is responsible for determining whether to impose a suspension or debarment. OIG continues to develop a robust Suspension and Debarment program and uses this tool to protect Government programs against fraud, waste, poor performance, and noncompliance with contract provisions or applicable law.

The following case examples involve debarment:

Alaska—Paige Bohall was convicted for embezzling \$14,622.65 in Health Resources and Services Administration (HRSA) HIV Care Formula Grants funds and embezzling a total of \$105,794.95. Bohall, the Financial Manager of the Alaskan AIDS Assistance Agency (4A), a nonprofit organization that is the subrecipient of HRSA and CDC funds through the State of Alaska Department of Health and Social Services, was ordered to serve 90 days in prison and 36 months probation and pay restitution in the total of \$120,000.

New York—Alexander Neumeister, a member of the New York University School of Medicine of Psychiatry, used HHS-National Institutes of Health grant funds for personal use, including for meals, personal travel, and personal expenses for his family and friends. He was convicted for one count of theft of Government funds and sentenced to 3 years' probation and ordered to pay restitution of \$87,763.96. He also entered into a civil False Claims Act settlement agreement to resolve his False Claims Act liability in connection with this conduct and agreed to pay \$33,215.43.

Civil Monetary Penalties Law

The Civil Monetary Penalties Law (CMPL) authorizes OIG to impose administrative penalties, assessments, and exclusions against a person who, among other things, submits, or causes to be submitted, claims to a Federal health care program that the person knows, or should know, are false or fraudulent. The exclusions statute also authorizes OIG to exclude a person who violates the CMPL. During this semiannual reporting period, OIG concluded cases involving more than \$12.5 million in CMPs and assessments.

Affirmative Litigation

The CMPL authorizes OIG to use its administrative remedies to affirmatively pursue cases. OIG may also exclude under the exclusions statute for engaging in conduct that violates the CMPL. When OIG excludes under the exclusions statute for engaging in conduct that violates the CMPL, it is known as an affirmative exclusion.

The following case examples involve affirmative litigation under the CMPL:

New York—Brooklyn Plaza Medical Center (BPMC) entered into a \$100,000 settlement agreement and a 5-year Recipient Compliance Agreement with OIG to resolve BPMC's liability under the Civil Monetary Penalties Law for knowingly submitting or causing to be submitted specified claims to HHS that BPMC knew or should have known were false or fraudulent and knowingly making representation to HHS that were false, in violation of 42 U.S.C. §§ 1320a-7a(o)(1) and (2). Specifically, OIG alleged that BPMC made false specified claims in the form of drawdowns from the HHS Payment Management System for Health Resources and Services Administration grant funds that were not supported by adequate documentation, timesheets, and a financial management and control system that ensured that HHS grant funds were used solely for authorized purposes in accordance with Federal statutes, regulations, and the terms and conditions of BPMC's Federal awards. The OIG further alleged that on various occasions during the same timeframe, BPMC falsely represented to HHS in funding applications that it had in place: (1) safeguards to prohibit employees from using their positions for personal gain; and (2) a financial management and control system that ensured that HHS grant funds were used solely for authorized

purposes in accordance with Federal statutes, regulations, and the terms and conditions of BPMC's Federal awards.

South Carolina—Vital Care EMS, Inc. (VC) entered into a \$2,213,516.71 settlement agreement with OIG to resolve allegations that VC knowingly presented claims to Medicare Part B for ambulance transportation to and from SNFs where such transportation was already covered by the SNF consolidated billing payment under Medicare Part A.

Patient Dumping

Some of the CMPL cases that OIG resolved during this semiannual reporting period were pursued under EMTALA, a statute designed to prevent hospitals from denying emergency care to patients and to ensure patient access to appropriate emergency medical services.

The following case example involves EMTALA:

Georgia—DeKalb Medical Center, Inc. (DeKalb) entered into a \$260,000 settlement agreement with OIG. The settlement agreement resolves allegations that, based on OIG's investigation, DeKalb violated EMTALA when it failed to provide an adequate screening examination and stabilizing treatment for 21 individuals. The following is an example of such incidents: Patient N.R.A., a 25-year-old female, presented to DeKalb's Emergency Department (ED) with complaints of acute gastric pain, nausea, and vomiting. The medical records also listed possible pregnancy as her chief complaint. N.R.A. had a prior history of peptic ulcer disease and gastric ulcers. The medical records indicated that N.R.A. was seen by a registered nurse and was triaged using an emergency severity level index at level 4 (indicating a non-urgent patient). The triage nurse recorded N.R.A.'s vital signs and marked "no" next to nine questions on a non-patient-specific checklist. Within 6 minutes of the nurse starting the triage process, N.R.A. was discharged from DeKalb's ED. OIG determined that DeKalb's ED was capable of providing an appropriate medical screening examination to determine whether the patients at issue had an emergency medical condition and providing stabilizing treatments in the event patients had such conditions, but OIG contends that DeKalb failed to do so.

Self-Disclosure Programs

Health care providers, suppliers, or other individuals or entities subject to CMPs can apply for acceptance into the Provider Self-Disclosure Protocol, a program created in 1998 for voluntary disclosure of self-discovered evidence of potential fraud. The self-disclosure program may give providers the opportunity to avoid costs or disruptions associated with Government-directed investigations and civil or administrative litigation.

Application processes for two additional self-disclosure programs were recently added to the OIG website for HHS contractors and grantees. The OIG contractor self-disclosure program provides contractors the opportunity to self-disclose when they have potentially violated the False Claims Act or other Federal criminal laws prohibiting fraud, conflict of interest, bribery, or gratuity. This self-disclosure process is only available to those with a Federal Acquisition Regulations (FAR)-based contract with HHS. The OIG Grant Self-Disclosure Program is available for application by HHS grantees or HHS grant subrecipients and provides the opportunity for voluntary disclosure to OIG of potential fraud. OIG evaluates the reported results of each internal investigation under the provider self-disclosure protocol to determine the appropriate course of action. The self-disclosure guidelines are available on the OIG website at <https://oig.hhs.gov/compliance/self-disclosure-info/index.asp>. During this semiannual reporting period, provider self-disclosure cases resulted in more than \$11.8 million in HHS receivables.

The following case examples pertain to provider self-disclosure settlements:

Alaska—After it self-disclosed conduct to OIG, the City and Borough of Sitka, formerly doing business as Sitka Community Hospital, a Department of the City and Borough of Sitka (Sitka) agreed to pay \$4,125,552 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks. OIG alleged that Sitka paid remuneration to providers in the form of: (1) excessive compensation under Emergency Department call coverage arrangements and (2) excessive compensation under advance practice providers arrangements.

Florida—After it self-disclosed conduct to OIG, St. Vincent's Medical Center (St. Vincent's) agreed to pay \$747,973.50 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks. OIG alleged that St. Vincent's paid remuneration to certain physicians under advance practice provider staffing arrangements in the form of providing clinical staff without cost, or at reduced cost, to the physicians to assist them in treating inpatients at the hospital St. Vincent's formerly owned and operated until October 1, 2019.

Corporate Integrity Agreements

Many health care providers elect to settle their cases before litigation. As part of the settlements, providers often agree to enter into CIAs with OIG to avoid exclusions from Medicare, Medicaid, and other Federal health care programs. Under a CIA, a provider commits to establishing a program and taking other specified steps to ensure future compliance with Medicare and Medicaid rules. The compliance programs are designed, in part, to prevent future fraud. OIG monitors providers' compliance with these agreements and may impose penalties on entities that fail to comply with the requirements of their CIAs.

The following case examples involve CIA enforcement:

Tennessee—On June 1, 2020, the Departmental Appeals Board (DAB) upheld OIG's demand that Friendship Home Health, Inc., et al. (Friendship Entities) pay \$1,322,500 in stipulated penalties for breaches of their CIA. On November 19, 2018, OIG sent the Friendship Entities a demand for \$1,322,500 in stipulated penalties for their failure to repay overpayments identified in their second and third annual reports. The Friendship Entities appealed this demand and requested a hearing with a DAB Administrative Law Judge (ALJ). On October 31, 2019, the ALJ upheld OIG's demand. The Friendship Entities then appealed to the DAB. In its decision, the DAB agreed with the ALJ's conclusions that the CIA's auditing and repayment provisions created independent obligations to repay overpayments to Medicare and Medicaid, and that each time the Friendship Entities violated those obligations to repay overpayments, it created a separate basis for OIG to demand stipulated penalties. The DAB also agreed that the Friendship Entities were properly subject to stipulated penalties arising from those failures and further held that the CIA authorizes per-day stipulated penalties to run concurrently for each failure to make timely repayment.

Tennessee—After it disclosed conduct to OIG pursuant to its CIA, Envision Healthcare Corporation and its subsidiaries and affiliates (Envision), entered into a \$50,250 settlement agreement with OIG. OIG alleged that Envision paid remuneration to approximately 500 hospital senior executives nationwide in the form of Google Home Mini devices with Envision's name printed on the devices.

Public Health and Human Service Agency Reports and Reviews

Public Health Agency Reports and Reviews

Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020 (OEI-06-20-00300), April 2020

In a pulse survey conducted on March 23–27, 2020, hospitals from across the country described challenges, mitigation strategies, and the need for assistance in responding to COVID-19. Hospitals reported that their most significant challenges centered on testing and caring for patients with known or suspected COVID-19 and keeping staff safe. Hospitals also reported substantial challenges to maintaining or expanding their facilities' capacity to treat patients with COVID-19. Specific challenges related to their capacity to treat patients include: personal protective equipment (PPE), testing, staffing, supplies and durable equipment, maintaining or expanding facility capacity, and financial concerns. We collected this information to aid HHS and other

decisionmakers as they continue to respond to the COVID-19 pandemic. In addition, hospitals may find the information about each other's strategies useful in their efforts to respond to COVID-19.

Office of the Assistant Secretary for Preparedness and Response

Selected Health Care Coalitions Increased Involvement in Whole Community Preparedness but Face Developmental Challenges Following New Requirements in 2017 ([OEI-04-18-00080](#)), April 2020

More diverse health care entities are participating in beneficial HCC preparedness activities, but new member entities did not always fill gaps in preparedness and response and they pulled resources from other HCC priorities. Our findings can help the Office of the Assistant Secretary for Preparedness and Response (ASPR) identify ways to further improve HCCs' preparedness for whole community emergency response to a range of public health emergencies, including emerging infectious diseases. ASPR concurred with all of our recommendations, which were for it to:

- clarify guidance that HCCs' membership should ensure strategic, comprehensive coverage of their communities' gaps in preparedness and response;
- continue to work with CMS to help health care entities comply with the CMS emergency preparedness Conditions of Participation;
- identify ways to incentivize core members' participation; and
- clarify to HPP awardees the flexibility available in meeting requirements.

Toolkit: Insights for Communities From OIG's Historical Work on Emergency Response ([OEI-09-20-00440](#)), August 2020 and *Toolkit: Insights for Healthcare Facilities from OIG's Historical Work on Emergency Response* ([OEI-06-20-00470](#)), August 2020

These toolkits contain key insights and lessons learned from Office of Inspector General (OIG) reports published from 2002 to 2020 about communities' and health care facilities' emergency preparedness and response. These reports address actions by health care facilities and State and local governments during outbreaks of emerging infectious diseases (such as Ebola and H1N1 pandemic influenza) and natural disasters (such as Hurricane Katrina and Superstorm Sandy), as well as bioterrorism preparedness and response. OIG conducted the referenced audits and evaluations prior to the COVID-19 pandemic. We provide this information to assist communities and health care facilities in responding to the current pandemic and to other emergencies as they arise. The toolkits contain no recommendations.

Food and Drug Administration

FDA's Risk Evaluation and Mitigation Strategies: Uncertain Effectiveness To Address the Opioid Crisis ([OEI-01-17-00510](#)), September 2020

Although opioid prescribing has decreased, data quality issues have made it challenging for the Food and Drug Administration (FDA) to determine whether the Risk Evaluation and Mitigation Strategies (REMS) for opioids have been effective. (A REMS is a drug safety program that is intended to mitigate a specific serious risk associated with the use of a drug.) Furthermore, REMS may not be well suited to quickly address the opioid crisis. While the opioid crisis continued with nearly 47,000 deaths in 2018, FDA used REMS as tools to mitigate misuse and abuse of opioids. Transmucosal immediate-release fentanyl (TIRF) drugs and extended-release/long-acting (ER/LA) opioids are two major classes of opioids that pose serious risk of addiction, abuse, and overdose. In 2011 and 2012, FDA approved the REMS for TIRF drugs and the REMS for ER/LA opioids, respectively, just as opioid prescribing reached its peak. While FDA and other agencies in HHS continue to address the opioid crisis using a variety of efforts, OIG has four recommendations for FDA to improve these two opioid REMS. FDA concurred with our first and third recommendations. It did not concur with our second, and it is considering our fourth recommendation. Our recommendations were for it to:

- use the new TIRF REMS patient registry to monitor for known areas of risk, such as inappropriate conversions (i.e., switching a patient between different TIRF drugs inappropriately) and off-label prescribing;
- enhance its REMS assessment review process by completing its reviews in a timely fashion and seeking information on inappropriate prescribing trends from FDA's Office of Prescription Drug Promotion;
- strengthen the REMS for opioid analgesics (the successor to the REMS for ER/LA opioids) by requiring training for prescribers; and
- seek additional authority to ensure that manufacturers are held accountable when appropriate.

Risk Assessment of Food and Drug Administration's Purchase Card Program ([A-04-19-06234](#)), September 2020

FDA generally designed and implemented controls and strategies to mitigate the potential risks of illegal, improper, or erroneous purchases in its purchase card program. Within the 6 risk areas related to FDA's purchase card program, we identified 56 sub-risk areas and assessed 50 as low risk and 6 as moderate risk. Overall, we assessed the FDA purchase card program as low risk. This report contains no recommendations.

Indian Health Service

Most Indian Health Service Purchased/Referred Care Program Claims Were Not Reviewed, Approved, and Paid in Accordance With Federal Requirements (A-03-16-03002), April 2020

Through the Purchased/Referred Care (PRC) Program, IHS pays for private providers to deliver health care services unavailable through the IHS network. Of the 100 PRC claims in our sample,

18 were paid in accordance with Federal requirements; however, the other 82 were not. These 82 claims did not meet 1 or more of the 9 requirements that we evaluated. These errors occurred because IHS did not have controls in place to prevent its Referred Care Information System (RCIS) from accepting claims missing information. In addition, IHS and providers did not conduct timely tracking of certain processes, and providers did not always submit completed claims.

Based on our sample results, we estimated that 658,025 of the 802,470 total claims were not paid in accordance with Federal requirements.

IHS generally concurred with our recommendation that it establish an edit in the RCIS to enforce the requirement that each beneficiary submits documentation showing that he or she meets the geographic component of IHS's eligibility requirements. IHS concurred with our recommendations that it: (1) educate PRC Program staff about the importance of documenting their review of medical necessity and priority-level requirements, (2) conduct outreach to beneficiaries and providers to ensure that they submit notifications of health care services within 72 hours (or 30 days for elderly and disabled beneficiaries), and (3) only pay for health care services after receiving all required alternate resource documentation and resolving all information gaps. We also made additional procedural recommendations.

Tribal Health Programs: Concerns About Background Verifications for Staff Working With Indian Children (A-01-20-01500), August 2020

Past and ongoing audits found that Tribal health programs that received Indian Self-Determination and Education Assistance Act funds from IHS were not conducting required FBI fingerprint background checks for all employees, contractors, and volunteers who have regular contact with Indian children. This creates an increased risk that an individual with a disqualifying criminal history in a different State could be hired into a position with regular contact with Indian children.

This vulnerability warrants IHS's immediate attention because it may compromise the safety and well-being of Indian children who receive treatment at Tribal health programs funded by IHS.

National Institutes of Health

The National Institutes of Health Administered Superfund Appropriations During Fiscal Year 2018 in Accordance With Federal Requirements (A-04-19-04072), April 2020

During FY 2018, NIH administered Superfund appropriations in accordance with applicable Federal requirements. Specifically, NIH obligated and disbursed Superfund appropriations in accordance with Federal requirements and in similar proportions to prior years. In addition, the Institute's monitoring of Superfund grants generally ensured that grantees met requirements for financial, performance, and audit reporting. We made no recommendations.

The National Eye Institute Generally Had Adequate Procedures To Assess an Applicant's Risk During the Pre-Award Process (A-05-19-00017), May 2020

The National Eye Institute (NEI) generally had adequate policies and procedures in place for its grant pre-award process. However, NEI did not perform or adequately document a required financial capability review for two of the six grant awards in our sample. The HHS Grants Policy and Administration Manual (GPAM) requires that, before making a grant award, the awarding agency conduct a financial capability review of a grant applicant that has not received an award from a Federal agency within the preceding 3 years. As a result, not all risks for applicants may have been identified and mitigated before grant funds were awarded.

NIH concurred with our recommendations that it direct NEI to develop written procedures for conducting and documenting the financial capability review required by the HHS GPAM and provide training to NEI Grants Management Specialists about how to adequately document their review of a grant applicant's financial statements and the organization's financial status.

The National Cancer Institute Needs To Strengthen Procedures in Its Pre-Award Process To Assess Risk for Higher Risk Applicants (A-03-19-03004), June 2020

The National Cancer Institute (NCI) generally had adequate policies and procedures in its pre-award process for identifying an applicant's risk before awarding grant funds. However, NCI did not adequately document its review process to assess financial capability for applicants that did not receive a grant from NCI in the 3 years before the current application. In addition, NCI did not have written policies and procedures for conducting and documenting financial capability reviews required by the HHS GPAM for applicants that have received funding from NCI within the past 3 years and are experiencing financial difficulty.

Documentation of applicants' financial capability was lacking because NCI did not have adequate written procedures for conducting and documenting financial capability reviews and for determining how to manage identified risks. In addition, NCI did not provide adequate training to guide NCI Specialists in their evaluation of applicants' financial capability. As a result, NCI may not be identifying and mitigating all risks for applicants before grant funds are awarded.

NIH partially concurred with our recommendation that it direct NCI to update and strengthen written procedures for conducting and documenting applicant financial capability reviews as required by the GPAM and for determining how to manage the risks identified by NCI Specialists. NIH concurred with our recommendation that it provide training to NCI Specialists about how to adequately document their evaluation of the financial capability of applicants.

The National Institutes of Health Should Improve Its Stewardship and Accountability Over Hardware and Software Assets (A-18-19-06004), September 2020

NIH had controls in place to effectively and efficiently track and monitor IT resources. However, NIH did not perform internal control activities in accordance with Federal directives and maintain a continual agencywide software license inventory. Specifically, Institutes and Centers (ICs) did not complete reports and perform investigations and reviews for lost, damaged, or destroyed property; identify accountable property and sensitive items as Government property; complete corrective action for property accountability and management control deficiencies; and meet minimum Department standards for NIH's accountable personal property management program. Additionally, NIH did not maintain a continual agencywide inventory of all software licenses.

There was inadequate oversight to hold the ICs' management accountable for the performance of internal control activities. Additionally, there was no software asset management tool employed across all the ICs' operating environments to centralize and automate the capture of software inventory and entitlement data. As a result, NIH was more susceptible to ineffective accountable property and control operations, which increased the risk that NIH would be unable to report reliable asset balances, to discover cost-saving opportunities, and to effectively safeguard assets from theft and other losses.

NIH concurred with our recommendations that it establish an oversight body that ensures that property accountability management responsibilities and control activities for Government property are performed and that it employ a primary software asset management tool that centralizes and automates the capture of software inventory and entitlement data into each of the ICs' operating environments. We also made procedural and operational recommendations.

Human Services Agency Reports and Reviews

Administration for Children and Families

The Office of Refugee Resettlement's Incident Reporting System Is Not Effectively Capturing Data To Assist Its Efforts To Ensure the Safety of Minors in HHS Custody (OEI-09-18-00430), June 2020

Facilities providing care to children in the Unaccompanied Alien Children Program are required to report a wide range of incidents to the Office of Refugee Resettlement (ORR) through ORR's incident reporting system. However, ORR's incident reporting system is not effective at capturing information about incidents to assist ORR's efforts to ensure the safety of minors. We reviewed incident reports that 45 care provider facilities submitted to ORR between January 1, 2018, and July 31, 2018, including 761 incidents of a sexual nature. We found that ORR's reporting system lacks designated fields that ORR can use to oversee facilities and to protect the minors in ORR care. Important information about facilities' actions are not systematically collected to help ORR determine whether facilities responded appropriately to incidents. In addition, the system does not effectively capture information in a way that allows for efficient identification of issues that require immediate attention and analysis to detect concerning trends. Further, facilities described

challenges with staffing youth care workers—who are essential to preventing, detecting, and reporting incidents—and difficulties determining which incidents should be reported to ORR.

ACF concurred with all of our recommendations that are aimed to improve the incident reporting system and reduce the challenges that facilities face. ACF should work with ORR to: (1) systematically collect key information about incidents that allows for efficient and effective oversight, (2) track and trend incident report information to identify opportunities to better safeguard minors, (3) work with facilities to address staffing shortages of youth care workers, and (4) improve its guidance to help facilities consistently identify and report significant incidents.

Unaccompanied Alien Children Program Care Provider Facilities Do Not Include All Required Security Measures in Their Checklists (OEI-05-19-00210), June 2020

ORR requires care provider facilities that house and care for unaccompanied children to employ three physical security measures to ensure that the children in their care are safe from harm: (1) controlled entry and exit, (2) alarm systems, and (3) video monitoring. ORR also requires these facilities to use facility inspection checklists to ensure that these required physical security measures are present and working.

However, we found that 39 of the 40 facilities that provided us with their inspection checklists did not include prompts in their inspection checklists to check for one or more of the physical security measures required by ORR. Additionally, facilities that included these measures in their inspection checklists did not always describe in detail what elements of the measures to check.

ORR does not provide guidance or routine oversight on whether facilities regularly use inspection checklists to ensure that the required physical security measures are present and working. If facilities do not regularly check that their security measures are functioning, children potentially could be exposed to safety risks.

ORR needs to ensure that facilities routinely check all required security measures to ensure children in their care are safe from harm. The Administration for Children and Families concurred with our recommendations, which were to:

- develop and implement methods to ensure that facilities' inspection checklists include all required physical security measures,
- develop and implement methods to ensure that facilities regularly report inspection checklist results, and
- conduct a review to determine whether to enhance required physical security measures.

New Hampshire's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 21 of 30 Providers Reviewed ([A-01-18-02504](#)), April 2020,

Illinois' Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 12 of 30 Providers Reviewed ([A-05-19-00016](#)), April 2020,

Utah's Monitoring Process Generally Ensured Child Care Provider Compliance With State Criminal Background Check Requirements ([A-07-19-06085](#)), July 2020,

New Jersey's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 9 of 30 Providers Reviewed ([A-02-19-02004](#)), July 2020,

Indiana's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 17 of 30 Providers Reviewed ([A-05-19-00012](#)), August 2020,

Rhode Island's Monitoring Did Not Ensure Child Care Provider Compliance With State Criminal Background Check Requirements at 18 of 30 Providers Reviewed ([A-01-18-02505](#)), August 2020, and

Hawaii's Monitoring Generally Ensured Child Care Provider Compliance With State Criminal Background Check Requirements ([A-09-19-01000](#)), September 2020.

New Hampshire's monitoring did not ensure provider compliance with State requirements related to criminal background checks at 21 of 30 child care provider locations we reviewed.

New Hampshire concurred with our recommendations that it: (1) conduct or renew all required criminal background checks for the 98 individuals who did not have all required checks or who had expired background checks at the time of our data requests and site visits; (2) develop a system that provides notifications to providers, employees, and department staff when criminal background checks need to be renewed or information to complete the required checks has not been submitted; (3) determine whether it is feasible to increase the ratio of State licensing inspectors to child care providers to meet industry standards so that it can review all employee criminal background checks at all child care centers; and (4) require the State's Child Care Licensing Unit to increase the number of current employees it reviews at all child care centers to ensure child care provider compliance with criminal background check requirements.

Illinois' monitoring of child care providers did not ensure provider compliance with State requirements related to criminal background checks at 12 of 30 child care provider locations we reviewed.

Illinois did not directly concur or nonconcur with our recommendations that it: (1) conduct all required criminal background checks for the 2 individuals we reviewed who did not have all required checks at the time of our data requests and site visits, (2) conduct all required criminal background checks for the 47 individuals we reviewed who did not have all recurring checks conducted within the past 5 years, (3) ensure that child care providers notify the State when a new employee is hired or a new household member is added so that the State may conduct the required criminal background checks, and (4) work with the State licensing agency to address staff and funding challenges to ensure that background checks are conducted on all licensed providers' employees or household members at least once every 5 years.

Utah's monitoring process generally ensured provider compliance with State requirements related to criminal background checks at the 30 child care provider locations we reviewed. Although 12 of the 30 child care providers had employees who did not have the required criminal background checks, the errors related to only 20 of 1,338 (1.5 percent) unique child care employees whom we reviewed.

Utah agreed with our recommendation that it consider improving its policies and procedures for the monitoring of criminal background checks so that it routinely obtains wage information from the Utah Department of Workforce Services prior to the inspections of child care providers, so as to reduce the State's dependence on provider disclosure of prospective covered individuals.

New Jersey's monitoring did not ensure provider compliance with State requirements related to criminal background checks at 9 of 30 child care provider locations we reviewed.

New Jersey did not indicate concurrence or nonconcurrence with our recommendations that it conduct all required criminal background checks for the 26 individuals we reviewed who did not have the required checks, develop a system that alerts it when criminal background checks need to be completed for prospective and current employees and household members, and continue to work with ACF to reach substantial compliance with criminal background check requirements.

Indiana's monitoring of child care providers did not ensure provider compliance with State requirements related to criminal background checks at 17 of 30 child care provider locations we reviewed.

Indiana generally concurred with our recommendations that it: (1) conduct all required criminal background checks for the 56 individuals we reviewed who did not have all required background checks, (2) verify that a disqualified employee was terminated and not allowed onsite, (3) conduct the required criminal background checks on all new employees and new household members, and (4) develop a system that regularly notifies providers to initiate required background check procedures for all new employees and notifies providers when background check applications have not been received or fully processed.

Rhode Island's monitoring did not ensure provider compliance with State requirements related to criminal background checks at 18 of 30 child care provider locations we reviewed.

Rhode Island did not directly concur or nonconcur with our recommendations that it: (1) conduct or renew all required criminal background checks for the 108 individuals we reviewed who did not have all required checks or who had expired background checks at the time of our data request and site visits, (2) determine whether it is feasible to develop a centralized process to monitor both family homes and child care centers, (3) determine whether it is feasible to increase the ratio of State licensing inspectors to child care providers to meet industry standards so that it can review all employee criminal background checks at all child care providers, and (4) require the State licensing agency to increase the number of current employees it reviews at all child care centers to ensure child care provider compliance with criminal background check requirements.

Hawaii's monitoring did not ensure provider compliance with State requirements related to criminal background checks at 27 of 30 child care provider locations we reviewed.

Hawaii generally concurred with our recommendation that it confirm that the licensing unit responsible for one child care center provider that did not complete a required criminal background check has implemented a corrective action plan to ensure that background checks are completed for all staff who have been fingerprinted.

Cape Cod Child Development Program Did Not Meet Its Head Start Non-Federal Share Obligations (A-01-19-02500), April 2020

Cape Cod Child Development Program, Inc. (CCCDP), did not meet its Head Start non-Federal share obligations. CCCDP received almost \$9.7 million in Federal Head Start funds from July 1, 2016, through June 30, 2019, and was obligated to contribute \$2.4 million. However, CCCDP only provided documentation for \$1.53 million in non-Federal share contributions. Of that amount, we determined that almost \$1.47 million was unallowable.

In addition, we identified \$859,527 in State Head Start funding that CCCDP could have included as non-Federal share contributions and which we considered allowable contributions. Thus, CCCDP's non-Federal share contribution shortfall was almost \$1.5 million. CCCDP received and spent almost \$1.2 million in Federal Head Start funding related to that shortfall to which it was not entitled.

CCCDP did not meet its Head Start non-Federal share because CCCDP: (1) did not understand the Head Start non-Federal share requirements for determining allowable non-Federal share and valuing donated program space; and (2) did not have written policies and procedures for ensuring that it met its Head Start non-Federal share requirements and maintained complete and accurate documentation for non-Federal share contributions, including how non-Federal share contributions were valued and the source of non-Federal funds.

ACF concurred with our recommendation that it take steps through the bankruptcy process to recover almost \$1.2 million in Federal Head Start funds based on CCCDP's approximately \$1.5 million non-Federal share shortfall. Because CCCDP filed for bankruptcy, we are addressing the recommendations of this audit to ACF.

Sharon Baptist Head Start Claimed Unallowable Rent and Failed To Return Embezzled Funds (A-02-17-02003), July 2020

Sharon Baptist Head Start (Sharon Baptist) did not comply with Federal requirements applicable to related-party rent and related-party receivable transactions. Specifically, Sharon Baptist claimed rent expense to which it was not entitled under Federal regulations on one of its properties, totaling \$36,264 during our audit period, as well as an additional \$489,564 during the period February 1, 2003, through January 31, 2012. Additionally, Sharon Baptist has not returned to the Federal Government \$171,000 in embezzled funds.

Sharon Baptist did not indicate concurrence or nonconcurrence with our recommendations that it: (1) refund to the Federal Government the \$36,264 in unallowable rent expense charged to its direct Head Start grant during our audit period, (2) work with ACF to determine the portion of the \$489,564 in rent expense from prior periods that should be refunded and refund the appropriate amount, and (3) refund to the Federal Government the \$171,000 in embezzled funds.

Southwest Key Programs Failed To Protect Federal Funds Intended for the Care and Placement of Unaccompanied Alien Children (A-06-17-07004), August 2020

Southwest Key Programs (Southwest Key) claimed unallowable costs related to the Unaccompanied Alien Children Program. Based on our financial review results, we determined that Southwest Key claimed unallowable costs for capital leases, a related-party lease, and other ancillary costs related to leases. Southwest Key also claimed unallowable compensation related to influx bonuses and executive compensation. Additionally, Southwest Key claimed other unallowable expenses. We also determined that Southwest Key's financial management system lacked effective controls for ensuring accountability of Federal funds.

Southwest Key disagreed or partially disagreed with all but one of our findings but did not address our recommendations that it: (1) refund to the Federal Government \$10,529,446 in unallowable direct costs and \$1,246,973 in associated indirect costs; (2) refund to the Federal Government \$1,354,429 in unallowable executive compensation; (3) implement procedures to review leases and ensure that all rental and ancillary costs claimed comply with Federal regulations; (4) ensure that no Federal funding, direct or indirect, is used for future compensation that exceeds the statutorily allowed rate for executive compensation; and (5) maintain documentation supporting Federal financial reports. We also made policy and procedural recommendations.

Additionally, we recommend that the Office of Refugee Resettlement: (1) review remaining Southwest Key leases to ensure that the leases are in compliance with Federal regulations and recover any unallowable costs, (2) provide guidance on allowable costs, and (3) review Southwest Key's bonus policy to ensure compliance with Federal regulations. We also made a procedural recommendation.

National Snapshot of State Agency Approaches to Child Care During the COVID-19 Pandemic (A-07-20-06092), September 2020

Nationally, State agencies reported that about 63 percent of child care centers and 27 percent of family child care providers (collectively, child care facilities) had closed during the COVID-19 pandemic. Eight States reported that more than 75 percent of their child care facilities had closed. Twenty other States reported that between 50 and 75 percent of these facilities had closed.

All of the State agencies reported that they issued guidance to child care providers on protective measures recommended by CDC. Many State agencies used the flexibilities afforded to them by ACF to lessen the impact of COVID-19 on child care providers and to ensure continued access to child care. To implement changes to their CCDF programs, many State agencies sought changes in their State requirements, requested waivers from ACF, and submitted plan amendments.

The most frequently identified challenges, according to State agencies, were communication with stakeholders, difficulties with fingerprinting for prospective child care employees' background checks, insufficient funding for providers, health and safety considerations on the part of child care staff members, and the lack of and inability to secure PPE and cleaning supplies. The State agencies' most frequently identified concerns once the pandemic has abated were the need to ensure that there would be enough providers to meet child care needs, the need for funding to stabilize the industry, and the need to hire and retain staff. This report made no recommendations.

Youth For Tomorrow - New Life Center, Inc., an Administration for Children and Families Grantee, Did Not Comply With All Applicable Federal Policies and Requirements (A-03-16-00250), September 2020

Youth For Tomorrow–New Life Center, Inc. (YFT), a UAC Program grantee responsible for caring for children in ORR custody, did not meet some requirements for the care and release of children in its custody. Specifically: (1) UAC assessments may not have been conducted within the required timeframe, (2) case files either did not have all evidence of the proper release of children or did not meet requirements for the release of children, and (3) employee files did not meet pre-employment requirements. In addition, the data in YFT's annual performance report were incorrect. YFT also claimed unallowable and potentially unallowable expenditures.

We recommend that YFT strengthen existing procedures to ensure that it meets all requirements for the care and release of children and refund to the Federal Government \$10,336 in unallowable employee appreciation expenditures and \$6,515 in unallowable expenditures not related to the

UAC program. We also made recommendations regarding the unallowable and potentially unallowable allocated expenditures and made other procedural recommendations. The detailed recommendations are listed in the body of the report. YFT concurred with one recommendation, partially concurred with three recommendations, and did not concur with the rest but described actions it took or plans to take to address them.

Safety of Children in Foster Care

Kansas Did Not Ensure That Group Homes for Children in Foster Care Complied With All State Health and Safety Requirements (A-07-19-06087), July 2020

Kansas did not ensure that all foster care group homes complied with State licensing requirements related to the health and safety of children in those group homes in accordance with Federal laws and regulations. Specifically, at the times of our site visits we found that 24 of the 31 group homes did not comply with State environmental requirements; this is because Kansas did not address all instances of noncompliance with environmental standards during annual inspections. In addition, 29 of the 31 group homes did not comply or could not document compliance with the required background record check or fingerprint submission requirements for employees. These instances occurred because Kansas did not ensure that the required background checks for all employees were requested in a timely manner. Furthermore, 1 of the 31 group homes did not comply with the terms of its State licensing requirements because it housed both male and female children but was licensed to house only female children.

Kansas concurred with our recommendations that it: (1) follow up with all foster care group homes to verify that all of the maintenance deficiencies that we identified are corrected, (2) improve controls to ensure that group homes are in compliance with State licensing requirements related to the health and safety of the residents, and (3) ensure that corrective action is taken when issues of noncompliance are found. We also made procedural recommendations to Kansas regarding background record checks and monitoring of the group homes.

Ohio Did Not Ensure the Accuracy and Completeness of Psychotropic and Opioid Medication Information Recorded in Its Child Welfare Information System for Children in Foster Care (A-05-18-00007), July 2020

Ohio did not always comply with State requirements related to the psychotropic and opioid medications prescribed for children in foster care who were eligible for assistance under Title IV-E of the Social Security Act. We found that the medications listed in 61 case records were not accurately documented in the Ohio Statewide Automated Child Welfare Information System (Ohio SACWIS). Additionally, we found that psychotropic medications prescribed for children in foster care were not always correctly identified as psychotropic in the Ohio SACWIS because the medication list in the Ohio SACWIS had not been updated, and the county agency workers were authorized to manually enter medication in the Ohio SACWIS.

Ohio concurred with our recommendations that it: (1) improve monitoring to ensure that county agencies maintain the required documentation in the Ohio SACWIS for the medications prescribed for children in its custody; (2) continue its efforts to obtain access to Medicaid claim data for children in its custody to assist with the monitoring of medications prescribed for the children; (3) implement procedures for the monitoring of opioid medications prescribed for children in its custody; (4) review and update the medication list in the Ohio SACWIS on a regular schedule, at least once a year and as medications are approved or discontinued, to improve the reliability and relevancy of the list; and (5) provide training and technical assistance to county agency workers who input medical and medication information into the Ohio SACWIS.

Health Resources and Services Administration

HRSA's Monitoring Did Not Always Ensure Health Centers' Compliance With Federal Requirements for HRSA's Access Increases In Mental Health and Substance Abuse Services Supplemental Grant Funding (A-02-18-02010), July 2020

HRSA followed its policies and procedures for awarding Access Increases in Mental Health (AIMS) grants but did not always follow its policies and procedures when monitoring health centers' compliance with supplemental funding requirements. Specifically, HRSA did not follow its policies and procedures when monitoring health centers' progress toward meeting AIMS grant award conditions related to ongoing and one-time funding and did not always respond timely to health centers' requests to carry over grant funds. HRSA officials stated that monitoring of health centers' progress toward meeting AIMS supplemental funding requirements is done in conjunction with its general monitoring of health centers through annual reviews. According to HRSA officials, HRSA did not always respond timely to health centers' requests to carry over grant funds because of other priorities, such as awarding other grants to health centers.

HRSA partially concurred with our recommendations that it: (1) assess health centers' progress toward meeting AIMS grant award conditions to increase personnel and patients' access to care and follow up with appropriate corrective action, such as providing technical assistance or discontinuing or reducing future AIMS grant funds; (2) review Budget Period Progress Reports to identify health centers that did not report progress toward meeting their health IT or training goals; and (3) ensure that it follows its policy for timely response to health centers' requests to carry over grant funds.

Legal and Investigative Activities Related to Public Health and Human Service Agencies

Health Education Assistance Loan Program Exclusions

OIG excludes from Federal health care programs individuals who have defaulted on Health Education Assistance Loan (HEAL) loans. Under the HEAL program, which stopped making loans in 1998, HRSA guaranteed commercial loans to students seeking education in health-related fields. The students can defer repayment of the loans until after they graduate and begin to earn income. Although HHS's Program Support Center (PSC) takes steps to ensure repayment, some loan recipients do not resolve their debt. After PSC has exhausted efforts to secure repayment of a debt, it declares an individual in default. The Social Security Act permits that thereafter, such individuals may not receive reimbursement under Medicare, Medicaid, and all other Federal health care programs for nonpayment of the loans.

After being excluded for nonpayment of their HEAL debts, 2,812 individuals chose to enter into settlement agreements or completely repay their debts during this semiannual reporting period. That figure includes 10 individuals who entered into such settlement agreements or completely repaid their debts. More than \$226,168,948 is being repaid through settlement agreements or through complete repayment. Of that amount, more than \$1,377,015 is attributable to this semiannual reporting period.

The following examples are settlement agreements.

California—Elaine Burke, Medical Doctor: \$41,400

California—Amir Abbas Nasser, Medical Doctor: \$24,200

Child Support Enforcement Activities

OIG Investigations

OIG investigates noncustodial parents who violate 18 U.S.C. § 228 by failing to pay court-ordered child support. OIG works with ACF's Office of Child Support Enforcement; DOJ; U.S. Attorneys' Offices; the U.S. Marshals Service; and Federal, State, and local partners to address egregious child support enforcement cases with appropriate law enforcement and prosecutorial action. During this semiannual reporting period, OIG investigations of child support enforcement cases nationwide resulted in two criminal actions and court-ordered restitution and settlements of \$260,849.

The following case example involves child support enforcement:

Georgia—On April 29, 2020, Charles Hefner was sentenced to 5 years of probation in the Southern District of Georgia. Hefner was also ordered to pay \$249,949 in restitution to the Child Support Enforcement Family Support Registry, to be paid to his ex-spouse. Hefner was originally indicted in 2000, but fled to Brazil, where he spent 19 years as a fugitive. In 2019, the U.S. Marshals Service notified OIG that it had apprehended Hefner based on the previously issued warrant.

Engaging the Public in Capturing Deadbeat Parents

Because of the success of OIG's Most Wanted Fugitives website, OIG launched its Most Wanted Deadbeat Parents website. The site identifies parents who fail to pay court-ordered child support for their children and thereby put an unnecessary strain on the custodial parents and the children as well as on agencies that enforce these matters. The site, which is updated frequently, includes information on OIG's role in pursuing parents who fail to pay court-ordered child support. OIG's Most Wanted Deadbeat Parents website can be found at <https://oig.hhs.gov/fraud/child-support-enforcement/index.asp>.

Other HHS-Related Reviews and Investigative Activities

General Departmental

Review of the Department of Health and Human Services' Compliance With the Federal Information Security Modernization Act of 2014 for Fiscal Year 2019 ([A-18-19-11200](#)), April 2020

HHS continues to implement changes to strengthen the maturity of its enterprisewide cybersecurity program. Ernst & Young LLP (EY) conducted the audit and identified opportunities where HHS can strengthen its overall information security program. Additionally, EY identified weaknesses in each of the IG FISMA domains: risk management, configuration management, identity and access management, data protection and privacy, security training, information security continuous monitoring, incident response, and contingency planning.

HHS concurred with all of EY's recommendations, including that HHS further strengthen its cybersecurity program and enhance information security controls at HHS. Specific recommendations were also provided to the HHS OpDivs for review.

HHS should commit to creating and implementing a Cybersecurity Maturity Migration Strategy to advance the cybersecurity program from its current maturity state to Managed and Measurable across HHS. A progression roadmap and plan should be developed that includes specific, measurable, attainable, relevant and time-bound milestones.

HHS's program should address current gaps between the current maturity levels to the level of Managed and Measurable. Roles and shared responsibilities should be articulated and implemented to meet the requirements for effective maturity, including whether requirements are to be implemented using centralized, federated, or hybrid controls.

Grants and Contracts

HHS is the largest grant-making organization and one of the largest contracting agencies in the Federal Government. In FY 2019, HHS awarded more than \$559 billion in grants and over \$26 billion in contracts across all program areas. OIG's direct annual discretionary appropriation funding is used to conduct program integrity and enforcement activities with regard to the more than 100 public health and human services programs carried out by more than 80,000 employees around the world. The size and scope of departmental awards make their operating effectiveness crucial to the success of programs designed to improve the health and well-being of the public.

CMS Did Not Administer and Manage Strategic Communications Services Contracts in Accordance With Federal Requirements ([A-12-19-20003](#)), July 2020

CMS prepared the required documentation for awarding contracts for strategic communications services in accordance with the FAR. However, CMS (including the CMS Administrator and other senior leaders) did not administer and manage the contracts in accordance with Federal requirements. CMS also administered its strategic communications services contracts as personal services contracts. Lastly, CMS did not comply with FAR requirements in managing contract deliverables and approving the use of a subcontractor, did not maintain complete working files for all three contracts, and paid some questionable costs.

We made recommendations to both HHS and CMS to address the significant deficiencies we identified. Specifically, we recommend that HHS determine whether any HHS contractors or subcontractors are performing inherently governmental functions and whether any active CMS service contracts or task orders are being administered as personal services contracts, and take action to correct their administration. We also made recommendations to both HHS and CMS to improve contract management and provide training related to contract administration. Our specific recommendations to HHS and CMS are listed in the report. HHS concurred with our recommendations. CMS neither concurred nor nonconcurred with three of our recommendations, concurred with one of our recommendations, and nonconcurred with two of our recommendations.

Grant Fraud Investigations

The following case example relates to misuse of grant funds:

Massachusetts—Harvard University has agreed to pay \$1,359,791 to resolve allegations that Harvard’s T.H. Chan School of Public Health (HSPH) overcharged certain grants funded by NIH and HRSA. This settlement resulted from Harvard’s self-disclosure of issues that it identified on NIH and HRSA grants by a particular professor and her team between at least 2009 and 2014. The Government contends that the HSPH professor, Donna Spiegelman, and her team overstated the time and effort spent working on certain NIH grants for which they provided support (and where they were not principal investigators or key personnel). The overcharges were associated with statistical analysis support that the professor and her team provided to other HSPH professors on grant-related research.

Small Business Innovative Research Program

The National Defense Authorization Act for Fiscal Year 2012, § 5143, requires OIG to report annually on the number of cases referred to OIG to fraud, waste, or abuse in the Small Business Innovation

Research/Small Business Technology Transfer (SBIR/STTR) program. OIG must also report on the actions taken in each case; justification for not taking action on a case; and an accounting of funds used to address waste, fraud, and abuse in this program. In our January 2020 report, we reported that OIG spent approximately \$278,733 in salaries on investigative and training activities related to fraud, waste, or abuse in the SBIR/STTR program.

Recovery Act Retaliation Complaint Investigations

The Recovery Act, § 1553, prohibits non-Federal employers that have received Recovery Act funding from retaliating against employees who disclose evidence of mismanagement of Recovery Act funds or any violation of law related to Recovery Act funds. OIGs are required to include in their Semiannual Report the retaliation complaint investigations that they decided not to conduct or continue during the reporting period. During this semiannual reporting period, OIG did not close, decline, or give extensions on Recovery Act Retaliation Complaint investigations of whistleblower retaliation.

Contract Audits

Pursuant to the National Defense Authorization Act for FY 2008, § 845, OIGs appointed under the Inspector General Act of 1978 are required to submit information on final completed contract audit reports issued during the period to the contracting activity as part of their semiannual report, pursuant to section 5 of the Inspector General Act. This information must contain significant audit findings. OIG issued no final reports meeting § 845 criteria during this semiannual period.

OIG Reviews of Non-Federal Audits

OIG reviews audits conducted by non-Federal auditors of entities receiving Federal awards. During this semiannual reporting period, OIG's National External Audit Review Center reviewed 407 reports covering \$1.9 trillion in audited costs. Federal dollars covered by these audits totaled \$634.4 billion, of which about \$384.1 billion were HHS funds.

Uniform guidance at 2CFR200 Subpart F establishes audit requirements for State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards. Under the uniform guidance, covered entities must conduct annual organizationwide "single audits" of all Federal money they receive. These audits are conducted by non-Federal auditors, such as public accounting firms and State auditors. OIG reviews the quality of these audits and assesses the adequacy of the entities' management of Federal funds.

OIG's oversight of non-Federal audit activity informs Federal managers about the soundness of management of Federal programs and identifies any significant areas of internal control weakness, noncompliance, and questioned costs for resolution or followup. We identify entities for high-risk monitoring, alert program officials to any trends that could indicate problems in HHS programs,

and profile non-Federal audit findings of a particular program or activity over time to identify systemic problems. We also provide training and technical assistance to grantees and members of the auditing profession. OIG maintains a process to assess the quality of the non-Federal reports received and the audit work that supports the selected reports.

OIG's reports on non-Federal audits reviewed during this reporting period are categorized in the following table.

Non-Federal Audits, April 1, 2020, Through September 30, 2020

Not requiring changes or having minor changes	394
Requiring major changes	5
Having significant technical inadequacies	8
Total Number of Non-Federal Audits	407

Other Reporting Requirements and Reviews

Legislative and Regulatory Reviews

Pursuant to the Inspector General Act, § 4(a)(2), OIG is required to review existing and proposed legislation and regulations relating to HHS's programs and operations and make recommendations concerning their impact on economy and efficiency or the prevention and detection of fraud and abuse. Most audits and other reviews that we conduct are designed to test compliance with and/or assess the administration and oversight of existing laws and regulations. Our reports of such reviews describe findings, which include questioned costs, inefficiencies, vulnerabilities to fraud, inconsistencies, errors in application, or weaknesses in oversight or supporting systems. Our corresponding recommendations tell HHS and its OpDivs or staff divisions (StaffDivs) what administrative, regulatory, or legislative actions we believe are needed to effectively respond to the findings. Our regularly published core publications reflect the relationship between our work and laws and regulations.

- This report, like our previous [Semiannual Reports to Congress](#), describes findings and recommendations from recently completed reviews, many of which focus on existing laws and regulations.
- Our [Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs: OIG's Top Recommendations](#) describes priority findings and recommendations from past periods that remain to be implemented.
- Our [Work Plan](#) provides citations to laws and regulations that are the subject of ongoing or future reviews.

We also review proposed legislation and regulations related to HHS programs and operations. In addition, we provide independent, objective technical assistance on a bipartisan, bicameral basis to congressional committees and members who request it.

Appendix A: Questioned Costs and Funds To Be Put to Better Use

The following tables summarize OIG’s monetary recommendations and HHS responses to them. This information is provided in accordance with the Inspector General Act, §§ 5(a)(8) and (a)(9) (5 U.S.C. App. §§ 5(a)(8) and (a)(9)), and the Supplemental Appropriations and Rescissions Act of 1980.

Audit Reports With Questioned Costs

As defined by the Inspector General Act, the term “questioned cost” means a cost that is questioned by OIG because of: (1) an alleged violation of a provision of law, regulation, contract, grant, cooperative agreement, or other agreement or document governing the expenditure of funds; (2) a cost that is not supported by adequate documentation at the time of the audit; or (3) the expenditure of funds for the intended purpose is unnecessary or unreasonable. Questioned costs that HHS program officials have, in a management decision, sustained or agreed, should not be charged to the Government are disallowed costs. Superscripts indicate end notes that follow the tables below.

Table 1: Audit Reports With Questioned Costs

Description	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
Section 1			
Reports for which no management decisions had been made by the beginning of the reporting period ¹	91	\$1,999,346,000	\$556,839,000
Issued during the reporting period	45	\$336,855,000	\$0
Total Section 1	136	\$2,336,201,000	\$556,839,000
Section 2			
Reports for which management decisions were made during the reporting period ^{2, 3}			
Disallowed costs	64	*\$445,527,000	\$717,000
Costs not disallowed	5	\$59,198,000	\$50,325,000
Total Section 2	69	\$504,725,000	\$51,042,000
Section 3			
Reports for which no management decisions had been made by the end of the reporting period (Section 1 minus Section 2)	67	\$1,831,476,000	\$505,797,000
Section 4			
Reports for which no management decisions were made within 6 months of issuance ⁴	30	\$1,569,403,000	\$505,797,000

* Audit receivables (expected recoveries)

Table 1 End Notes

¹ The opening balance was adjusted upward by \$64.2 million because of a reevaluation of previously issued recommendations.

² Revisions to previously reported management decisions:

- A-06-15-00045, *ACA Increased Primary Care Service Payments in Texas*. CMS's subsequent review of additional documentation related to the 2009 Medicaid managed care rate, determined that \$10,514,389 of the questioned costs totaling \$20,714,957, were allowable cost.
- A-02-16-01006, *Payments Made by Novitas Solutions, Inc., to Hospitals for Certain Advanced Radiation Therapy Services Did Not Fully Comply With Medicare Requirements*. CMS determined that the providers were not at fault for overpayments due to unclear CMS guidance/policy. As a result, disallowed costs were reduced by \$2,269,775.
- A-02-16-01007, *Payments Made by National Government Services, Inc., to Hospitals for Certain Advanced Radiation Therapy Services Did Not Comply With Medicare Requirements*. CMS determined that the providers were not at fault for overpayments due to unclear CMS guidance/policy. As a result, disallowed cost was reduced by \$1,535,144.
- A-07-16-05092, *Mederi Caretenders Home Health Billed for Home Health Services That Did Not Comply with Medicare Billing Requirements*. Based on subsequent clinical review of records, an appeals decision was partially favorable. Overpayment recoveries were reduced by \$1,255,015.
- Not detailed are reductions to previously disallowed management decisions totaling \$1.92 million.

³ Included are management decisions to disallow \$62.14 million in questioned costs that were identified by non-Federal auditors in audits of State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards conducted in accordance with Office of Management and Budget Circular A-133. OIG is currently ensuring that work performed by these non-Federal auditors complies with Federal audit standards; accordingly, OIG tracks, resolves, and reports on recommendations in these audits.

⁴ Because of administrative delays, some of which were beyond management control, resolution of the following 30 audits were not completed within 6 months of issuance of the reports; however, agency management has informed us that the agency is working to resolve the outstanding recommendations before the end of the next semiannual reporting period.

Audits Not Completed Within 6 Months of Issuance

Audit CIN	Audit Title
A-02-15-02013	<i>CMS Did Not Always Accurately Authorize Financial Assistance Payments to Qualified Health Plan Issuers in Accordance With Federal Requirements During the 2014 Benefit Year, August 2018, \$939,287,686</i>
A-02-15-01010	<i>New Jersey Claimed Hundreds of Millions in Unallowable or Unsupported Medicaid School-Based Reimbursement, November 2017, \$300,452,930</i>

A-02-14-02017	<i>New York Misallocated Costs to Establishment Grants for a Health Insurance Marketplace, November 2016, \$149,654,512</i>
A-02-16-02007	<i>Lincoln Hall Boys' Haven, an Administration for Children and Families Grantee, Did Not Always Comply With Applicable Federal and State Policies and Requirements, February 2019, \$29,807,160</i>
A-01-14-02503	<i>Maryland Misallocated Millions To Establishment Grants For A Health Insurance Marketplace, March 2015, \$28,400,000</i>
A-04-14-07050	<i>Kentucky Misallocated Millions to Establishment Grants for a Health Insurance Marketplace, February 2017, \$25,530,429</i>
A-02-15-02008	<i>New York Did Not Comply with Federal Grant Requirements for Allocating and Claiming Marketplace Contract Costs, December 2017, \$20,415,344</i>
A-01-17-00506	<i>Medicare Paid Twice for Ambulance Services Subject to Skilled Nursing Facility Consolidated Billing Requirements, February 2019, \$19,938,117</i>
A-07-15-04226	<i>Not All of Missouri's Child Care Subsidy Program Payments Complied With Federal and State Requirements, November 2017, \$19,076,167</i>
A-01-15-02500	<i>Vermont Did Not Properly Allocate Millions to Establishment Grants for a Health Insurance Marketplace, September 2016, \$11,243,006</i>
A-02-14-02024	<i>Newark Preschool Council, Inc., Did Not Always Comply With Head Start Requirements, February 2017, \$9,950,556</i>
A-02-16-02013	<i>The Children's Village Inc., an Administration for Children and Families Grantee, Did Not Always Comply With Applicable Federal and State Policies and Requirements, April 2019, \$2,623,785</i>
A-07-17-02808	<i>The Colorado Health Insurance Marketplace's Financial Management System Did Not Always Comply With Federal Requirements, July 2018, \$2,567,604</i>
A-09-19-03003	<i>CMS's Controls Over Assigning Medicare Beneficiary Identifiers and Mailing New Medicare Cards Were Generally Effective but Could Be Improved in Some Areas, January 2020, \$2,263,465</i>
A-07-11-06013	<i>The University Of Colorado Denver Did Not Always Claim Selected Costs Charged Directly to Department of Health And Human Services Awards in Accordance With Federal Regulations, June 2013, \$1,419,524</i>
A-05-14-00045	<i>The Minnesota Marketplace Misallocated Federal Funds and Claimed Unallowable Costs, November 2016, \$1,279,677</i>
A-09-18-03020	<i>CMS Made an Estimated \$93.6 Million in Incorrect Medicare Electronic Health Record Incentive Payments to Acute-Care Hospitals, or Less Than 1 Percent of \$10.8 Billion in Total Incentive Payments, December 2019, \$1,266,111</i>
A-01-18-02501	<i>Vermont's Office of Child Support Needs Better Oversight Over Its Administrative Costs Claimed, September 2019, \$1,058,309</i>
A-09-14-01007	<i>Nevada Misallocated Costs for Establishing a Health Insurance Marketplace to Its Establishment Grants, February 2016, \$893,464</i>
A-02-18-01003	<i>New York Improperly Claimed Medicaid Reimbursement for Some Bridges to Health Waiver Program Services That Were Not in Accordance With an Approved Plan of Care and Did Not Meet Documentation Requirements, January 2020, \$614,530</i>

A-07-18-04106	<i>The Fort Peck Assiniboine and Sioux Tribes Improperly Administered Some Low-Income Home Energy Assistance Program Funds for Fiscal Years 2011 Through 2015, August 2018, \$436,765</i>
A-09-17-01002	<i>Florence Crittenton Services of Orange County, Inc., Did Not Always Claim Expenditures in Accordance With Federal Requirements, October 2018, \$342,263</i>
A-01-18-02503	<i>Pathways for Children Needs To Strengthen Documentation Requirements, November 2019; \$341,637</i>
A-12-17-00002	<i>The Office of the Secretary of Health and Human Services Did Not Comply With Federal Regulations for Chartered Aircraft and Other Government Travel Related to Former Secretary Price, July 2018, \$341,616</i>
A-05-18-00008	<i>The Next Door Foundation Claimed Unallowable Indirect Costs and Did Not Document the Funding Source of Program Expenditures in Accordance With Federal Requirements, September 2019, \$142,104</i>
A-09-18-03018	<i>Medicare Improperly Paid Suppliers an Estimated \$92.5 Million for Inhalation Drugs, October 2019, \$36,825</i>
A-04-18-02010	<i>Florida's Refugee Medical Assistance Payments Were Generally Allowable, January 2020, \$8,772</i>
A-06-18-07002	<i>Seminole Nation of Oklahoma Did Not Adequately Operate and Manage Its Head Start Program, December 2019, \$5,095</i>
A-06-18-02002	<i>Opportunities for Williamson and Burnet Counties Had Ineffective Accounting Controls and Used Unapproved or Questionable Cost Allocation Methods, February 2020, \$3,207</i>
A-05-18-00015	<i>The University of Minnesota Complied With Federal Requirements To Perform Risk Assessments and Monitor Subrecipients, November 2019, \$1,924</i>
TOTAL CINS: 30	
TOTAL AMOUNT: \$1,569,403,000	

Audit Reports With Funds Recommended To Be Put to Better Use

The phrase “recommendations that funds be put to better use” means that funds could be used more efficiently if management took action to implement an OIG recommendation through reductions in outlays, deobligation of funds, and/or avoidance of unnecessary expenditures. Table 2 reports HHS program officials’ decisions to take action on these audit recommendations.

Table 2: Audit Reports With Funds Put to Better Use

Description	Number of Reports	Dollar Value
Section 1		
Reports for which no management decisions had been made by the beginning of the reporting period	13	\$16,392,253,000
Reports issued during the reporting period	7	\$1,980,419,000

Total Section 1		20	\$18,372,672,000
Section 2			
Reports for which management decisions were made during the reporting period			
Value of recommendations agreed to by management			
Based on proposed management action	4		\$750,481,000
Based on proposed legislative action	0		\$0
Value of recommendations not agreed to by management	0		\$0
Total Section 2		4	\$750,481,000
Section 3			
Reports for which no management decisions had been made by the end of the reporting period ¹ (Sec. 1 minus Sec. 2).		16	\$17,622,191,000

Table 2 End Notes

¹ Because of administrative delays, some of which were beyond management control, 10 of the 16 audits open at end of the period were not resolved within 6 months of issuance of reports. OIG is working with management to reach resolution on these recommendations before the end of the next semiannual reporting period.

Audits Open at End of the Period	
Audit CIN	Audit Title
A-05-12-00020	Medicare and Beneficiaries Could Save Billions if CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures To Ambulatory Surgical Center Payment Rates, April 2014, \$15,000,000,000
A-05-17-00033	Medicare Allowable Amounts for Certain Orthotic Devices Are Not Comparable With Payments Made by Select Non-Medicare Payers, October 2019, \$337,547,542
A-03-16-03001	The Centers For Medicare & Medicaid Services Did Not Identify and Report Potential Antideficiency Act Violations for 12 Contracts Used To Establish the Federal Marketplace Under the Affordable Care Act, February 2020, \$186,993,209
A-06-17-08004	Medicare Part D Is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit, August 2019, \$160,800,000
A-05-16-00060	Hospitals Received Millions in Excessive Outlier Payments Because CMS Limits the Reconciliation Process, November 2019, \$125,000,000
A-09-18-03020	CMS Made An Estimated \$93.6 Million in Incorrect Medicare Electronic Health Record Incentive Payments to Acute-Care Hospitals, or Less Than 1 Percent of \$10.8 Billion in Total Incentive Payments, December 2019, \$93,591,531
A-09-19-03007	Medicare Improperly Paid Acute-Care Hospitals \$54.4 Million for Inpatient Claims Subject to the Post-Acute-Care Transfer Policy, November 2019, \$70,011,503
A-03-13-03002	HHS Did Not Identify and Report Antideficiency Act Violations, May 2017: \$49,445,025

A-02-18-01003	<i>New York Improperly Claimed Medicaid Reimbursement for Some Bridges to Health Waiver Program Services That Were Not in Accordance With an Approved Plan of Care and Did Not Meet Documentation Requirements, January 2020, \$3,281,635</i>
A-09-18-03030	<i>Medicare Incorrectly Paid Providers for Emergency Ambulance Transports From Hospitals to Skilled Nursing Facilities, September 2019, \$968,718</i>
TOTAL CINS: 10	
TOTAL AMOUNT: \$16,027,639,000	

Appendix B: Savings Decisions Supported by OIG Recommendations

The table below lists policy decisions reflected in legislation, regulations, or other directives from prior years that are supported by OIG recommendations and for which cost savings were estimated, usually by third parties, such as the Congressional Budget Office (CBO) or HHS actuaries. Of the \$23.9 billion in savings estimated for the decisions below, \$2.4 billion was attributed to FY 2020. This figure reflects the most recent available savings estimates issued by the third-party appraiser; actual savings may be higher or lower.

After laws involving HHS programs are enacted, OIG analyzes the laws to identify the provisions that comport with our prior recommendations, that is, whether our recommendations support the decisions that were made. A similar process occurs with respect to administrative decisions in regulations or other directives or agreements (e.g., modifications to Medicaid State Plans). Most of the decisions reported in this appendix reflect ways in which funds could be put to better use, such as reductions in Federal spending or the avoidance of unnecessary or inappropriate expenditures, or both.

To quantify the value of administrative decisions, we use estimates developed by, or in consultation with, HHS OpDivs or StaffDivs. To quantify the value of legislative decisions, we generally use estimates developed by CBO. CBO projects the annual increases or reductions in Federal spending that it expects would result from enacting the legislation. The policy decisions shown on the table beginning on the next page mirror both OIG's recommendations and the contributions of others, such as HHS staff and OpDivs, congressional committees, and the GAO.

Centers for Medicare & Medicaid Services Programs		
OIG Recommendations	Policy Decisions	Estimated Savings
Calculation of AMP under the Medicaid Drug Rebate Program Seek legislative change to exclude authorized generic drug transactions to secondary manufacturers from the AMP calculation of the brand name drug. The recommendation reflected findings in OIG report A-06-18-04002.	Section 1603 of the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 amended section 1927(k)(1)(C) of the Social Security Act (the Act) to exclude generic drug transactions to secondary manufacturers in the brand name drug's AMP calculations. CBO estimated savings of \$3.15 billion over 10 years.	\$70,000,000
Medicaid Rebate for Generic Drugs	Section 602 of the Bipartisan Budget Act of 2015 (P.L. No. 114-74) (See Tab 2) was enacted	\$120,000,000

Generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 22 percent of the quarterly AMPs that OIG reviewed. If the provision for brand-name drugs were extended to generic drugs, the Medicaid program would receive additional rebates. This finding was noted in OIG reports A-06-07-00042 and A-06-15-00030.	and included provisions extending the additional rebate to generic drugs. The additional rebate for generic drugs will apply to rebate periods beginning with the first quarter of 2017. CBO estimated savings of \$1.008 billion over 10 years.	
Hospital Transfer Policy for Early Discharges to Hospice Care Change regulations or pursue a legislative change, if necessary, to establish a hospital transfer payment policy for early discharges to hospice care. The recommendation reflected findings in OIG report A-01-12-00507.	Section 53109 of the Bipartisan Budget Act of 2018 modified existing law to require that, beginning in FY 2019, discharges to hospice care would also qualify as a post-acute-care transfer and be subject to payment adjustments.	\$500,000,000
Reductions in Medicare Bad Debt Reimbursement Seek legislative authority to eliminate (or reduce) Medicare payments to hospitals for bad debt associated with beneficiaries' failure to pay their deductibles and coinsurance. The recommendations reflected findings in OIG report A-14-90-00339 and subsequent reviews.	Section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 applied percentage reductions in bad debt reimbursement to all providers eligible to receive bad debt reimbursement. CMS estimated savings to Medicare of \$10.92 billion over 10 years with \$1.39 billion attributed to FY 2020. (77 Fed. Reg. 67450, 67523 (Nov. 9, 2012))	\$1,390,000,000
Payments for Prescription Drugs Provided to Incarcerated Beneficiaries Work with prescription drug plan sponsors to identify and resolve improper Medicare Part D payments made for prescription drugs provided to incarcerated beneficiaries. The	CMS issued a final rule about the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug programs. The eligibility requirements to enroll in Medicare Advantage and Part D are outlined in Sections 1851(a)(3)(B) and 1860D-1(a)(3)(A) of the Act. To enroll in Medicare Advantage, a beneficiary must be entitled to	\$172,000,000

recommendation reflected findings in OIG report A-07-12-06035.	Part A and enrolled in Part B. To enroll in Part D, a beneficiary must be entitled to Part A and/or enrolled in Part B. An incarcerated beneficiary is not precluded from meeting the eligibility requirements for Part A and Part B, but in general, no Medicare Payment is made for these individuals. CMS promulgated regulations to require Part D plans to disenroll incarcerated beneficiaries. CMS estimated savings of \$1.6 billion over 10 years with \$172 million attributed to FY 2020. (79 Fed. Reg. 29844, 29953 (May 23, 2014))	
Medicare Payments for Vacuum Erection Systems Seek legislative authority to include vacuum erection systems (VES) in the Competitive Bidding program and then implement a National Mail-Order Competitive Bidding Program for VES. The recommendation reflected findings in OIG report A-07-12-05024.	Section 203 of the Achieving a Better Life Experience Act of 2014 implements changes to treat VES prosthetic devices and related accessories as statutorily noncovered in the same manner that erectile dysfunction drugs are treated in Medicare Part D. CBO estimated savings of \$444 million over 10 years.	\$44,400,000
Excessive Medicaid Payments to New York State Ensure that expenditures related to developmental centers and other intermediate care facilities and any revised payment methodology be consistent with efficiency and economy. The recommendation reflected findings in OIG reports A-02-11-01029, A-02-13-01008, and other reviews.	Agreement between CMS and the State of New York, dated March 20, 2015, to repay \$1.95 billion over 12 years with \$100 million attributed to FY 2020.	\$100,000,000

Appendix C: Peer-Review Results

The Inspector General Act of 1978, as amended, requires OIGs to report the results of peer reviews of their operations conducted by other OIGs, the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by an OIG of other OIGs in the semiannual period. Peer reviews are conducted by member organizations of the Council of the Inspectors General on Integrity and Efficiency (CIGIE).

Office of Audit Services

During this semiannual reporting period, no peer reviews involving OAS were completed. Information concerning OAS's peer-review activity during a prior reporting period is also listed below.

OAS	Date	Reviewing Office	Office Reviewed
	April 2019	HHS-OIG, OAS	U.S. Department of Transportation (DOT) OIG

The system of quality control for the audit organization of DOT OIG in effect for the year ending September 30, 2018, has been suitably designed and complied with to provide DOT OIG with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Federal audit organizations can receive a rating of pass, pass with deficiencies, or fail. DOT OIG received a peer-review rating of pass.

OAS	Date	Reviewing Office	Office Reviewed
	March 2018	U.S. Postal Service OIG	HHS-OIG, OAS

The system of quality control for the audit organization of HHS-OIG in effect for the year ending September 30, 2017, has been suitably designed and complied with to provide HHS-OIG with reasonable assurance of performing and reporting in conformity with applicable professional standards in all material respects. Federal audit organizations can receive a rating of pass, pass with deficiencies, or fail. HHS-OIG received a peer-review rating of pass.

Office of Investigations

During this semiannual reporting period, no peer reviews involving OI were completed. Listed below is information concerning OI's peer-review activities during prior reporting periods.

OI	Date	Reviewing Office	Office Reviewed
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October 2018

SSA OIG

HHS-OIG, OI

The system of internal safeguards and management procedures for the investigative function of HHS-OIG in effect for the year ending September 30, 2018, was in full compliance with the quality standards established by CIGIE and the Attorney General’s guidelines.

OI	Date	Reviewing Office	Office Reviewed
	August 2017	HHS-OIG, OI	U.S. Postal Service OIG

The system of internal safeguards and management procedures for the investigative function of the U.S. Postal Service OIG in effect for the year ending September 30, 2015, was in full compliance with the quality standards established by CIGIE and the Attorney General’s guidelines.

Office of Evaluation and Inspections

During this semiannual reporting period, one peer review involving OEI was completed. Information concerning OEI’s peer-review activity during a prior reporting period is also listed below.

OEI	Date	Reviewing Office	Office Reviewed
	June 2020	HHS-OIG, OEI	Department of Veterans Affairs (VA) OIG

The Department of Veterans Affairs, Office of Inspector General, Office of Audits and Evaluations and Office of Healthcare Inspections (collectively VA-OIG) policies and procedures addressed the Quality Standards for Inspection and Evaluation of the Council of the Inspectors General on Integrity and Efficiency. The seven covered standards consist of: Quality Control; Planning; Data Collections and Analysis; Evidence; Records Maintenance; Reporting; and Followup. In addition, each of the four reviewed VA-OIG reports complied with those standards and the VA-OIG’s internal policies and procedures. As a result of our findings, there are no recommendations associated with this external peer review. The report also noted a VA-OIG beneficial practice of using specialized staff to conduct independent referencing reviews of its reports to achieve greater consistency in its quality assurance processes.

OEI	Date	Reviewing Office	Office Reviewed
	September 2019	HHS-OIG, OEI	U.S. Department of Interior (DOI) OIG

The DOI OIG Inspection and Evaluation component’s policies and procedures mostly met CIGIE’s *Quality Standards for Inspection and Evaluation* (Blue Book) standards. We reviewed four reports: two fully met the applicable Blue Book standards and two did not. DOI OIG concurred with

recommendations related to Evidence, Planning, and Data Collection and Analysis but did not concur with recommendations related to Reporting.

OEI	Date	Reviewing Office	Office Reviewed
	September 2018	HHS-OIG, OEI	U.S. Department of Defense (DoD) OIG

The DoD OIG Inspection and Evaluation components' policies and procedures generally met CIGIE's *Quality Standards for Inspection and Evaluation* (Blue Book) standards. In addition, the 10 reports reviewed generally met the applicable Blue Book standards. Onsite visits for these reviews were conducted from October 2, 2017, through November 17, 2017.

Appendix D: Summary of Sanction Authorities

The Inspector General Act of 1978, as amended, specifies requirements for semiannual reports to be made to the HHS Secretary for transmittal to Congress. A selection of other authorities appears below.

Program Exclusions

The Social Security Act, § 1128 (42 U.S.C. § 1320a-7), provides several grounds for excluding individuals and entities from participation in Medicare, Medicaid, and other Federal health care programs. Exclusions are required (mandatory exclusion) for individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud; (2) patient abuse or neglect; (3) felonies for other health care fraud; and (4) felonies for illegal manufacture, distribution, prescription, or dispensing of controlled substances.

OIG is authorized (permissive exclusion) to exclude individuals and entities on several other grounds, including misdemeanors for other health care fraud (other than Medicare or Medicaid); suspension or revocation of a license to provide health care for reasons bearing on professional competence, professional performance or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a Federal health care program; or engaging in unlawful kickback arrangements.

The ACA added another basis for imposing a permissive exclusion, that is, knowingly making, or causing to be made, any false statements or omissions in any application, bid, or contract to participate as a provider in a Federal health care program, including managed care programs under Medicare and Medicaid, as well as Medicare's prescription drug program.

Providers subject to exclusion are granted due process rights. These include a hearing before an administrative law judge and appeals to the HHS Departmental Appeals Board and Federal district and appellate courts regarding the basis for and the length of the exclusion.

Civil Monetary Penalties Law

The CMPL of the Social Security Act, 1128A (42 U.S.C. § 1320a 7a), imposes penalties, assessments, and exclusion from participation in Federal health care programs for engaging in certain activities. For example, a person who submits, or causes to be submitted, to a Federal health care program a claim for items and services that the person knows, or should know, is false or fraudulent is subject to a penalty of up to \$15,270 for each item or service falsely or fraudulently claimed, an assessment of up to three times the amount falsely or fraudulently claimed, and exclusion.

For the purposes of the CMPL, "should know" is defined to mean that the person acted in reckless disregard or deliberate ignorance of the truth or falsity of the claim. The law and its implementing

regulations also authorize actions for a variety of other violations, including submission of claims for items or services furnished by an excluded person; requests for payment in violation of an assignment agreement; violations of rules regarding the possession, use, and transfer of biological agents and toxins; and payment or receipt of remuneration in violation of the anti-kickback statute (42 U.S.C. § 1320a 7b (b)).

The ACA added more grounds for imposing CMPs. These include, among other types of conduct, knowingly making, or causing to be made, any false statements or omissions in any application, bid, or contract to participate as a provider in a Federal health care program (including Medicare and Medicaid managed care programs and Medicare Part D); the ACA authorizes a penalty of up to \$55,262 for each false statement, as well as activities relating to fraudulent marketing by MCOs, their employees, or their agents.

The 21st Century Cures Act (enacted on December 13, 2016) added more grounds for imposing CMPs, assessments, and exclusion from Federal health care programs for fraudulent conduct in an HHS grant, contract, or other agreement. OIG may assess CMPs of up to \$10,000 per claim and assessments of up to three times the amount claimed for knowingly presenting a false or fraudulent claim. In addition, OIG may impose a penalty of up to \$50,000 and assessments of up to three times the amount of funds at issue: (1) for each instance of knowingly making a false statement in a document required to be submitted to receive funds under an HHS contract, grant, or other agreement; (2) for knowingly making or using a false record or statement that is material to a false or fraudulent claim; and (3) for knowingly making or using a false record or statement material to an obligation to pay or transmit funds or property owed to HHS. OIG may impose a penalty of up to \$10,000 per day and assessments of up to three times the amount at issue for knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation owed to HHS with respect to an HHS grant, contract, or other agreement. Finally, HHS-OIG may impose a penalty of up to \$15,000 per day for failing to grant timely access to OIG upon reasonable request for audits or to carry out other statutory functions in matters involving an HHS grant, contract, or other agreement.

Patient Dumping

The Social Security Act, §1867 (42 U.S.C. § 1395dd), provides that when an individual goes to the ER of a Medicare-participating hospital, the hospital must provide an appropriate medical screening examination to determine whether that individual has an emergency medical condition. If an individual has such a condition, the hospital must provide either treatment to stabilize the condition or an appropriate transfer to another medical facility.

If a transfer is ordered, the transferring hospital must provide stabilizing treatment to minimize the risks of transfer and must ensure that the receiving hospital agrees to the transfer and has available space and qualified personnel to treat the individual. In addition, the transferring hospital must effect the transfer through qualified personnel and transportation equipment. Further, a participating hospital with specialized capabilities or facilities may not refuse to accept an appropriate transfer of an individual who needs services if the hospital has the capacity to treat the individual.

OIG is authorized to collect CMPs of up to \$53,484 against small hospitals (fewer than 100 beds) and up to \$106,965 against larger hospitals (100 beds or more) for each instance in which the hospital negligently violated any of the section 1867 requirements. In addition, OIG may collect a penalty of up to \$106,965 from a responsible physician for each negligent violation of any of the section 1867 requirements and, in some circumstances, may exclude a responsible physician.

Anti-Kickback Statute and Civil False Claims Act Enforcement Authorities

The Anti-Kickback Statute

The anti-kickback statute authorizes penalties against anyone who knowingly and willfully solicits, receives, offers, or pays remuneration, in cash or in kind, to induce or in return for: (1) referring an individual to a person or an entity for the furnishing, or arranging for the furnishing, of any item or service payable under the Federal health care programs; or (2) purchasing, leasing, or ordering, or arranging for or recommending the purchasing, leasing, or ordering, of any good, facility, service, or item payable under the Federal health care programs (Social Security Act, § 1128B(b) (42 U.S.C. § 1320a-7b(b)).

Individuals and entities that engage in unlawful referral or kickback schemes may be subject to criminal penalties under the general criminal anti-kickback statute; a CMP under OIG's authority pursuant to the Social Security Act, § 1127(a)(7) (42 U.S.C. § 1320a-7a); and/or program exclusion under OIG's permissive exclusion authority under the Social Security Act, § 1128(b)(7) (42 U.S.C. § 1320a-7(b)(7)).

The False Claims Act

Under the False Claims Act, as amended by the False Claims Amendments Act of 1986 (31 U.S.C. §§ 3729–3733), a person or an entity is liable for up to treble damages and a penalty between \$11,181 and \$22,363 for each false claim it knowingly submits, or causes to be submitted, to a Federal program. Similarly, a person or an entity is liable under the False Claims Act if it knowingly makes or uses, or causes to be made or used, a false record or statement to have a false claim paid. The False Claims Act defines “knowing” to include the traditional definition and also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Under the False Claims Act, no specific intent to defraud is required. Further, the False Claims Act contains a qui tam, or whistleblower, provision that allows a private individual to file a lawsuit on behalf of the United States and entitles that whistleblower to a percentage of any fraud recoveries. The False Claims Act was amended again in 2009 in response to recent Federal court decisions that narrowed the law's applicability. Among other things, these amendments clarify the reach of the False Claims Act to false claims submitted to contractors or grantees of the Federal Government.

Appendix E: Reporting Requirements in the Inspector General Act of 1978

The reporting requirements of the Inspector General Act of 1978, as amended, are listed in the following table along with the location of the required information.

Section	Requirement	Location
Section 4		
(a)(2)	Review of legislation and regulations	"Other HHS-Related Reviews and Investigations" section
Section 5		
(a)(1)	Significant problems, abuses, and deficiencies	Throughout this report
(a)(2)	Recommendations with respect to significant problems, abuses, and deficiencies	Throughout this report
(a)(3)	Prior significant recommendations on which corrective action has not been completed	<i>Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs: Top Unimplemented Recommendations</i> (previously known as the Compendium of Unimplemented Recommendations)
(a)(4)	Matters referred to prosecutive authorities	"Legal and Investigative Activities Related to the Medicare and Medicaid Programs" section
(a)(5)	Summary of instances in which information requested by OIG was refused	None for this reporting period
(a)(6)	List of audit reports	Submitted to the Secretary under separate cover
(a)(7)	Summary of significant reports	Throughout this report
(a)(8)	Statistical Table 1—Reports With Questioned Costs	Appendix A
(a)(9)	Statistical Table 2—Funds Recommended To Be Put to Better Use	Appendix A
(a)(10)	Summary of previous audit reports without management decisions, in which no establishment comment was returned	Appendix A

Section	Requirement	Location
	within 60 days, and in which there are any outstanding unimplemented recommendations	
(a)(11)	Description and explanation of revised management decisions	Appendix A
(a)(12)	Management decisions with which the Inspector General disagrees	None for this reporting period
(a)(13)	Information required by the Federal Information Security Management Act.	"Other HHS-Related Reviews and Investigative Activities" section
(a)(14)-(16)	Results of peer reviews of HHS-OIG conducted by other OIGs or the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by HHS-OIG of other OIGs	Appendix C
(a)(17)	Investigative statistical tables	Appendix F
(a)(18)	Metrics description for statistical tables	Appendix F
(a)(19)	Investigations on senior Government employees	Appendix F
(a)(20)	Description of whistleblower retaliation instances	Appendix F
(a)(21)	Description of attempts to interfere with OIG independence	Appendix F
(a)(22)	Description of closed and nondisclosed reports and investigations regarding senior Government employees	Appendix F

Other Reporting Requirements

Section	Requirement	Location
845	Significant contract audits required to be reported pursuant to the National Defense Authorization Act for FY 2008 (P.L. No. 110-181), § 845.	"Other HHS-Related Reviews and Investigations" section
205	Pursuant to HIPAA (P.L. No. 104-191), § 205, the Inspector General is required to solicit proposals annually via a <i>Federal Register</i> notice for developing new and modifying existing safe harbors to the anti-kickback statute of the Social Security Act, § 1128(b) and for developing special fraud alerts. The Inspector General is also required to report annually to Congress on the status of the proposals received related to new or modified safe harbors.	Appendix G

Section	Requirement	Location
1553	Pursuant to the American Recovery and Reinvestment Act of 2009, P.L. No. 111-5, § 1553, OIG reports to Congress the retaliation complaint investigations it decided not to conduct or continue during the period.	"Other HHS-Related Reviews and Investigations" section

Appendix F: Reporting Requirements in the Inspector General Empowerment Act of 2016

The Inspector General Empowerment Act of 2016 establishes new reporting requirements for the Semiannual Reports. These requirements amend portions of § 5 of the Inspector General Act. The requirements are below in italics, followed by OIG’s responses.

Each Inspector General shall, not later than April 30 and October 31 of each year, prepare semiannual reports summarizing the activities of the Office during the immediately preceding 6-month periods ending March 31 and September 30. Such reports shall include, but need not be limited to-

(10) A summary of audit, inspection, and evaluation reports issued before the commencement of the reporting period-

(A) for which no management decision has been made by the end of the reporting period (including the date and title of each such report), an explanation of the reasons such management decision has not been made, and a statement concerning the desired timetable for achieving a management decision on each such report;

For audit and evaluation reports issued from FY 2011 through FY 2020, OIG had a total of 101 reports with overdue final management decisions (FMD) as of the end of this reporting period.² The breakdown of those 101 reports by HHS OpDiv is as follows:

OpDiv	Overdue FMDs
ACF	17
CDC	1
CMS	44
FDA	1
IHS	13
NIH	6
OASH	1
OS	17
SAMHSA	1

² OIG can track the status of management decisions for all reports back to FY 2011. OIG can track the status of management decisions for audit reports back to FY 1990. We have identified three additional audit reports (one CMS, one FDA, and one OS) with overdue management decisions from FYs 1990 through 2010.

OIG is unable to provide reasons and timetables for each of these overdue management decisions, because of the volume and that OIG did not historically track this information.

(B) for which no establishment comment was returned within 60 days of providing the report to the establishment; and

For draft reports that include recommendations, OIG typically requests establishment comments within 30 days. In some instances, OIG grants extensions when requested and appropriate. When OIG does not receive establishment comments or a request for extension within the 30-day timeframe, OIG typically issues the report and notes the lack of establishment comments.

For this semiannual reporting period, OIG had no reports for which no establishment comment was returned within 60 days of providing the report to the establishment.

(C) for which there are any outstanding unimplemented recommendations, including the aggregate potential cost savings of those recommendations.

OIG is actively tracking 1,441 unimplemented open recommendations made in reports issued since FY 2011. Given the volume of recommendations OIG makes each year, the table below reflects summary data by FY:

FY (2011–2020)	No. of Reports With Unimplemented Recommendations	No. of Unimplemented Recommendations	Dollar Value of Aggregate Potential Cost Savings
2011	13	20	\$446,994,129
2012	23	28	\$397,437,195
2013	30	45	\$235,963,777
2014	33	56	\$15,142,396,350
2015	28	46	\$333,957,018
2016	28	70	\$191,570,237
2017	39	106	\$1,116,136,306
2018	54	175	\$2,213,559,395
2019	88	327	\$878,622,570
2020	146	568	\$3,189,892,988
Totals	482	1441	\$24,146,529,965

OIG annually produces a [Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs: OIG's Top Recommendations](#) (previously known as the Compendium of Unimplemented Recommendations), which constitutes OIG's response to a specific requirement of the Inspector General Act, as amended (§ 5(a)(3)). It identifies significant recommendations with respect to problems, abuses, or

deficiencies for which corrective actions have not been completed. It also includes an appendix listing OIG’s significant unimplemented recommendations, which represent opportunities to achieve expected impact through cost savings, improvements in program effectiveness and efficiency, or increasing quality of care and safety of beneficiaries. In OIG’s view, these recommendations would most positively impact HHS programs in terms of cost savings and/or quality improvements and should therefore be prioritized for implementation.

(17) Statistical tables showing-

(A) the total number of investigative reports issued during the reporting period;

(B) the total number of persons referred to the DOJ for criminal prosecution during the reporting period;

(C) the total number of persons referred to State and local prosecuting authorities for criminal prosecution during the reporting period; and

(D) the total number of indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities;

Total number of investigative reports issued during the reporting period, including Management Implication Reports and Investigative Advisories	None
Total number of persons referred ³ to Federal prosecuting authorities for criminal prosecution during the reporting period ⁴	1,635
Total number of persons referred to State and local prosecuting authorities for criminal prosecutions during the reporting period	112
Total number of Federal indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities	277
Total number of State and local indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities	27

(18) A description of the metrics used for developing the data for the statistical tables under paragraph (17);

Regarding (17)(A), OIG considers Investigative Reports as Management Implication Reports and Investigative Advisories. A Management Implication Report identifies systemic weaknesses or vulnerabilities within HHS programs, which are generally identified during the

³ A referral includes OIG presentations to DOJ and/or State/local prosecutorial authorities.

⁴ OIG counts “persons” as both individuals and entities.

course of an OIG investigation and could lead to fraud, waste, or abuse. It provides recommendations to correct or minimize the problem. Corrective actions may require administrative, procedural, policy, regulatory, or legislative change. When a Management Implication Report is issued to an HHS OpDiv or StaffDiv, it is generally signed by the Inspector General. Investigative Advisories are similar documents that bring renewed attention to an identified HHS issue and are generally signed by the Deputy Inspector General for Investigations.

Regarding (17)(B) and (C), OIG defines this measure as the term “presentations” to both Federal and State/local prosecuting jurisdictions as the representation of the work we do. For example, when OIG opens an investigation, it evaluates the complaint and decides whether to “present” the matter for prosecution. Generally, if the case has prosecutorial merit, and is accepted for Federal prosecution, OIG works with DOJ as the primary investigative agency, as opposed to referring the matter to DOJ without further involvement on OIG's part. OIG works with State and local prosecutorial authorities in addition to working with DOJ.

Regarding (17)(D), the table above provides the number of indictments/criminal information during the semiannual reporting period, including sealed indictments/criminal information. However, the information cannot be limited to only those that occurred as a result of a presentation in a previous period. In certain situations, the presentation and charging dates are in the same reporting period.

(19) A report on each investigation conducted by the Office involving a senior Government employee where allegations of misconduct were substantiated, including a detailed description of-

(A) the facts and circumstances of the investigation; and

(B) the status and disposition of the matter, including-

(i) if the matter was referred to the Department of Justice, the date of the referral; and

(ii) if the Department of Justice declined the referral, the date of the declination;

To respond fully to this subparagraph, OIG would need to make a finding of misconduct. However, OIG does not make findings regarding its investigations relating to substantiated allegations of departmental employee misconduct. Our reports relay the facts obtained during the investigations (e.g., parties involved, dates of events) related to any substantiated allegations. At the conclusion of an OIG investigation related to substantiated allegations concerning possible employee misconduct, OIG provides a report to management in the employing agency. The agency management makes determinations of employee misconduct. The disposition of the matter and any resulting administrative actions are taken by the agency.

However, we request from the agency a copy of an SF-50 documenting a personnel action, if one is taken. To the extent that we have information regarding subsequent administrative action, OIG can provide that information. However, because there are sometimes settlement agreements that may impact the final action, OIG may not have a complete record of the disposition of the investigation.

Accordingly, such information might be more efficiently and effectively provided directly by the employing agency.

For this section, OIG describes investigations during this reporting period, both criminal and administrative, involving senior Government employees for whom allegations of misconduct were substantiated. The descriptions below include a level of detail appropriate for each investigation, depending on whether the case details were available in public documents. During this reporting period, OIG investigated no senior Government employee for misconduct.

(20) A detailed description of any instance of whistleblower retaliation, including information about the official found to have engaged in retaliation and what, if any, consequences the establishment imposed to hold that official accountable;

For departmental agencies, OIG conducts investigations and gathers facts related to whistleblower complaints. Before 2015, OIG made no determinations as to whether retaliatory action had been taken. However, to better facilitate the report review process, OIG changed its process in 2015 to include findings in its reports as to whether it was more likely than not that whistleblower retaliation had occurred. Although OIG now includes these findings in its reports, it does not make recommendations as to what, if any, corrective action(s) should be taken.

During the time period from April 1, 2020, through September 30, 2020, OIG did not issue any reports that included findings of retaliation.

When determining the level of detail to provide for a description of any instance of whistleblower retaliation, OIG is always mindful of the risk that a detailed description of the allegation could inadvertently reveal the whistleblower's identity, thus having a chilling effect on future whistleblowers.

(21) A detailed description of any attempt by the establishment to interfere with the independence of the Office, including-

(A) with budget constraints designed to limit the capabilities of the Office; and

(B) incidents where the establishment has resisted or objected to oversight activities of the Office or restricted or significantly delayed access to information, including the justification of the establishment for such action; and

Although there have been instances in which HHS agencies have questioned OIG oversight activities or have not provided all information in the precise content, format, and timeline as requested, OIG has not identified any instances in which HHS interfered with the independence of OIG during this reporting period. OIG would immediately notify Congress if it were unable to resolve these issues within HHS.

(22) Detailed descriptions of the particular circumstances of each-

(A) inspection, evaluation, and audit conducted by the Office that is closed and was not disclosed to the public; and

The table below lists evaluation and audit reports for this semiannual reporting period that did not result in public reports. However, in some circumstances, a public summary of these nonpublic reports was published.

Nonpublic Reports by Category, April 1, 2020, Through September 30, 2020

Category/Description	No. of Reports
IT security reviews (involve IT systems, e.g., penetration test audits)	6
Homeland security issues (involve particularly sensitive topics, e.g., bioterrorism, emergency preparedness, and classified or potentially classified information)	None
Recipient Capability Audits (primarily in Head Start/Early Head Start programs)	None
Reimbursable audits performed for other Federal agencies (primarily contract audits)	None
Confidential or proprietary information (e.g., Medicare Part B drug claims/imaging services, Medicare investment income)	None
Medicare Adverse Event Reviews (required by law not to disclose)	None
Medicare Prescription Drug Event Reviews	None
Other	None
HHS technical assistance reports ⁵	None
Finance-related attestation reviews	3
Total	9

(B) Investigation conducted by the Office involving a senior Government employee that is closed and was not disclosed to the public.

In section 5(a)(19), we detail investigations of senior Government employees in which allegations were substantiated. Those investigations are all closed and none have been disclosed to the public. OIG interprets section 5(a)(22)(B) as requiring reporting on investigations with either substantiated or unsubstantiated allegations. As such, we refer to our section 5(a)(19) response to address investigations of senior Government employees in which allegations were substantiated that were closed and not disclosed to the public. Our section 5(a)(22)(B) response describes

⁵ OIG routinely provides technical assistance to HHS. Generally, that technical assistance is not part of a formal report and is not formally tracked. However, in some limited circumstances, OIG does provide technical assistance in a formal report, and only that category of technical assistance is reflected in this table.

investigations during this reporting period, both criminal and administrative, involving a senior Government employee in which OIG did not substantiate allegations of misconduct.

When determining the level of detail to provide for the investigations described above, OIG is mindful of the risk that a detailed description of the investigation could inadvertently reveal the subject's identity. During this reporting period, OIG investigated two senior Government employees for misconduct, but OIG determined the allegations to be unsubstantiated. Descriptions of the investigations are below.

Description of Investigation	Status	Disposition	DOJ Referral	DOJ Referral Date	DOJ Declination	DOJ Declination Date
A complainant stated that a senior Government employee violated their civil rights by not providing requested record.	Closed	Unsubstantiated	No	N/A	N/A	N/A
A complaint stated that a senior Government employee was forcing contracts with a business in which she has an interest.	Closed	Unsubstantiated	No	N/A	N/A	N/A

Appendix G: Anti-Kickback Statute—Safe Harbors

Pursuant to HIPAA, § 205, the Inspector General is required to solicit proposals annually via a *Federal Register* notice for developing new and modifying existing safe harbors to the anti-kickback statute, section 1128B(b) of the Social Security Act and for developing special fraud alerts. The Inspector General is also required to report annually to Congress on the status of the proposals received related to new or modified safe harbors.

In 2018, OIG did not publish its typical December annual solicitation in the *Federal Register*.⁶ For 2018, OIG issued a request for information (OIG RFI) regarding the Federal anti-kickback statute and beneficiary inducements CMP, which published in the *Federal Register* on August 27, 2018.⁷ In the OIG RFI, we sought feedback on ways in which OIG might modify or add new safe harbors to the Federal anti-kickback statute and exceptions to the beneficiary inducements CMP definition of “remuneration” to foster arrangements that would promote care coordination and advance the delivery of value-based care while also protecting patients and taxpayer dollars against harms caused by fraud and abuse. Consequently, below OIG reports on the proposals repeatedly set forth in numerous comments responding to the OIG RFI.

In crafting safe harbors for a criminal statute, it is incumbent upon OIG to engage in a complete and careful review of the range of factual circumstances that may fall within the proposed safe harbor subject area to uncover all potential opportunities for fraud and abuse by unscrupulous providers. Having done so, OIG must then determine, in consultation with DOJ, whether it can develop effective regulatory limitations and controls—not only to foster beneficial or innocuous arrangements but also to protect the Federal health care programs and their beneficiaries from abusive practices.

Public proposals for new and modified safe harbors

In response to the OIG RFI, OIG received 359 comments from a variety of individuals and organizations. Due to the number and variety of proposals for new and modified safe harbors set forth in the comments received in response to the OIG RFI, we highlight some of the most common proposals below.

Although most commenters to the OIG RFI strongly asserted the need for regulatory reform to the anti-kickback statute safe harbors, a number of commenters acknowledged that increased regulatory flexibility

⁶ See, e.g., OIG, Notification of intent to develop regulations, 81 Fed. Reg. 95,551 (Dec. 28, 2016), available at <https://www.govinfo.gov/content/pkg/FR-2016-12-28/pdf/2016-31170.pdf>; OIG, Notification of intent to develop regulations, 82 Fed. Reg. 61,229 (Dec. 27, 2017), available at <https://www.govinfo.gov/content/pkg/FR-2017-12-27/pdf/2017-27117.pdf>.

⁷ OIG, Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, 83 Fed. Reg. 43,607 (Aug. 27, 2018), available at https://oig.hhs.gov/authorities/docs/2018/RFI_Regarding_AKS_Beneficiary_Inducements_CMP.pdf.

could create program integrity vulnerabilities or increase the risk of harms associated with fraud and abuse and urged OIG to exercise caution and include adequate safeguards in any regulatory proposals. Comments supporting regulatory reform encompassed a number of themes, including requests for:

- new safe harbors protecting financial arrangements among parties participating in alternative payment models (APMs), value-based arrangements, and care coordination activities;
- safe harbor protection for financial arrangements with entities not participating in Innovation Center models, including commercial and self-pay APM arrangements;
- additional protection for patient tools and supports, such as in-kind items and services to support patient compliance with discharge and care plans, services and supports to address unmet social needs affecting health, and expanded protections under the local transportation safe harbor;
- enhanced safe harbor protection for transfers of IT, data, and cybersecurity tools;
- modifications to the current “patchwork” fraud and abuse waiver framework for Innovation Center models and the Medicare Shared Savings Program; and
- a variety of protections for pharmaceutical and medical device manufacturer arrangements, including broad protections for drug and medical device manufacturer participation in value-based contracts, pricing arrangements, warranty arrangements, and APMs, as well as protection for coupons and other means of direct copayment assistance to Medicare Part D beneficiaries in certain situations.

In the October 17, 2019, *Federal Register*, OIG issued a Notice of Proposed Rulemaking, “Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements” (OIG NPRM).⁸ The OIG NPRM includes proposals that may be responsive to certain of the abovementioned requests for additional protections included in comments responding to the OIG RFI.

In particular, among other proposals, and subject to definitions and conditions set forth in the OIG NPRM, the OIG NPRM includes the following proposals:

- three proposed new safe harbors for certain remuneration exchanged between or among participants in a value-based arrangement (as further defined) that fosters better coordinated and managed patient care: (i) care coordination arrangements to improve quality, health outcomes, and efficiency (1001.952(ee)); (ii) value-based arrangements with substantial downside financial risk (1001.952(ff)); and (iii) value-based arrangements with full financial risk (1001.952(gg)). These proposed safe harbors vary by the types of remuneration protected (in-kind or in-kind and monetary), the level of financial risk assumed by the parties, and the types of safeguards included as safe harbor conditions, among other ways, by the types of remuneration protected (in-kind or

⁸ OIG, Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 Fed. Reg. 55,694 (Oct. 17, 2019), available at <https://www.govinfo.gov/content/pkg/FR-2019-10-17/pdf/2019-22027.pdf>.

in-kind and monetary), the level of financial risk assumed by the parties, and the types of safeguards included as safe harbor conditions;

- a proposed new safe harbor (1001.952(hh)) for certain tools and supports furnished under patient engagement and support arrangements to improve quality, health outcomes, and efficiency;
- a proposed new safe harbor (1001.952(ii)) for certain remuneration provided in connection with a CMS-sponsored model, which should reduce the need for OIG to issue separate and distinct fraud and abuse waivers for new CMS-sponsored models;
- a proposed new safe harbor (1001.952(jjj)) for donations of cybersecurity technology and services;
- proposed modifications to the existing safe harbor for electronic health record (EHR) items and services (1001.952(y)) to add protections for certain cybersecurity technology included as part of an EHR arrangement, to update provisions regarding interoperability, and to remove the sunset date;
- proposed modifications to the existing safe harbor for personal services and management contracts (1001.952(d)) to add flexibility with respect to outcomes-based payments and part-time arrangements;
- proposed modifications to the existing safe harbor for warranties (1001.952(g)) to revise the definition of "warranty" and provide protection for warranties for one or more items and related services; and
- proposed modifications to the existing safe harbor for local transportation (1001.952(bb)) to expand and modify mileage limits for rural areas and for transportation for discharged patients.

Comments to the OIG NPRM were due December 31, 2019, and are currently under consideration. No final determination has been made that the arrangements described in the OIG NPRM's proposals are, or should be, exempt from liability under the anti-kickback statute. In addition, any final safe harbors would only provide prospective protection. In the meantime, questions about the application of the anti-kickback statute to specific arrangements should be addressed on a case-by-case basis, such as under the advisory opinion process.