

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

# Semiannual Report to Congress

October 1, 2019–March 31, 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 March 31, 2020. This report describes OIG's work to detect and prevent fraud, waste, and abuse and to promote the economy, efficiency, and effectiveness of HHS programs and operations.

During this reporting period, OIG continued its priority work to combat opioid-related fraud and provide valuable data to policymakers on opioid prescribing and treatment services. An OIG audit uncovered \$92.5 million in improper Medicare payments to suppliers of inhalation drugs, and an OIG investigation of a massive sober home fraud scheme led to prison sentences for three individuals. Other notable work included a report that found poor interagency communication and internal management decisions failed to protect children's interests and left HHS unprepared for the zero-tolerance policy, and a review that found the National Institutes of Health can do more to address concerns about foreign threats to the confidentiality of the peer-review process. Our work recommended improvements to program integrity, including stronger monitoring of incidents of abuse and neglect involving Medicaid beneficiaries with developmental disabilities. The *Semiannual Report* more fully describes our portfolio of completed work for the reporting period.

Along with other agencies across the Federal Government, OIG recently turned our attention to the coronavirus disease 2019 (COVID-19) public health emergency. OIG is investigating and holding accountable those who would exploit the emergency to defraud the public and HHS programs, including through fraudulent marketing schemes for COVID-19 tests, identity theft, and submission of false claims for payment. Building on longstanding work focused on emergency preparedness and response, OIG is undertaking and planning oversight of HHS's COVID-19-related programs to ensure that program requirements are met to protect patient health and safety, that taxpayer funds invested to provide relief to providers and care to patients are not misspent, and that critical infrastructure supporting an effective emergency response is secure. OIG is working to provide the public and policymakers in HHS and Congress with sophisticated analyses and relevant, reliable, and actionable data and information.

In March, OIG released our [strategic plan for 2020–2025](#). We set three goals: to fight fraud, waste, and abuse; to promote quality, safety, and value in HHS programs and for HHS beneficiaries; and to advance excellence and innovation. In today's rapidly changing health and human services environment, OIG will continue to conduct the most consequential oversight work and optimize resources to deliver impactful results. We do this through data-driven reviews and investigations, supported with modern auditing, investigative, and evaluative methods, and a team of over 1,600 dedicated public servants. Impact. Innovation. People focus. These are the core values that inspire OIG to serve the American public with independent, objective oversight.

OIG appreciates the ongoing support of Congress and HHS for our 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), the Department of Justice (DOJ), and the 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 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 (IT) infrastructure that enables OIG components to conduct their work efficiently and effectively.

## 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 own assessment of its 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 of October 1, 2019, through March 31, 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, October 1, 2019, through March 31, 2020. In this section, we highlight significant results from selected audits, evaluations, and enforcement activities completed during the reporting period.

## At-a-Glance Highlights

Statistic	Semiannual Reporting Period (10/1/2019–3/31/2020)
Audit Reports Issued	81
Evaluations Issued	14
Expected Audit Recoveries	\$605.2 million
Questioned Costs	\$288.4 million
Potential Savings	\$911.3 million
New Audit and Evaluation Recommendations	273
Recommendations Implemented by HHS Operating Divisions	130
Expected Investigative Recoveries	\$1.51 billion
Criminal Actions	443
Civil Actions	370
Exclusions	903

## Results for the Semiannual Reporting Period

During this semiannual reporting period (October 1, 2019, through March 31, 2020), we issued 81 audit reports and 14 evaluation reports. Our audit work identified \$605.2 million in expected recoveries, as well as \$288.4 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 \$911.3 million 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 273 new audit and evaluation recommendations, which are crucial to encourage positive change in HHS programs. Meanwhile, HHS operating divisions implemented 130 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 \$1.51 billion in expected investigative recoveries and 443 criminal actions during this reporting period. OIG also took civil actions, such as assessing monetary penalties, against 370 individuals and entities, and excluded 903 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 of October 1, 2019, through March 31, 2020, organized by subject area. A comprehensive list of OIG work during the reporting period follows, and Appendices A–F provide data to meet the reporting requirements in the Inspector General Act of 1978.

## **Preparing for and Responding to the COVID-19 Pandemic and Other Public Health Emergencies**

OIG plays a vital role in supporting the nation's ability to prepare, respond, and recover from natural disasters and public health emergencies. In response to the novel coronavirus disease 2019 (COVID-19) pandemic, OIG immediately deployed law enforcement personnel in its Emergency Support Function No. 13 role to provide Federal public safety and security assistance to local, State, Tribal, territorial, and Federal organizations. OIG staff protected quarantined patients at health care facilities and aided in the safe transport of patients to and from health care facilities.

In addition, OIG rapidly launched a series of oversight and enforcement actions related to the COVID-19 pandemic. By mid-March, OIG had developed a dedicated system to report fraud schemes for COVID-19, issued a Special Fraud Alert on COVID-19 to protect Medicare beneficiaries from identity theft, issued a Policy Statement to waive cost-sharing requirements for telehealth services, and initiated an assessment of CDC's provision of COVID-19 test kits and its oversight of laboratory testing. For a complete listing of our oversight and enforcement actions, please see OIG's [COVID-19 Portal](#). In addition, OIG made operational and procedural changes to protect the safety and wellbeing of OIG employees and contractors while continuing to fulfill our mission. OIG's modern approach to oversight and effort will allow us to quickly adapt and plan work responsive to the COVID-19 pandemic.

Prior to the COVID-19 pandemic, OIG continued its longstanding work focused on ensuring the safety of nursing homes and ensuring health care facilities are prepared for a public health emergency. In 2016, CMS updated its life safety and emergency preparedness regulations to improve protections for all Medicare and Medicaid beneficiaries, including those residing in nursing homes. The regulatory updates included requirements that nursing homes have expanded sprinkler systems and smoke detector coverage; an emergency preparedness plan that is reviewed, trained on, tested, and updated at least annually; and provisions for sheltering in place and evacuation. In response, OIG reviewed selected

nursing homes in California, Texas, Florida, and Missouri to determine whether the nursing homes complied with Federal requirements for life safety and emergency preparedness.

OIG found deficiencies in all four States. Deficiencies varied among the States. Life safety deficiencies generally related to building exits, fire detection and suppression systems, hazardous storage, smoking policies, and electrical equipment maintenance, among others. Emergency preparedness deficiencies generally related to written plans, emergency power, emergency communications, and training, among others. OIG recommended that followup actions be taken with each nursing home to ensure that corrective actions have been taken regarding the identified deficiencies. The States either agreed or partially agreed with our recommendations. (See reports [A-09-18-02009](#), [A-06-19-08001](#), [A-04-18-08065](#), and [A-07-18-03230](#).)

## Protecting Unaccompanied Children in the Department's Care

HHS, through ACF's Office of Refugee Resettlement (ORR), is responsible for ensuring the shelter and care of thousands of unaccompanied alien children who enter the United States without legal status. Most of these children were transferred into ORR's custody after initially being taken into custody at the border by the Department of Homeland Security (DHS). ORR provides temporary shelter, care, and other related services to children before they are released to sponsors (most often, family members). OIG has devoted substantial efforts to protect the health and safety of children in ORR custody. Significant OIG work during this semiannual reporting period related to ORR includes the following:

OIG found that poor interagency communication and internal management decisions that failed to protect children's interests left HHS unprepared for the zero-tolerance policy. This lack of preparation impeded HHS's ability to identify, care for, and reunify separated children. ACF needs to address the management concerns that we identified to improve its operation of the Unaccompanied Alien Children (UAC) Program. ACF agreed with our recommendations to address these issues. (See report [OEI-BL-18-00510](#).)

## Preventing and Treating Opioid Misuse

OIG continued its multidisciplinary approach to addressing the national opioid epidemic in this reporting period. As Deputy Inspector General for Investigations Gary Cantrell described in his October 2019 testimony before the Senate Committee on Finance, OIG's work covers both the prescribing and treatment dimensions of the opioid crisis. OIG's ongoing efforts to combat inappropriate prescribing and distribution include investigations of "pill mills" that illegally dispense prescription opioids and the doctors involved in the fraud. To address the treatment dimension, OIG's multifaceted approach has included evaluating access to drugs that treat opioid use disorder, overseeing Medicaid claims for treatment services and HHS grants to States, and investigating of fraud schemes involving substance abuse treatment centers. Significant OIG work during this semiannual reporting period includes the following:

OIG's investigation helped convict a doctor of illegally prescribing and distributing large quantities of prescription opioids. A provider was convicted on 861 Federal counts of drug distribution, including distribution resulting in death, for operating a "pill mill" in Martinsville, Virginia. Patients travelled hundreds of miles and paid cash to receive opioid prescriptions at his office, which regularly stayed open after midnight and lacked basic medical supplies. Opioid prescriptions written by this provider caused Medicaid and Medicare Part D to pay hundreds of thousands of dollars in suspected fraudulent claims. This provider was sentenced to 40 years in prison.

OIG found that buprenorphine-waivered providers may not always be located in the areas where access to treatment for opioid use disorder is most critical. Buprenorphine, a key drug used in medication-assisted treatment (MAT) for opioid use disorder, can be prescribed in office settings only by providers that obtain waivers from the Substance Abuse and Mental Health Administration (SAMHSA). Among the 1,100 U.S. counties identified as having the greatest need for opioid use disorder treatment services, OIG's analysis of waived providers showed that 56 percent likely had inadequate capacity to treat patients with buprenorphine in an office setting. SAMHSA concurred with OIG's recommendation to target efforts to increase the participation of waived providers in high-need counties. (See report [OEI-12-17-00240](#).)

OIG found that the State of New York claimed Medicaid funds for opioid treatment program (OTP) services that did not meet requirements. New York improperly claimed an estimated \$39.3 million in Federal Medicaid reimbursement for OTP services that did not comply with Federal and State requirements. The improper claims identified by OIG occurred because providers had inadequate documentation of services, did not ensure that services were provided in accordance with beneficiaries' treatment plans, and did not maintain necessary signatures for services. OIG recommended that New York refund the \$39.3 million to the Federal Government and ensure that providers comply with requirements for OTP services. (See report [A-02-17-01021](#).)

OIG's review of Federal grants to States for opioid response activities identified unspent funds and limited data on a key metric. OIG found that over \$300 million of grant funding for SAMHSA's State Targeted Response to the Opioid Crisis grant program remained unspent after 2 years, with 14 States having spent less than half of their grant allocations. Additionally, while States reported using their grants to expand access to treatment, SAMHSA did not track how many patients received MAT, the primary form of evidence-based treatment. SAMHSA concurred with OIG's recommendations to work with States to address barriers to timely spending and require States to specifically report how many patients are receiving MAT. (See report [OEI-BL-18-00460](#).)

OIG investigated a massive sober home fraud scheme, leading to prison sentences for three individuals. Three former co-owners and clinical directors of a group of purported substance abuse treatment centers and sober homes were sentenced to prison for their roles in a \$21 million health care fraud conspiracy. According to court documents, the scheme involved submitting fraudulent claims for substance abuse treatment services to several health insurance companies. The three conspirators pleaded guilty and were sentenced to a combined 15 years and 4 months in prison and ordered to pay \$4.2 million in restitution.

An electronic health record (EHR) vendor admits to kickback scheme aimed at increasing opioid prescriptions. The vendor agreed to pay \$145 million to resolve criminal and civil investigations relating to its EHR software. The vendor admitted that it solicited and received kickbacks from a major opioid company in exchange for utilizing its EHR software to influence physician prescribing of opioid pain medications.

## Fighting Fraud To Protect the Medicare and Medicaid Programs

In 2018, Medicare spent nearly \$741 billion, and provided health coverage to 59.9 million beneficiaries. OIG has sustained efforts to root out illegal activity that can unnecessarily raise costs for the Medicare program or put beneficiaries at risk. Significant OIG work during this semiannual reporting period includes the following:

OIG found that some providers may be using beneficiaries' Medicare Part D eligibility information improperly. OIG discovered that providers were taking advantage of gaps in CMS's program integrity in Medicare Part D Eligibility Verification Transactions (E1 transactions). Because E1 transactions contain beneficiary protected health information, we wanted to verify that the providers were appropriately using E1 transactions for their intended purposes. The majority of providers used E1 transactions for some purpose other than to bill for a prescription or determine drug coverage billing order. CMS agreed with our recommendations to ensure that providers are using eligibility information properly. (See report [A-05-17-00020](#).)

A pharmaceutical company agreed to pay almost \$12 million and enter into a CIA with OIG for violating the anti-kickback statute. A pharmaceutical company entered into a \$11.85 million False Claims Act settlement with the United States to resolve allegations that it paid the copayments of Medicare patients taking a certain drug to induce the patients to purchase, or their physicians to prescribe, the drug. The pharmaceutical company agreed to pay \$11.85 million to resolve its liability and entered into a CIA with OIG in connection with the settlement.

OIG found that Medicare Part D does not have three key tools to protect against pharmacy fraud that are available in other parts of Medicare. Three tools—pharmacy enrollment, revocation, and preclusion—apply to pharmacies when they bill Medicare Parts B or C, but not when they bill Part D. CMS agreed with our recommendations to allow Medicare Part D the ability to utilize these fraud prevention tools. (See report [OEI-02-15-00440](#).)

## Ensuring Medicaid Program Integrity

Medicaid spending represents one-sixth of the of the national health care economy, and Medicaid serves more people, including some of the Nation's most vulnerable individuals, than any other Federal health care program. A key component of OIG's mission is to promote integrity and efficiency in Medicaid through a nationwide program of audits, evaluations, inspections, investigations, and enforcement actions.

[OIG testified about OIG’s Medicaid Program Integrity work at a congressional hearing.](#) In October, Brian Ritchie, Assistant Inspector General for Audit Services, testified at a congressional hearing before the Senate Committee on Finance, Subcommittee on Health Care. The testimony addressed OIG’s work on Medicaid beneficiary eligibility and OIG’s commitment to ensure that Medicaid pays the right amount, to the right provider, for the right service, on behalf of the right beneficiary. (See [OIG congressional testimony](#).)

[OIG found that States could do more to prevent terminated providers from serving Medicaid beneficiaries.](#) We found that nearly 1,000 terminated providers—or 11 percent of all terminated providers—were inappropriately enrolled in State Medicaid programs. These providers were associated with \$50.3 million in Medicaid payments. Despite legislative requirements in the 21st Century Cures Act designed to strengthen Medicaid program integrity, terminated providers continue to serve Medicaid beneficiaries. Some of these providers were terminated for criminal convictions, licensure issues, and provider misconduct, representing a risk to beneficiaries’ safety and their quality of care. CMS agreed with our recommendations to help protect taxpayer dollars and the beneficiaries served by the Medicaid program. (See report [OEI-03-19-00070](#).)

[OIG found that 23 States allowed unenrolled providers to serve Medicaid beneficiaries.](#) We found that 23 States had not enrolled all Medicaid providers. When States do not enroll and screen providers, Medicaid beneficiaries are exposed to potentially harmful providers. CMS agreed with our recommendations to ensure that States enroll all providers. (See report [OEI-05-19-00060](#).)

## Ensuring Appropriate Use of HHS Funds

OIG reviews of the administration of Medicaid and Medicare are critical to ensuring that Medicare and Medicaid funds are spent in accordance with payment rules and on behalf of eligible beneficiaries. Significant OIG work during this semiannual reporting period includes the following:

[OIG found billions of estimated Medicare Advantage \(MA\) payments from chart reviews raised concerns.](#) OIG found billions of estimated risk-adjusted payments supported solely through chart reviews raised potential concerns about the completeness of payment data submitted to CMS, the validity of the diagnoses on chart reviews, and the quality of care provided to beneficiaries. The risk adjustment program helps to ensure that sicker beneficiaries have continued access to MA plans. Chart reviews can be a tool to improve the accuracy of risk-adjusted payments. However, chart reviews—particularly those not linked to service records—may provide MA organizations with opportunities to circumvent CMS face-to-face requirements and inflate payments inappropriately. CMS agreed with our recommendations to address the vulnerabilities associated with chart reviews, particularly unlinked chart reviews, as a mechanism. (See report [OEI-03-17-00470](#).)

[OIG found that 60 hospitals received \\$3.5 billion in excessive outlier payments.](#) These payments represented a net of \$502 million more than hospitals would have been paid if their outlier payments had



not been reconciled. CMS did not detect or recover these excessive outlier payments. CMS agreed with our recommendation that it require reconciliation of all hospital cost reports with outlier payments during the cost-reporting period. If this requirement had been in effect for the 60 hospitals in our review, CMS would have saved approximately \$125 million per year. (See report [A-05-16-00060](#).)

OIG found that New Jersey claimed \$63 million for unallowable Medicaid school-based administrative costs. New Jersey improperly claimed \$63.8 million after using a random moment sampling methodology that did not comply with statistical sampling requirements and was not adequately supported. OIG recommended that the State refund \$63.8 million in Federal Medicaid payments and revise its random moment sampling methodology to comply with Federal requirements. (See report [A-02-17-01006](#).)

OIG found that Medicare improperly paid acute-care hospitals \$54 million for inpatient claims. Medicare improperly paid acute-care hospitals \$54.4 million for 18,647 claims subject to Medicare's post-acute-care transfer policy. These hospitals improperly billed the claims by using incorrect patient discharge status codes. Specifically, they coded these claims as discharges to home or to certain types of health care institutions, rather than as transfers to post-acute care. CMS agreed with our recommendations that it direct the Medicare contractors to recover the \$54.4 million in identified overpayments. (See report [A-09-19-03007](#).)

OIG found that Medicare improperly paid suppliers \$92.5 million for inhalation drugs. On the basis of our sample results, we estimated that \$92.5 million paid to suppliers was unallowable for Medicare reimbursement. Medicare contractor oversight was not sufficient to ensure that suppliers complied with documentation requirements. CMS agreed with our recommendations that it identify suppliers that consistently bill for inhalation drugs that do not comply with Medicare documentation requirements, perform reviews of those suppliers, collect the amount overpaid for unallowable claims, and educate them on Medicare requirements for inhalation drugs. (See report [A-09-18-03018](#).)

OIG found that New York State claimed Federal reimbursement for unallowable childcare subsidies. OIG found that New York State claimed Federal reimbursement for childcare subsidy payments made to New York City that did not comply with Federal and State requirements. Based on our sample results, we estimated that New York State claimed Federal reimbursement of \$24.7 million related to these unallowable payments. During our audit period, New York City did not have controls in place to prevent these unallowable payments. New York State agreed with our recommendation that it refund \$24.7 million in unallowable childcare subsidies claimed for Federal reimbursement and ensure that New York City's recently implemented program controls are properly functioning. (See report [A-02-17-02010](#).)

## Protecting Beneficiaries From Abuse, Neglect, and Unsafe Conditions

Protecting individuals served by HHS programs from abuse, neglect, and unsafe conditions is central to OIG's mission. Oversight work to ensure safety and well-being is particularly important for facilities and home-based programs that care for children and other vulnerable populations. Significant OIG work during this semiannual reporting period includes the following:

A pediatrician employed with the Indian Health Service (IHS) was sentenced to five consecutive life sentences for multiple sex offenses against children. While employed with IHS in South Dakota, a pediatrician sexually abused multiple Native American children between 1999 and 2011. The pediatrician was sentenced to five consecutive life sentences in Federal prison and was ordered to pay \$800,000 in criminal fines and an \$800 special assessment to the Federal Crime Victims Fund.

OIG found that IHS strengthened patient protection policies but still needs to fully integrate them into practice and organizational culture. In response to several recent cases of health care providers abusing patients under care at facilities, IHS strengthened patient protection policies. Although IHS's policies are consistent with those of other health care organizations, the policies have coverage gaps and are still early in implementation. IHS agreed with our recommendations to continue to actively promote the policies in practice and promote an organizational culture of transparency. (See report [OEI-06-19-00330](#).)

OIG found that Pennsylvania did not adequately report and monitor incidents involving Medicaid beneficiaries with developmental disabilities who resided in community-based settings. Specifically, Pennsylvania did not have adequate controls to detect unreported 24-hour reportable incidents and did not have controls in place to ensure that all beneficiary deaths were investigated and that all suspicious deaths were referred to law enforcement. Pennsylvania agreed with our recommendations to improve its controls regarding the reporting and monitoring of 24-hour reportable incidents involving Medicaid beneficiaries with developmental disabilities residing in community-based settings. (See report [A-03-17-00202](#).)

## Safeguarding the Security and Integrity of Medical Research

Congress, NIH, and Federal intelligence agencies have raised concerns about foreign and other threats to the integrity of taxpayer-funded research and intellectual property. In FY 2020, OIG received \$5 million in congressional appropriations to conduct oversight of NIH grant programs and operations. OIG's oversight work is reviewing (1) intellectual property and cybersecurity protections, (2) compliance with Federal requirements and NIH policies for grants and contracts, and (3) integrity of grant application and selection processes. Significant OIG work completed during this semiannual reporting period includes the following:

OIG found that NIH had IT control weaknesses in its EHR system. Among the interests to Congress were matters pertaining to cybersecurity protections and NIH compliance with Federal requirements. This review found that NIH's information security policies and practices were not operating effectively to preserve the security, confidentiality, integrity, and availability of its electronic health information systems. This resulted in potential risks of unauthorized access, use, disclosure, disruption, modification, or destruction. NIH agreed with recommendations to enhance its information security environment related to its EHR system. (See report [A-18-19-06003](#).)

OIG found that NIH can do more to address concerns about foreign threats to the confidentiality of the peer-review process. Each year NIH relies on thousands of peer reviewers to review tens of thousands of extramural grant applications, helping NIH determine the most promising research to fund. OIG found that NIH enforces policies and procedures that protect confidential information in grant applications handled by peer reviewers, but that it could do more to address the risk that undue foreign influence poses to maintaining confidentiality. NIH agreed with our recommendations regarding developing a measured, risk-based approach so that NIH can focus its oversight efforts on those circumstances or reviewers shown to pose the greatest risk to peer review integrity. (See report [OEI-05-19-00240](#).)

## Promoting Information Sharing in the Drug Supply Chain

Drug diversion, counterfeiting, and the importation of unapproved drugs may result in potentially dangerous drugs entering the drug supply chain, posing a threat to public health and safety. To enhance the security of this supply chain, the Drug Supply Chain Security Act (DSCSA) requires trading partners in the drug supply chain to create a record of each drug product transaction. The Food and Drug Administration (FDA) can use these records to investigate and identify potentially harmful drug products, prevent further distribution, and facilitate efficient recalls.

OIG found that ownership—but not physical movement—of selected drugs can be traced through the supply chain. OIG found that drug product tracing information can be used to trace ownership, but not physical movement, of selected drug products through the supply chain. Knowing which trading partner owns a drug, where it is in the supply chain, and where it has been can help investigators from FDA do the following: ensure that a potentially dangerous drug is removed the drug supply; identify breaches; and protect patients from harmful, ineffective, and illegitimate drugs. FDA agreed with our recommendations to continue establishing a system to trace drug product ownership through the supply chain to ensure the security of the drug supply. (See report [OEI-05-17-00460](#).)

# OIG Participation in Congressional Hearings

<i>Date</i>	<i>Witness</i>	<i>Testimony/Committee</i>
10/24/2019	Gary Cantrell, Deputy Inspector General for Investigations	<u>"OIG's Efforts to Address the Prescribing and Treatment Dimensions of the Opioid Crisis,"</u> Senate Committee on Finance
10/30/2019	Brian P. Ritchie, Assistant Inspector General for Audit Services	<u>"Medicaid: Compliance with Eligibility Requirements,"</u> Senate Committee on Finance, Subcommittee on Health Care
11/14/2019	Statement for the Record	<u>"Caring for Aging Americans,"</u> House Committee on Ways and Means
2/27/2020	Suzanne Murrin, Deputy Inspector General for Evaluation and Inspections	<u>"Oversight of the Food and Drug Administration,"</u> House Committee on Appropriations," Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

## 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

*Medicare Allowable Amounts for Certain Orthotic Devices Are Not Comparable With Payments Made by Select Non-Medicare Payers (A-05-17-00033), October 2019*

Medicare allowable amounts for certain orthotic devices are not comparable with payments made by select non-Medicare payers. For calendar years (CYs) 2012 through 2015, we estimated that Medicare and beneficiaries paid \$341.7 million more than select non-Medicare payers on 142 Healthcare Common Procedure Coding System (HCPCS) codes and \$4.2 million less than select non-Medicare payers on 19 HCPCS codes. Generally, Medicare allowable amounts are more than select non-Medicare payer payments because CMS does not routinely evaluate pricing trends for orthotic devices or payments made by select non-Medicare payers. Instead, CMS uses statutorily mandated fee schedule payments that have an economic update factor applied to them annually.

We identified 95 of the 161 codes for which the Medicare allowable amounts could be adjusted using existing legislative authority to make those amounts comparable with payments made by select non-Medicare payers. For the remaining 66 codes, CMS would be required to seek new legislative authority to make those adjustments.

CMS concurred with our recommendations that it (1) review the allowable amounts for 161 orthotic device HCPCS codes and adjust the allowable amounts, as appropriate, using regulations promulgated under existing legislative authority or, if the allowable amounts cannot be adjusted using regulations promulgated under existing legislative authority, seek authority to align Medicare allowable amounts for these items with payments made by select non-Medicare payers and (2) routinely review Medicare allowable amounts for new and preexisting orthotic devices to ensure that Medicare allowable amounts are in alignment with payments made by select non-Medicare payers or pricing trends.

*Medicare Improperly Paid Acute-Care Hospitals \$54.4 Million for Inpatient Claims Subject to the Post-Acute-Care Transfer Policy (A-09-19-03007), November 2019*

Medicare improperly paid acute-care hospitals \$54.4 million for 18,647 claims subject to Medicare's post-acute-care transfer policy. These hospitals improperly billed the claims by using incorrect patient discharge status codes. Specifically, they coded these claims as discharges to home or to certain types of health care institutions, such as facilities that provide custodial care, rather than as transfers to post-acute care.

Medicare makes the full Medicare Severity Diagnosis-Related Group (MS DRG) payment to an acute-care hospital that discharges an inpatient to home or certain types of health care institutions. In contrast, Medicare pays an acute-care hospital that transfers a beneficiary to post-acute care a per diem rate for each day of the beneficiary's stay in the hospital. The total overpayment of \$54.4 million represented the difference between the amount of the full MS DRG payments and the amount that would have been paid if the per diem rates had been applied.

CMS concurred with our recommendations that it direct the Medicare contractors to (1) recover the \$54.4 million in identified overpayments, (2) identify any claims for transfers to post-acute care in which incorrect patient discharge status codes were used and direct the Medicare contractors to recover any overpayments after our audit period, and (3) ensure that the Medicare contractors are receiving the post-payment edit's automatic notifications of improperly billed claims and are taking action by adjusting the original inpatient claims to initiate recovery of the overpayments.

*Medicare Made Hundreds of Thousands of Dollars in Overpayments for Chronic Care Management Services (A-07-17-05101), November 2019*

Physician and outpatient payments made by CMS for chronic care management (CCM) services provided during CYs 2015 and 2016 did not always comply with Federal requirements, resulting in \$640,452 in overpayments associated with 20,165 claims. For these 20,165 claims, beneficiaries were overcharged a total of up to \$173,495 in cost sharing.

Further, we identified 37,124 claims totaling \$1.2 million in potential overpayments for instances in which a CCM service was billed by an outpatient facility, but a corresponding claim was not submitted by a physician. We set aside these potential overpayments for review and determination by CMS. Additionally, for these 37,124 claims, beneficiaries may have been overcharged a total of up to \$373,726 in cost sharing.

These errors occurred because CMS did not have adequate controls in place, including claim system edits, to identify and prevent overpayments.

CMS concurred with our recommendations that it (1) recoup \$640,452 from providers and instruct providers to refund overcharges totaling up to \$173,495 to beneficiaries; (2) review the 37,124 outpatient claims totaling \$1.2 million in potential overpayments to determine whether the outpatient facilities met the requirement to bill for CCM services and recoup any overpayments from outpatient facilities and instruct the outpatient facilities to refund corresponding overcharges to beneficiaries; and (3) implement claim processing controls, including system edits, to prevent and detect overpayments for CCM services.

*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 (A-09-18-03020), December 2019*

CMS did not always make Medicare EHR incentive payments to acute-care hospitals in accordance with Federal requirements. The incorrect net incentive payments occurred because (1) the Medicare administrative contractors (MACs) did not review the supporting documentation for all hospitals to identify errors in the hospitals' cost-report numbers used to calculate the incentive payments and (2) CMS did not include labor and delivery services in the incentive payment calculations, which resulted in hospitals receiving inflated incentive payments. Based on our sample results, we estimated that CMS made incorrect net incentive payments of \$93.6 million, or less than 1 percent of the \$10.8 billion in total incentive payments for our audit period.

CMS concurred with our recommendations that it (1) recover from acute-care hospitals the portion of the \$1.3 million in incorrect net incentive payments that are within the reopening period; (2) for the remaining portion of the \$1.3 million, which is outside of the recovery period, notify the acute-care hospitals associated with the incorrect payments so that those hospitals can exercise reasonable diligence to investigate and return any identified similar incorrect payments; (3) instruct the MACs to review all hospitals' supporting documentation to identify errors in the hospitals' cost-report numbers; and (4) revise the incentive payment calculations to include labor and delivery inpatient bed-days.

*Billions in Estimated Medicare Advantage Payments From Chart Reviews Raise Concerns (OEI-03-17-00470), December 2019*

Billions of estimated MA risk-adjusted payments supported solely through chart reviews raise potential concerns about the completeness of payment data submitted to CMS, the validity of diagnoses on chart reviews, and the quality of care provided to beneficiaries. Diagnoses that MA organizations reported only on chart reviews—and not on any service records—resulted in an estimated \$6.7 billion in risk-adjusted payments for 2017. CMS based an estimated \$2.7 billion in risk adjusted payments on chart review diagnoses that MA organizations did not link to a specific service provided to the beneficiary. Although limited to a small number of beneficiaries, almost half of MA organizations reviewed had payments from unlinked chart reviews where there was not a single record of a service being provided to the beneficiary in all of 2016. CMS concurred with our recommendations, which were:

- Provide oversight of MA organizations that had payments resulting from unlinked chart reviews for beneficiaries who had no service records in 2016;
- Conduct audits that validate diagnoses reported on chart reviews in the encounter data; and
- Reassess the risks and benefits of allowing unlinked chart reviews to be used as sources of diagnoses for risk adjustment.

## Quality of Care, Safety, and Access

*Registered Nurses Did Not Always Visit Medicare Beneficiaries' Homes at Least Once Every 14 Days To Assess the Quality of Care and Services Provided by Hospice Aides (A-09-18-03022), November 2019*

Registered nurses did not always (1) visit hospice beneficiaries' homes at least once every 14 days to assess the quality of care and services provided by hospice aides or (2) document the visits in accordance with Federal requirements. Of the approximately 189,000 high-risk date-pairs in our sample, we identified (1) an estimated 99,000 instances in which the registered nurses did not make the required supervisory visits at least once every 14 days and (2) an estimated 5,000 instances in which supervisory visits were not documented in accordance with Federal requirements.

These deficiencies occurred because of hospices' lack of oversight, scheduling errors, employee turnover, and the registered nurses not being aware of the 14-day supervisory visit requirement. As a result, there was no assurance that beneficiaries admitted to those hospices received the appropriate care while in hospice care.

CMS concurred with our recommendations (1) that it promote hospices' compliance with the standard that requires registered nurses to visit hospice beneficiaries' homes at least once every 14 days, which could include working with State survey agencies and accreditation organizations to increase emphasis on this requirement, educating hospices about the requirements associated with this standard, and making this standard a quality measure and (2) that it take action to ensure that all registered nurses' supervisory visits of hospice aides are documented in accordance with applicable CMS regulations and interpretive guidelines.

## Program Integrity

*CMS's Controls Over Assigning Medicare Beneficiary Identifiers and Mailing New Medicare Cards Were Generally Effective but Could Be Improved in Some Areas (A-09-19-03003), January 2020*

CMS's controls were generally effective in ensuring that (1) beneficiaries were properly assigned Medicare Beneficiary Identifiers (MBIs), (2) deceased beneficiaries were not mailed new Medicare cards, and (3) payments were not made on behalf of deceased beneficiaries. However, in a small percentage of cases, CMS's controls did not prevent multiple MBIs from being assigned to beneficiaries or prevent mailing of new Medicare cards to deceased beneficiaries. In addition, CMS made improper payments of \$2.3 million on claims for deceased beneficiaries.

Specifically, we found that CMS assigned to 22,662 beneficiaries 2 or more MBIs associated with multiple enrollment records that contained the same SSN and date of birth. In addition, CMS mailed 58,420 new Medicare cards after the beneficiaries' dates of death. Finally, CMS made

improper payments for claims with dates of service after the beneficiaries' dates of death. By improving its controls, CMS can limit unintended consequences, such as claim processing errors and inappropriate release of personally identifiable information.

CMS concurred with our recommendations that it (1) improve its system controls by checking the Medicare Enrollment Database's date-of-death information as close as reasonably possible to the date that card mailing data are sent to the print/mail contractor to ensure that Medicare cards are not mailed to deceased beneficiaries and (2) instruct the Medicare contractors to review incorrectly collected deductible amounts that may have been for claims with dates of service after the beneficiaries' dates of death and initiate recoupment for amounts identified as improper payments.

*Medicare Market Shares of Diabetes Test Strips From April Through June 2019 (OEI-04-19-00481), January 2020*

Non mail-order claims composed 85 percent of the total Medicare market for diabetes test strips (DTS) during the time period we reviewed. The suppliers in our sample provided 25 types of DTS to Medicare beneficiaries via non-mail order and 21 types of DTS via mail order. The suppliers in our samples provided eight types of DTS to Medicare beneficiaries both via non-mail order and mail order. The Medicare Improvements for Patients and Providers Act of 2008 prohibits CMS from awarding contracts in the National Mail-Order Program to a supplier of DTS if the supplier's bid does not cover at least 50 percent, by volume, of all types of DTS provided to Medicare beneficiaries. OIG's analysis assists CMS in determining whether bidding suppliers meet this 50-percent rule.

This report contains no recommendations.

*The Majority of Providers Reviewed Used Medicare Part D Eligibility Verification Transactions for Potentially Inappropriate Purposes (A-05-17-00020), February 2020*

The majority of providers reviewed (25 of 30) used Medicare Part D eligibility verification transactions (E1 transactions) for some purpose other than to bill for a prescription or determine drug coverage billing order. On average, 98 percent of these 25 providers' E1 transactions were not associated with a prescription. We did not contact 10 providers because they were closed, under investigation, or both. Fifteen providers submitted or hired other entities to submit E1 transactions for inappropriate purposes, which involved using a beneficiary's protected health information.

After our audit period, CMS took additional steps to monitor use of the eligibility verification system and take appropriate enforcement action when abuse is identified.

The deficiencies we identified occurred because CMS had not yet (1) fully implemented controls to monitor providers submitting a high number of E1 transactions relative to prescriptions processed



until after our audit period, (2) published clear guidance that E1 transactions are not to be used for marketing purposes, and (3) limited nonpharmacy access.

CMS concurred with our recommendations that it (1) continue to monitor providers submitting a high number of E1 transactions relative to prescriptions processed, (2) issue guidance that clearly states that E1 transactions should not be used for marketing purposes, (3) ensure that only pharmacies and other authorized entities submit E1 transactions, and (4) take appropriate enforcement action when abuse is identified.

*Key Medicare Tools To Safeguard Against Pharmacy Fraud and Inappropriate Billing Do Not Apply to Part D (OEI-02-15-00440), March 2020*

Part D does not have three key tools to protect against pharmacy fraud that are available in other parts of Medicare: pharmacy enrollment, revocation, and preclusion. These three tools apply to pharmacies only when they bill Parts B or C, not when they bill Part D. We continue to recommend that CMS require pharmacies that bill Part D to enroll in the Medicare program. This was an integral part of a previous recommendation that CMS has yet to implement. CMS concurred with all three of our new recommendations, which were:

- Allow revocation of Medicare enrollment for inappropriate billing of Part D;
- Include on the Preclusion List pharmacies that inappropriately bill Part D; and
- Apply the Preclusion List payment prohibitions to pharmacies and other providers that dispense Part D drugs.

## Drug Pricing and Reimbursement

*Medicare Improperly Paid Suppliers an Estimated \$92.5 Million for Inhalation Drugs (A-09-18-03018), October 2019*

Not all suppliers complied with Medicare requirements when billing for inhalation drugs. For 81 of the 120 sampled claim lines, suppliers complied with the requirements; however, for the remaining 39 claim lines, 22 suppliers did not comply with documentation requirements. We found the following documentation-related deficiencies: incomplete, invalid, or missing detailed written orders (28 claim lines); incomplete proof of delivery (6 claim lines); incomplete refill requests (6 claim lines); and medical records not provided (1 claim line). (The total exceeds 39 because 2 claim lines had 2 deficiencies.)

Based on our sample results, we estimated that approximately \$92.5 million paid to suppliers for inhalation drugs was unallowable for Medicare reimbursement. Medicare contractor oversight was not sufficient to ensure that suppliers complied with documentation requirements.

CMS concurred with our recommendations that it (1) instruct the Medicare contractors to recover \$36,825 in overpayments for the 39 unallowable claim lines and notify the 22 suppliers associated

with those 39 claim lines so that those suppliers can exercise reasonable diligence to investigate and return any identified overpayments; (2) work with the durable medical equipment MACs to expand their review of suppliers' claims to include additional inhalation drugs; (3) provide additional training to suppliers on Medicare documentation requirements for inhalation drugs; and (4) identify suppliers that consistently bill for inhalation drugs that do not comply with Medicare documentation requirements, perform reviews of those suppliers, collect the amount overpaid for unallowable claims, and educate them on Medicare requirements for inhalation drugs.

*CMS's Implementation of a 2014 Policy Change Resulted in Improvements in the Reporting of Coverage Gap Discounts Under Medicare Part D (A-07-16-06067), January 2020*

The Coverage Gap Discount Program made manufacturer discounts equal to 50 percent of the negotiated price of applicable, covered Part D drugs available to Medicare Part D beneficiaries during CYs 2011 through 2018. Although CMS generally ensured that Part D sponsors accurately reported Coverage Gap discounts, we identified instances in which sponsors should have reported these discounts but did not. Specifically, for CYs 2013 and 2014, we identified \$1.1 million in Coverage Gap discounts that should have been invoiced to manufacturers but were not because the discounts were not reflected in the prescription drug event (PDE) records submitted by sponsors.

These discrepancies occurred because CMS did not always have the sponsor information it needed. For that reason, CMS was not always able to accurately, and in a timely manner, identify beneficiaries who were in the Coverage Gap. Effective January 1, 2014, a policy change enabled CMS to more easily identify PDEs that should have reflected Coverage Gap discounts. After implementation of the policy change, Employer Group Waiver Plans more accurately reported Coverage Gap discounts.

CMS concurred with our recommendations that it (1) verify that Part D sponsors adjusted PDE records for \$658,396 in validated Coverage Gap discounts and, of this amount, instruct the sponsors to remit \$363,287 to the beneficiaries and (2) research the remaining records for which we estimated missed Coverage Gap discounts totaling \$406,755 and instruct Part D sponsors to validate and adjust PDE records accordingly and remit applicable amounts to the beneficiaries.

## Medicaid Program Reports and Reviews

### Financial Management and Improper Payments

*Texas Did Not Ensure That Its Managed-Care Organizations Complied With Requirements Prohibiting Medicaid Payments for Services Related to Provider-Preventable Conditions (A-06-16-01001), October 2019*

Texas did not ensure that its Medicaid managed-care organizations (MCOs) complied with Federal and State requirements prohibiting payments to providers for inpatient hospital services related to treating certain provider-preventable conditions (PPCs). For our audit period, we identified Medicaid claims totaling \$29.4 million that contained PPCs for five MCOs. Of this amount, we determined that claims totaling \$12.7 million were in compliance with Federal and State regulations regarding nonpayment of PPCs. However, claims totaling \$16.7 million were not in compliance.

Texas's internal controls were not adequate to ensure that its MCOs complied with Federal and State requirements. Specifically, Texas (1) did not have policies and procedures to determine whether its MCOs complied with Federal and State requirements and provisions of the managed-care contract relating to the nonpayment of PPCs and (2) did not ensure that the MCOs' payment rates were based only on services that were covered in the State plan.

Texas generally agreed with our recommendations that it (1) work with the five MCOs to determine what portion of the \$16.7 million is unallowable for Federal Medicaid reimbursement, (2) prohibit payments for inpatient hospital services related to treating PPCs, (3) review all claims for inpatient hospital services that were paid after our audit period, (4) strengthen its monitoring of its MCOs, (5) ensure that all MCOs implement edits to appropriately reduce or deny claims for other PPCs, (6) consider allowing liquidated damages to be imposed on the five MCOs, and (7) allow itself to recoup funds from all MCOs when contract provisions and Federal and State requirements are not met.

*New Jersey Improperly Claimed Tens of Millions for Medicaid School-Based Administrative Costs Based on Random Moment Sampling That Did Not Meet Federal Requirements (A-02-17-01006)*, November 2019

The random moment sampling methodology New Jersey used to claim Medicaid school-based administrative costs did not meet Federal requirements. Specifically, it did not comply with statistical sampling requirements and was not adequately supported. Also, the methodology did not comply with New Jersey's approved cost allocation plan. In addition, New Jersey's coding of what school employees were doing during random moments was mostly incorrect or unsupported.

The random moment sampling methodology New Jersey used did not comply with Federal requirements because New Jersey disregarded CMS guidance and assurances it made to CMS. Therefore, we determined that New Jersey claimed \$63.8 million in unallowable Federal Medicaid reimbursement.

New Jersey disagreed with our findings but did not indicate concurrence or nonconcurrence with our recommendations that it refund \$63.8 million in Federal Medicaid payments and revise its random moment sampling methodology to comply with Federal requirements, its implementation plan, CMS guidance, and assurances it made to CMS.

*More Than One-Third of New Jersey's Federal Medicaid Reimbursement for Providing Community-Based Treatment Services Was Unallowable (A-02-17-01020), January 2020*

Of New Jersey's 100 sampled claims for Federal Medicaid reimbursement of payments for Programs of Assertive Community Treatment (PACT) services, 50 complied with Federal and State requirements, but 50 did not. Of the 100 claims, 21 contained more than 1 deficiency. We also identified potential quality-of-care issues related to PACT services. Specifically, PACT team psychiatrists associated with 33 of our sample claims did not provide the minimum amount of face-to-face psychiatric time required for their caseload. Also, despite defining the PACT program as rehabilitative, New Jersey did not require periodic reauthorizations or reevaluations of beneficiaries' program eligibility.

The deficiencies occurred because New Jersey did not inform PACT providers of all Federal and State requirements for providing PACT services and did not adequately monitor or have procedures in place to ensure that providers claimed PACT services in accordance with these requirements.

Based on our sample results, we estimated that New Jersey improperly claimed at least \$14.9 million in Federal Medicaid reimbursement.

New Jersey disagreed with our recommendation that it (1) refund \$14.9 million to the Federal Government, agreed to (2) reinforce program guidance to PACT providers, partly agreed to (3) improve its monitoring of the PACT program, and disagreed with our recommendation that it (4) consider developing regulations for periodic reassessments to determine whether beneficiaries continue to require PACT services.

*New York Claimed Tens of Millions of Dollars for Opioid Treatment Program Services That Did Not Comply With Medicaid Requirements Intended To Ensure the Quality of Care Provided to Beneficiaries (A-02-17-01021), February 2020*

New York claimed Federal Medicaid reimbursement for OTP services that did not comply with Federal and State requirements. Of the 150 claims in our random sample, 115 claims complied with Medicaid requirements, but 35 claims did not. In addition, of the 598 claims in our nonstatistical sample, 299 claims were billed in error. Based on our sample results, we estimated that New York improperly claimed at least \$39.3 million in Federal Medicaid reimbursement for OTP services during our audit period.

These improper claims occurred because providers (1) failed to maintain or provide documentation of OTP services, (2) did not ensure that OTP services were provided in accordance with beneficiaries' treatment plans, and (3) did not maintain signatures for OTP services. Further, although New York inspects providers to verify compliance with Federal and State Medicaid requirements, it did not ensure that its oversight prevented the errors identified by our audit.

New York did not indicate concurrence or nonconcurrence with our recommendations that it (1) refund \$39.3 million to the Federal Government, (2) ensure that providers comply with Federal and State requirements for providing and claiming reimbursement for OTP services, and (3) implement procedures to detect and prevent duplicate claims for OTP services.

*Michigan Made Capitation Payments to Managed Care Entities After Beneficiaries' Deaths (A-05-17-00048), February 2020*

We estimated that Michigan made unallowable capitation payments totaling at least \$39.9 million (\$27.5 million Federal share) to managed care entities on behalf of deceased beneficiaries during our audit period. Of the 100 capitation payments in our stratified random sample, Michigan made 99 unallowable payments totaling \$117,746 (\$79,348 Federal share).

The unallowable payments occurred because Michigan did not always identify and process Medicaid beneficiaries' death information. Although Michigan's Medicaid Management Information System (MMIS) and eligibility systems interfaced with State and Federal death files that identify dates of death, Michigan did not always identify those dates of death in its MMIS system, and the MMIS system and eligibility system did not share dates of death information with each other. Michigan also did not recover payments caused by dates of death not promptly identified in its MMIS system.

Michigan did not say whether it agreed or disagreed with our recommendations that it (1) refund \$27.5 million to the Federal Government; (2) identify and recover unallowable payments made to managed care entities during our audit period on behalf of deceased beneficiaries, which we estimated to be at least \$39.9 million; (3) identify capitation payments made on behalf of deceased beneficiaries before and after our audit period and repay the Federal share of amounts recovered; (4) strengthen its policies and procedures for identifying deceased beneficiaries to ensure that dates of death are recorded accurately and in a timely manner; and (5) ensure that capitation payments are recovered when a date of death is retroactively entered.

*New York Made Unallowable Payments Totaling More Than \$10 Million for Managed Care Beneficiaries Assigned Multiple Medicaid Identification Numbers (A-02-18-01020), February 2020*

New York improperly claimed Federal Medicaid reimbursement for Medicaid beneficiaries who were assigned more than one Medicaid identification (ID) number. Specifically, for 102 of the 103 beneficiary-matches in our sample, New York made managed care payments to different managed care organizations for the same beneficiary for the same month under different Medicaid ID numbers.

These errors occurred because (1) New York's procedures for identifying whether a Medicaid applicant had already been assigned a Medicaid ID number were not always followed, (2) system



queries were not adequate to ensure that all individuals with existing Medicaid ID numbers were identified, and (3) staff did not use all available resources to ensure that qualified applicants were not issued multiple Medicaid ID numbers.

Based on our sample results, we estimated that New York improperly claimed \$11.5 million in Federal Medicaid reimbursement for payments made on behalf of beneficiaries assigned more than one Medicaid ID number. We reduced this estimate to \$11.3 million because New York recovered some managed care payments after the start of our audit.

New York did not specifically indicate concurrence or nonconcurrence with our recommendations that it (1) refund \$11.3 million to the Federal Government, (2) identify and recover improper managed care payments made to different MCOs on behalf of beneficiaries with multiple Medicaid ID numbers and repay the Federal share of the amounts recovered, and (3) strengthen its procedures for determining whether an individual applying for Medicaid already has a Medicaid ID number.

*CMS Could Take Actions To Help States Comply With Federal Requirements Prohibiting Medicaid Payments for Inpatient Hospital Services Related to Provider-Preventable Conditions (A-09-18-02004)*, March 2020

In 2011, CMS issued Federal regulations prohibiting Federal Medicaid payments for services related to PPCs. The goal of the regulations is to improve quality of care by prohibiting payments for medical errors. Prior OIG audits of nine States found that none of them fully complied with Federal requirements. This audit found that CMS could take actions to (1) verify that all State plans fully comply with Federal requirements prohibiting Medicaid payments for inpatient hospital services related to treating PPCs and (2) issue clarifying guidance to address specific areas in which States did not comply with those requirements. If CMS does not verify that State plans fully comply with Federal requirements and provide clear guidance on these requirements, States may continue to struggle to prevent unallowable payments for PPCs and may not take measures to improve the quality of inpatient hospital services through the prevention of medical errors.

CMS concurred with our recommendations that it verify that all State plans comply with Federal requirements prohibiting payments for PPCs, issue a revised State plan preprint that contains all of the provisions identified in Federal requirements, issue clarifying guidance to States to help ensure that they identify and process claims containing PPCs correctly, understand how and when to apply the “reasonably isolate” language in Federal regulations, make the necessary corrections to the FY 2016 Medicare hospital-acquired conditions list, and work with States to ensure that their systems and processes for identifying PPCs use all diagnosis codes reported by inpatient hospitals.

## Quality of Care, Safety, and Access

*Pennsylvania Did Not Fully Comply With Federal and State Requirements for Reporting and Monitoring Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities (A-03-17-00202), January 2020*

*Iowa Did Not Comply With Federal and State Requirements for Major Incidents Involving Medicaid Members With Developmental Disabilities (A-07-18-06081), March 2020*

Pennsylvania and Iowa did not fully comply with Federal Medicaid waiver and State requirements for reporting and monitoring incidents involving Medicaid beneficiaries with developmental disabilities who resided in community-based settings. Specifically, Pennsylvania did not (1) ensure that community-based providers reported thousands of 24-hour reportable incidents within required timeframes, (2) ensure that community-based providers and county and regional investigators analyzed and investigated all beneficiary deaths, and (3) ensure that community-based providers referred all suspicious deaths to law enforcement.

Iowa did not (1) ensure that community-based providers reported all major incidents to the State, (2) ensure that community-based providers documented the resolution of reported major incidents to prevent or diminish the probability of future occurrences, (3) review Critical Incident Reports to determine trends, problems, and issues in service delivery, (4) ensure that community-based providers report all member deaths to the State, and (5) report all known major incidents to CMS.

Pennsylvania concurred with six of our recommendations that it improve its controls regarding the reporting and monitoring of 24-hour reportable incidents involving Medicaid beneficiaries with developmental disabilities residing in community-based settings. Pennsylvania did not concur with our recommendation that it record the 24-hour reportable incidents noted in our report.

Iowa concurred with our recommendations that it train community-based providers on how to identify, report, and appropriately document the resolution of all major incidents; perform trend analysis that identifies patterns and trends to assess the health and safety of members and determine whether changes or staff training are needed to prevent recurrences of major incidents and to reduce the number or severity of incidents; ensure that community-based providers report to Iowa all member deaths; include all major incidents reported by MCOs in Iowa's reports to CMS; and develop and implement internal controls adequate to ensure full compliance with Federal and State requirements.

*New York's Oversight of Medicaid Managed Care Organizations Did Not Ensure Providers Complied With Health and Safety Requirements at 18 of 20 Adult Day Care Facilities Reviewed (A-02-18-01027), March 2020*

New York's oversight of Medicaid MCOs did not ensure that 18 of the 20 adult day care services providers we audited complied with Federal and State health and safety requirements. Specifically,

we found 476 instances of noncompliance with requirements for staff training, physical environment and safety, emergency preparedness, and staff health status.

The instances of noncompliance occurred because the MCOs did not adequately monitor their contracted providers to ensure compliance with health and safety requirements. Specifically, we found that the survey tools and procedures used during the MCOs' required annual site visits to providers were not adequate. Further, New York's oversight of the MCOs did not include obtaining or reviewing the results of the site visits, which would be necessary to verify the MCOs' compliance with health and safety requirements.

These deficiencies could have significantly impacted the health and safety of vulnerable Medicaid beneficiaries.

New York did not indicate concurrence or nonconcurrence with our recommendations that it (1) ensure that the MCOs work with their contracted adult day care services providers to correct the 476 instances of noncompliance with health and safety requirements that we identified, (2) require MCOs to improve their site visit procedures to ensure compliance with health and safety requirements detailed in New York's CMS-approved MCO contract and New York's regulations on adult day care programs, and (3) obtain and review the results of MCO site visits at adult day care facilities as part of its beneficiary health and safety monitoring activities.

## Program Integrity

*Most of the Non-Newly Eligible Beneficiaries for Whom Colorado Made Medicaid Payments Met Federal and State Requirements, but Documentation Supporting That All Eligibility Requirements Were Verified Properly Was Not Always in Place (A-07-18-02812), March 2020*

Most of the Medicaid payments that Colorado made during our audit period were on behalf of non-newly eligible beneficiaries who met Federal and State eligibility requirements. However, Colorado made Medicaid payments on behalf of some non-newly eligible beneficiaries who may not have met Federal and State eligibility requirements. Colorado correctly determined eligibility and, therefore, correctly claimed Federal Medicaid reimbursement, on behalf of 135 of the 140 beneficiaries in our statistical sample. For the remaining five beneficiaries, Colorado had no documentation (specifically, that it had performed annual verifications of resources) to support that all eligibility requirements were verified properly during redeterminations as required by Federal and State regulations and by Colorado's State Medicaid plan. Although Colorado had policies and procedures in place, it did not always follow them to ensure that redeterminations were properly documented.

On the basis of our sample results, we estimated that Colorado made Medicaid payments of at least \$46.7 million (\$23.8 million Federal share) on behalf of at least 3,603 potentially ineligible beneficiaries.

Colorado agreed with our recommendations that it redetermine, as appropriate, the current Medicaid eligibility of the potentially ineligible sampled beneficiaries and ensure that (1) all eligibility requirements, including those pertaining to resources, are properly verified during annual redeterminations for all non-newly eligible beneficiaries and (2) information is maintained to support that eligibility determinations were performed in accordance with Federal and State requirements.

*States Could Do More To Prevent Terminated Providers From Serving Medicaid Beneficiaries (OEI-03-19-00070), March 2020*

Nearly 1,000 terminated providers—or 11 percent of all terminated providers—were inappropriately enrolled in State Medicaid programs or were associated with \$50.3 million in Medicaid payments. Despite legislative requirements in the 21st Century Cures Act designed to strengthen Medicaid program integrity, terminated providers continue to serve Medicaid beneficiaries. Some of these providers were terminated for criminal convictions, licensure issues, and provider misconduct, representing a risk to beneficiaries' safety and their quality of care. In addition, only eight States' managed care contracts all clearly included the provision—required by the Cures Act—that prohibits terminated providers from participating in Medicaid managed care networks. This vulnerability may allow terminated providers to serve Medicaid beneficiaries and reduce States' ability to limit these providers' participation in Medicaid managed care networks.

CMS concurred with all six of our recommendations, which were:

- Recover from States the Federal share of inappropriate fee-for-service Medicaid payments associated with terminated providers,
- Implement a method to recover from States the Federal share of inappropriate managed care capitation payments associated with terminated providers,
- Follow up with States to remove terminated providers that OIG identified as inappropriately enrolled in Medicaid,
- Confirm that States do not continue to have terminated providers enrolled in their Medicaid programs,
- Safeguard Medicaid from inappropriate payments associated with terminated providers, and
- Review States' contracts with Medicaid managed care organizations to ensure that they clearly and specifically include the required provision that prohibits terminated providers from participating in Medicaid managed care networks.

*Twenty-Three States Reported Allowing Unenrolled Providers To Serve Medicaid Beneficiaries (OEI-05-19-00060), March 2020*

We found that 23 States had not enrolled all Medicaid providers. Of the 27 States that reported enrolling all providers, 16 reported lacking enrollment processes or enforcement controls to ensure ongoing compliance with Federal provider enrollment requirements. When States do not enroll and screen providers, Medicaid beneficiaries are exposed to potentially harmful providers.

CMS concurred with our recommendations, which were:

- Take steps to disallow Federal reimbursements to States for expenditures associated with unenrolled MCO network providers, including seeking necessary legislative authority;
- Work with States to ensure that unenrolled MCO network providers do not participate in Medicaid managed care and assist States in establishing ways to do so;
- Work with States to ensure that they have the controls required to prevent unenrolled ordering, referring, or prescribing providers from participating in Medicaid fee-for-service; and
- Work with States to ensure that they are complying with requirements to collect identifying and ownership information on Medicaid provider enrollment forms.

## Drug Pricing and Reimbursement

*New York Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs (A-02-18-01011), February 2020*

New York did not always comply with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. Specifically, New York did not invoice manufacturers for rebates associated with \$3.3 million (Federal share) in single-source and top-20 multiple-source physician-administered drugs. Although New York's policies and procedures require the collection of utilization data necessary to invoice for rebates on all claims, its internal controls did not always ensure that the data were used to invoice manufacturers to secure rebates.

Further, New York did not submit the drug utilization data necessary to secure rebates for claims associated with all other physician-administered drugs. These drugs were included in claims totaling \$2.3 million (Federal share) that did not have drug codes and in claims totaling \$714,777 (Federal share) that contained drug codes.

New York generally agreed with our recommendations that it (1) refund to the Federal Government \$3.3 million for single-source and top-20 multiple-source physician-administered drugs, (2) work with CMS to determine the unallowable portion of the \$3 million for other drug claims in question, and (3) strengthen its internal controls to ensure that all physician-administered drugs eligible for rebates are invoiced.

## Centers for Medicare & Medicaid Services

*The Centers for Medicare & Medicaid Services Could Improve Its Processes for Evaluating and Reporting Payment Recovery Savings Associated With the Fraud Prevention System (A-01-15-00510), October 2019*

The Fraud Prevention System's (FPS's) adjusted savings for overpayment determinations and law enforcement referrals were approximately 10 percent of the identified savings for its second and third implementation years because (1) the MACs' opportunities to collect FPS-identified overpayments were often limited by both the time it took to get referrals from the Zone Program Integrity Contractors and Program Safeguard Contractors (Contractors) and by unique challenges in attempting to recover overpayments from providers and (2) CMS has not established a standard process for the Program Integrity Contractors to estimate the value of law enforcement referrals.

CMS's reported FPS savings and return on investment (ROI) after the third implementation year gave stakeholders an incomplete picture of the FPS's value because CMS has continued to rely primarily on identified savings for its reporting. Historically, the overwhelming majority of the identified savings from payment recovery administrative actions have not been recovered. Reporting adjusted savings and the corresponding adjusted ROI in addition to identified savings would provide a more complete picture of the value of the FPS.

CMS concurred with our recommendations that it (1) continue to work with the Contractors and the MACs to develop strategies that improve timely coordination to give the MACs a better opportunity to recover overpayments, (2) establish a uniform methodology for the Contractors to use when reporting estimates for the value of law enforcement referrals, and (3) update the FPS's law enforcement referral adjustment factor.

*Hospitals Received Millions in Excessive Outlier Payments Because CMS Limits the Reconciliation Process (A-05-16-00060), November 2019*

From FYs 2011 through 2014, CMS paid 60 hospitals that had received \$3.5 billion in outlier payments a net of \$502 million more than the hospitals would have been paid if their outlier payments had been reconciled. (We refer to this net amount as excessive outlier payments.) CMS did not detect or recover these excessive outlier payments because the 236 associated cost reports did not meet the 10-percentage-point threshold for reconciliation.

The cost reports did not meet CMS's 10-percentage-point threshold because when hospitals increased their charges at a rate higher than that of cost increases, this usually resulted in only a small percentage-point change in their cost-to-charge ratios. CMS set the 10-percentage-point threshold because it believed that the threshold would appropriately capture those hospitals whose outlier payments would be substantially inaccurate when the hospital uses the ratio from the contemporaneous cost-reporting period. Based on the estimated time and costs that we



received from 7 MACs, we estimate that the administrative burden on the MACs to reconcile the 236 cost reports that did not meet the 10-percentage-point threshold would be a minimum of \$11,800 and a maximum of \$425,000 per year.

CMS concurred with our recommendation that it require reconciliation of all hospital cost reports with outlier payments during a cost-reporting period. If this had been in effect for the 60 hospitals in our review, CMS would have saved approximately \$125 million per year.

*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 (A-03-16-03001), February 2020*

CMS correctly obligated and expended funds for 62 of the 74 Federal marketplace contracts we reviewed. For the remaining 12 contracts, CMS did not obligate and expend funds in compliance with applicable laws and requirements.

These errors resulted in potential, unreported Antideficiency Act obligation violations totaling \$164.6 million (\$155.9 million related to the Federal marketplace) and expenditure violations totaling \$22.4 million (\$18.3 million related to the Federal marketplace). In addition, for three contracts, CMS failed to record obligations totaling \$2.9 million in a timely manner. Failure to record obligations in a timely manner can result in Antideficiency Act violations.

CMS did not specifically concur with our recommendations that it (1) correct the bona fide needs obligation violations totaling \$164.6 million (\$155.9 million related to the Federal marketplace) and, if CMS is unable to correct those violations, report the Antideficiency Act violations; (2) correct the bona fide needs expenditure violations totaling \$22.4 million (\$18.3 million related to the Federal marketplace) and, if CMS is unable to correct those violations, report the Antideficiency Act violations; (3) coordinate with HHS, in consultation with the Office of the General Counsel, to develop guidance and train Office of Financial Management personnel on the correct process to record obligations and expenditures to avoid potential Antideficiency Act violations; and (4) develop automated controls in the Healthcare Integrated General Ledger Accounting System to ensure that contract expenditures for each program year are paid using appropriate program-year obligations.

*California Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety and Emergency Preparedness (A-09-18-02009), November 2019*

*Life Safety and Emergency Preparedness Deficiencies Found at 18 of 20 Texas Nursing Homes (A-06-19-08001), February 2020*

*Florida Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety and Emergency Preparedness (A-04-18-08065), March 2020*

*Missouri Should Improve Its Oversight of Selected Nursing Homes' Compliance With Federal Requirements for Life Safety and Emergency Preparedness (A-07-18-03230), March 2020*

We reviewed selected nursing homes in California, Texas, Florida, and Missouri that received Medicare funds, Medicaid funds, or both, to determine whether the nursing homes complied with Federal requirements for life safety and emergency preparedness.

During our site visits in California, we identified deficiencies at all 19 nursing homes that we audited. Specifically, we found 137 instances of noncompliance with life safety requirements and 188 instances of noncompliance with emergency preparedness requirements. In Texas, we identified deficiencies at 18 of the 20 nursing homes that we audited. Specifically, we found 235 instances of noncompliance with life safety requirements and 55 instances of noncompliance with emergency preparedness requirements. In Florida, we identified deficiencies at all 20 nursing homes that we reviewed. Specifically, we found 100 instances of noncompliance with life safety requirements and 87 instances of noncompliance with emergency preparedness requirements. In Missouri, we identified deficiencies at all 20 nursing homes that we audited. Specifically, we found 178 areas of noncompliance with life safety requirements and 149 areas of noncompliance with emergency preparedness requirements.

The identified deficiencies occurred because nursing homes lacked adequate management oversight and had high staff turnover. In addition, California did not adequately follow up on deficiencies previously cited, ensure that surveyors were consistently enforcing CMS requirements, or have a standard life safety training program for all nursing home staff. Texas indicated that building maintenance is challenging because of the advanced age of some buildings. Florida did not have a standard life safety training program for all nursing home staff and generally performed life safety surveys no more frequently than once every 12 to 15 months. Missouri did not adequately follow up on deficiencies previously cited.

California partly agreed with our recommendations that it follow up with the 19 nursing homes to ensure that corrective actions have been taken regarding the deficiencies we identified and ensure that all surveyors consistently enforce CMS requirements. Texas agreed with our recommendation that it follow up with the 18 nursing homes to verify that corrective actions have been taken regarding the life safety and emergency preparedness deficiencies we identified. Florida partly agreed with our recommendations that it follow up with the 20 nursing homes to ensure that corrective actions have been taken regarding the deficiencies we identified, work with CMS on developing life safety training for nursing home staff, and conduct more frequent surveys at nursing homes with a history of multiple high-risk deficiencies and follow up to ensure that corrective actions have been taken. Missouri generally disagreed with our recommendations that it follow up with the 20 nursing homes to ensure that corrective actions have been taken, develop standardized life safety training for nursing home staff, conduct more frequent surveys and

followup at nursing homes with a history of multiple high-risk deficiencies, and update facility-specific plans.

*The Federal Marketplace Properly Determined Individuals' Eligibility for Enrollment in Qualified Health Plans but Improperly Determined That an Estimated 3 Percent of Individuals Were Eligible for Insurance Affordability Programs (A-09-18-01000), February 2020*

For our sample of 110 of 7.5 million individuals, the Federal marketplace properly determined that all 110 individuals were eligible for enrollment in qualified health plans and that 102 individuals were eligible for insurance affordability programs. However, for the remaining eight individuals, the marketplace improperly determined that three individuals were eligible and may have improperly determined that five individuals were eligible.

On the basis of our sample results, for the 2018 coverage year, we estimated that the Federal marketplace (1) improperly determined that 191,896 (3 percent) of the 7.5 million individuals were eligible for insurance affordability programs and (2) may have improperly determined that 402,207 individuals (5 percent) of the 7.5 million were eligible for those programs. We also identified a weakness in the Federal marketplace's procedures related to determining eligibility for insurance affordability programs.

CMS agreed with our recommendations that it ensure the Federal marketplace (1) corrects errors in its eligibility and enrollment system, (2) establishes guidance to exclude income from other gains on an individual's Federal tax return, and (3) performs subsequent verifications for an individual who failed to file taxes on time. CMS disagreed with our recommendations that it (1) redetermine the eligibility of the eight sampled individuals who may not have been eligible, (2) ensure that the Federal marketplace revises its written guidance so that it does not extend an individual's inconsistency period, and (3) require an individual to submit supporting documentation when he or she attests to having filed a tax return to reconcile a previous year's premium tax credit payments.

# 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; the 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 412 criminal and 367 civil actions against individuals or entities that engaged in offenses related to health care. We also reported over \$1.3 billion in investigative receivables due to HHS and more than \$191.2 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.

## Patient Abuse

The following case example involves patient abuse:

**South Dakota**—Dr. Stanley Patrick Weber was convicted of multiple sex offenses against children. Evidence at trial established that Weber, while employed as a pediatrician with the Indian Health Service at Pine Ridge, South Dakota, sexually abused multiple Native American children between 1999 and 2011. Weber was sentenced to 5 consecutive life sentences in Federal prison for the five aggravated sexual abuse charges, and 15 years on each of the three counts of sexual abuse of a minor. All of these sentences are to be served consecutively to each other, and also consecutive to his previous sentence in the District of Montana of 18 years in Federal prison. Weber was also ordered to pay \$800,000 in criminal fines and an \$800 special assessment to the Federal Crime Victims Fund.

## Prescription Drugs

The following case example involves prescription drugs:

**Virginia**—Dr. Joel Smithers was convicted on 861 Federal counts of drug distribution, including distribution resulting in death, for operating a “pill mill.” Evidence presented at trial showed Smithers opened an office in Martinsville, Virginia, in August 2015, and prescribed controlled substances to every patient in his practice, resulting in over 500,000 Schedule II controlled substances being distributed. The drugs involved included oxycodone, oxycodone, hydromorphone, and fentanyl. A majority of those receiving prescriptions from Smithers traveled hundreds of miles, one-way, to receive the drugs. His office lacked basic medical supplies, his receptionist lived out of a back room during the work week, and many patients slept outside and urinated in the parking lot. At trial, one woman, who described herself as an addict, compared Smithers’ practice to pill mills she frequented in Florida where she received medication without any kind of physical exam or medical records. Patients who came to the office would wait up to 12 hours to see Smithers, who regularly kept his office open past midnight. Smithers did not accept insurance and took in over \$700,000 in cash and credit card payments prior to a search warrant being executed at his office on March 7, 2017. Smithers caused West Virginia Medicaid to pay \$469,220 and Medicare Part D to pay \$775,479 in suspected fraudulent prescriptions. Smithers was found guilty of 1 count of maintaining a place for the purpose of illegally distributing controlled substances, 1 count of possession with the intent to distribute controlled substances, and 859 counts of illegally prescribing Schedule II controlled substances, and was sentenced to 40 years in prison.

## Pharmacies

The following case example involves a pharmacy:

**Florida**—A doctor, pharmacists, and marketers in a compounding pharmacy scheme were sentenced for conspiring to pay and receive health care kickbacks for prescriptions for compounded creams billed to TRICARE, Medicare, and private insurance. According to court documents, in 2014 and 2015, the marketing firm Centurion was operated by Frank V. Monte and Kimberly S. Anderson. Centurion employed sales representatives to market compounded prescription medications, specifically, creams for pain and scars, to beneficiaries of health care plans, especially TRICARE. In May 2014, Centurion entered into an exclusive, illegal kickback arrangement with LifeCare pharmacy, owned by Carlos Mazariegos and Benjamin Nundy, whereby Centurion and LifeCare agreed to share equally in the profits from the claims paid by health benefit programs for compounded medications prescribed to beneficiaries. Baldizzi agreed with Monte, Anderson, Mazariegos, and Nundy, that, in exchange for kickbacks, he would write prescriptions for compounded creams marketed by Centurion to TRICARE beneficiaries. Between May and November 2014, LifeCare billed health insurers more than \$12.4 million for compounded cream prescriptions written by Baldizzi and marketed by Centurion. Even after LifeCare closed and Baldizzi withdrew from the conspiracy, Centurion transferred the existing refills from Baldizzi's prescriptions to a new pharmacy, which filled the prescriptions and billed TRICARE. In all, Centurion caused TRICARE to be billed more than \$50 million for compounded creams prescribed to patients that it had recruited. The five codefendants involved in the scheme were sentenced to a combined 5 years, 6 months, and 2 days in prison and ordered to pay \$6.4 million in restitution.

## Mental Health

The following case example involves mental health:

**Ohio**—Ryan P. Sheridan, owner and operator of Braking Point Recovery Center, was convicted of charges from his involvement in a \$48 million scheme to defraud Medicaid. Sheridan was the sole owner of Braking Point Recovery Center, which operated drug and alcohol rehabilitation centers in Austintown and Whitehall, Ohio, that provided detox, intensive outpatient treatment, day treatment, and residential living rehabilitation. Sheridan also owned and operated numerous other businesses, including Braking Point Health and Fitness LLC and Braking Point Recovery Housing LLC, which owned recovery houses (or "sober houses") for individuals attempting to maintain abstinence from drugs and alcohol. According to court documents, between January 12, 2015 and October 18, 2017, Sheridan and his codefendants submitted or caused to be submitted billings to Medicaid for drug and alcohol services that were: coded to reflect a service more costly than was actually provided; without proper documentation; without proper assessment documents containing valid diagnosis; billings for patients whose records did not contain diagnosis by a physician; related to treatment at unlicensed inpatient beds; billings related to dispensing of Suboxone, even though the treating physician did not have the authority to do so; for



case management services when, in fact, the clients were working out at Sheridan's gym; billings based on quotas provided to the nurses by the defendants to bill 4 to 5 hours of treatment daily, even if the services were not medically necessary; billing for inpatient detox and drug treatment services that were, in fact, provided in an outpatient setting, among other violations. Sheridan and his codefendants developed a standard protocol of distributing the same amount of Suboxone to every patient seeking drug treatment immediately upon entering Braking Point's detox program without being evaluated by a properly licensed physician to determine the medical necessity for the use of Suboxone. Sheridan had the treating physician use another physician's DEA data waiver license to dispense more than 3,000 doses of Suboxone in 2017 alone without the data waiver physician having seen the patients. Sheridan pleaded guilty to 60 counts related to health care fraud and controlled substances and was sentenced to 7 years and 6 months in prison and ordered to pay \$24.4 million in restitution, joint and several. Three defendants involved in the scheme were sentenced to probation for their role.

## Electronic Health Records

The following case example involves electronic health records (EHRs):

**California**—On January 26, 2020, Practice Fusion, Inc. (Practice Fusion), a health IT software company, entered into a \$113,374,962 False Claims Act settlement agreement with the United States. The settlement agreement resolves allegations that Practice Fusion falsely represented to its Office of National Coordinator Authorized Certification Body (ONC-ACB) that its EHR software products met certification criteria under ONC's Health IT Certification Program. Practice Fusion knew that use of certified software is a requirement for eligible health care providers to receive incentive payments under the CMS EHR Incentive Payment Programs (aka the "Meaningful Use programs"). Consequently, Practice Fusion knowingly caused eligible health care providers, who used certain versions of its EHR software, to falsely attest to compliance with CMS requirements necessary to receive Medicare and Medicaid incentive payments. In addition, the settlement agreement resolves allegations that Practice Fusion knowingly and willfully solicited and received illegal remuneration from pharmaceutical manufacturers, in exchange for influencing and implementing clinical decision support (CDS) alerts in its EHR software, which did not always reflect accepted medical standards, and were designed to increase prescriptions for their drug products in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. These CDS alerts could influence health care providers to prescribe the pharmaceutical manufacturers' drugs resulting in kickback tainted claims being submitted to Medicare, Medicaid, and TRICARE, in violation of the False Claims Act. Practice Fusion has also executed a deferred prosecution agreement (DPA) and agreed to pay over \$26 million in criminal fines and forfeiture. In the DPA, Practice Fusion admits that it solicited and received kickbacks from a major opioid company in exchange for utilizing its EHR software to influence physician prescribing of opioid pain medications.

## Laboratories

The following case example involves a laboratory:

**South Carolina**—On October 23, 2019, Myriad Genetics, Inc. (Myriad) entered into an \$8,250,000 settlement agreement with a Relator to resolve allegations that Myriad inappropriately billed genetic testing, specifically their Integrated BRACAnalysis and their myRisk test, using the wrong procedure codes and modifiers to obtain higher reimbursement. Of the \$8,250,000 settlement agreement, \$3,513,849 is restitution for the Medicare Part B program and \$1,159,536 is payment to HHS due to multiple damages. HHS OIG OI will be reimbursed \$46,720 in investigative costs.

## Home Health Agencies

The following case example involves home health agencies:

**Florida**—Rodolfo and Marta Pichardo were sentenced to prison for their roles in a \$38 million health care fraud and wire fraud scheme. According to court documents, the Pichardos built a vast empire of fraud, consisting of at least six fraudulent home health agencies, three fraudulent therapy staffing companies, and two fraudulent pharmacies. Each of these entities purportedly provided home health services, therapy services, and prescription drugs, respectively, to qualified Medicare beneficiaries, though in fact they did not. From May 2010 through September 2016, the Pichardos and their co-conspirators used this empire to submit more than \$38 million in fraudulent claims to Medicare, for which the trust-based program then paid out more than \$33 million. The Pichardos then used this money to purchase multiple properties, high-end vehicles, expensive jewelry, plane tickets, vacations, cosmetic procedures, and more, both for themselves and their family members. As part of the scheme, Rodolfo Pichardo offered and paid kickbacks, both by cash and by check, to numerous patient recruiters, in exchange for the referral of Medicare beneficiaries to home health agencies that he owned. The conspirators also offered and paid cash kickbacks to owners and operators of multiple Miami-Dade medical clinics, in return for acquiring medically unnecessary home health prescriptions for the recruited Medicare beneficiaries. These prescriptions were then used by the Pichardos' various home health agencies and pharmacies to bill Medicare for purported services and pharmaceutical drugs that were provided to allegedly qualified Medicare beneficiaries. Rodolfo and Marta were sentenced to a total of 23 years and 8 months in prison and ordered to pay \$33.8 million in restitution, joint and several with a codefendant. Four defendants involved in the scheme were previously sentenced to a combined 12 years and 1 month in prison and ordered to pay \$135,245 in restitution.

## DME Company

The following case example involves a DME company:

**California**—On December 19, 2019, ResMed Corp. (ResMed) agreed to pay more than \$37.5 million under a False Claims Act settlement agreement with the United States. The settlement agreement resolves allegations that ResMed (1) provided DME companies with free telephone call center services and other free patient outreach services that enabled these companies to order resupplies for their patients with sleep apnea; (2) provided sleep labs with free and below-cost positive airway pressure masks and diagnostic machines, as well as free installation of these machines; (3) arranged for, and fully guaranteed the payments due on, interest-free loans that DME supplies acquired from third-party financial institutions for the purchase of ResMed equipment; and (4) provided non-sleep specialist physicians free home sleep testing devices referred to as “ApneaLink.” ResMed agreed to enter into a 5-year CIA with OIG in conjunction with the settlement.

## Hospital

The following case example involves a hospital:

**Kentucky**—On October 30, 2019, Jewish Hospital and St. Mary’s Healthcare, Inc. d/b/a Pharmacy Plus and Pharmacy Plus Solutions (collectively, Jewish Hospital) entered into a \$10,101,132 False Claims Act settlement agreement with the United States. The settlement agreement resolves allegations that Jewish Hospital submitted claims to Medicare Part B for prescriptions drugs that did not meet Medicare coverage requirements for a detailed written order or did not contain documentation supporting the prescription refill. The agreement also resolves allegations that Jewish Hospital provided improper remuneration to Medicare beneficiaries in the form of free blood glucose testing supplies, and waiver of copayments and deductibles for insulin.

## Kickbacks

The following case example involves kickbacks:

**South Dakota**—On October 28, 2019, Sanford Health, Sanford Clinic, and Sanford Medical Center (collectively, Sanford) entered into a \$20,250,000 False Claims Act settlement agreement with the United States. The settlement agreement resolves allegations that Sanford knowingly submitted false claims to Federal health care programs predicated on illegal kickbacks. Specifically, the United States alleged that a Sanford physician solicited and received improper remuneration, including profit distributions, from various physician-

owned distributorships in exchange for the Sanford physician's use of certain products. Sanford agreed to enter into a 5-year CIA with OIG in connection with the settlement.

## Nonprofit Organization

The following case example involves a nonprofit organization:

**Massachusetts**—The Assistance Fund, Inc. (TAF) entered into a civil settlement agreement with the United States under which it agreed to pay \$4 million. TAF is a nonprofit foundation that receives funding from pharmaceutical manufacturers and then uses the funds, less administrative fees, to cover the drug copay obligations of patients, including Medicare patients. Through the settlement, TAF resolved allegations that it violated the False Claims Act by enabling pharmaceutical manufacturers to pay kickbacks (in the form of copayment assistance) to Medicare patients taking the drugs of drug manufacturers that donated monies to TAF. More specifically, the United States alleged that TAF conspired with three pharmaceutical manufacturers to enable them to pay kickbacks to Medicare patients taking the manufacturers' drugs. TAF agreed to enter a 3-year Integrity Agreement with OIG in connection with the settlement.

## Nursing Home

The following case example involves a nursing home:

**Nevada**—On October 25, 2019, Encompass Health Corp. (formerly known as HealthSouth Corporation); Encompass Health Rehabilitation Hospital of Henderson, LLC (EHRHH); and Kenneth Bowman (Bowman) (collectively, Encompass) entered into a False Claims Act settlement agreement with the United States. Encompass agreed to pay \$4 million to resolve allegations that Encompass filed improperly coded claims for Inpatient Rehabilitation Facility (IRF) services provided at HealthSouth Henderson, Inc. (HHI). Specifically, the United States alleged that Encompass, through HHI, submitted false claims to Medicare because HHI had improperly assigned inaccurate and artificially low admission Functional Independence Measure scores on Patient Assessment Instrument forms (IRF-PAIs) for some of its patients, resulting in HHI receiving greater reimbursement for its services for those patients than was warranted.

## Occupational Therapy

The following case example involves occupational therapy:

**New York**—Dr. Paul Mathieu was sentenced for his participation in a \$30 million scheme to defraud Medicare and the New York State Medicaid Program. Between 2007 and 2013, Mathieu falsely posed as the owner of three medical clinics, which were actually owned by

a corrupt businessman, and falsely claimed that he had examined and treated thousands of patients whom he had not in fact seen. Mathieu was convicted in on charges of health care fraud, wire fraud, mail fraud, conspiracy to commit those offenses, and conspiracy to make false statements in connection with a Federal health care program. Between 2007 and 2013, Aleksandr Burman owned and operated six medical clinics in Brooklyn that fraudulently billed Medicare and Medicaid for medical services and supplies that were not provided, were provided without regard to medical necessity, or were otherwise fraudulently billed. Under New York State law, professional medical corporations must be owned by a medical professional. To circumvent this requirement, Burman and Mathieu agreed to have Mathieu pose as the true owner of a succession of three different clinics, which Burman owned and operated for more than 5 years, from 2007 through 2013. Throughout those years, Mathieu signed a variety of fraudulent documents that falsely represented to banks, Medicare, Medicaid, and others that Mathieu was the sole owner of The Medical Office of Paul J. Mathieu, P.C.; Sunlight Medical, P.C.; and Ocean View Medical of Brooklyn, P.C. Burman also hired two other doctors, Ewald J. Antoine and Mustak Y. Vaid, to pose fraudulently as the owners of three additional, related clinics. Mathieu also came weekly to several of the clinics, where he signed stacks of false and fraudulent medical charts, and issued referrals for expensive additional testing, occupational therapy, and physical therapy. For the last 3½ years of the scheme, Mathieu saw no patients at all, simply falsifying enormous stacks of phony medical records falsely stating that he had seen and treated such patients. In addition to his role in the clinics, Mathieu also wrote unneeded prescriptions for adult diapers and other incontinence products, which prescriptions were filled at Universal Supply Depot, a medical supply company also owned by Burman. Mathieu was so prolific in this regard that, throughout the period of the fraud, he was the No. 1 top prescriber of adult diapers in the State of New York. Mathieu continued to write such prescriptions, even after the medical clinics closed after Medicare stopped paying any of the clinics' claims. Mathieu was convicted on charges of health care fraud, wire fraud, mail fraud, conspiracy to commit those offenses, and conspiracy to make false statements in connection with a Federal health care program and was sentenced to 4 years in prison and ordered to pay \$16.3 million in restitution, joint and several. Nine codefendants involved in the scheme were previously sentenced to a combined 26 years and 8 months in prison.

## State Agency

The following case example involves a state agency:

**Louisiana**—On November 4, 2019, the Louisiana Department of Health (LDH) entered into a \$13,442,550.96 False Claims Act settlement agreement with the United States. LDH is the State agency that administers the Louisiana Medical Assistance Program, known as the Louisiana Medicaid Program. The settlement agreement resolves allegations that LDH falsely claimed expenditures in connection with long-term care, hospice, and adult day care

services on four CMS-64 reports submitted to CMS. LDH's conduct resulted in the state receiving a higher amount of the Federal financial participation reimbursement, or Federal share, than it was entitled to receive. In connection with the settlement, LDH agreed to enter into a 3-year State Agency Compliance Agreement with OIG, the first-of-its-kind compliance agreement with a Medicaid agency. The State Agency Compliance Agreement will require LDH to engage an Independent Review Organization to conduct Quarterly Medicaid Assistance Expenditures Reviews.

## 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 86 individuals or entities, 118 criminal actions, and more than \$262.4 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 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 examples involve Strike Force cases:

**Florida**—Raymond Shores was convicted of charges resulting from his involvement in a scheme to defraud Medicare and TRICARE. Shores owned and operated several durable medical equipment supplier companies in Florida, California, and Georgia, which included: Alliance Medical Supplies, LLC; Empire Medical Equipment and Supplies, LLC; Hogan Prosthetics & Orthotics Inc.; Bradley Healthcare Group, Inc.; Universal Healthcare Group DME, Inc.; Atlantic Coastal Medical Supplies, LLC; and Arbor Medical Equipment, Inc. According to court documents, from approximately November 2015 through March 2019, Shores and his codefendants paid kickbacks and bribes in exchange for signed doctors' orders for orthotic braces that were not medically necessary. The



combined billed amount for both Medicare and TRICARE is \$125.1 million and the combined paid amount is \$70.3 million. Shores pleaded guilty to conspiracy to commit health care fraud and was sentenced to 6 years and 8 months in prison and ordered to pay restitution of \$70.3 million (which includes \$69.6 million to Medicare Part B and \$751,406 to TRICARE), joint and several with other co-conspirators. Shores was also ordered to forfeit \$35.1 million.

**Florida**—Three former co-owners and clinical directors of a group of purported substance abuse treatment centers and sober homes were sentenced to prison for their roles in a conspiracy to commit health care fraud and wire fraud in which the conspirators sought to obtain more than \$21 million. According to court documents, from June 2016 through April 2019, Ali Ahmed, Sebastian Ahmed, and Mauren Morel submitted and caused others to submit, via interstate wire communications, approximately \$1.6 million in claims that falsely represented that various health care benefits, primarily substance abuse Partial Hospitalization Program (PHP), Intensive Outpatient Program (IOP), and Outpatient Program (OP) services, were medically necessary, prescribed by a doctor, and provided by Jacob’s Well to insurance beneficiaries of Aetna, Blue Cross Blue Shield (BCBS), Cigna, and UnitedHealthcare (UHC). As a result of such fraudulent claims, the insurance companies made payments to the corporate bank accounts of Jacob’s Well in the approximate amount of \$320,301. Furthermore, during the same approximate time period, Ali Ahmed, Sebastian Ahmed, and Hector Efrain Alvarez submitted and caused others to submit, via interstate wire communications, approximately \$21.8 million in claims which falsely represented that various health care benefits, primarily substance abuse PHP, IOP, and OP services, were medically necessary, prescribed by a doctor, and provided by Medi MD to insurance beneficiaries of Aetna, BCBS, Cigna, Humana, and UHC. As a result of such fraudulent claims, the insurance companies made payments to the corporate bank accounts of Medi MD in the approximate amount of \$3.8 million. Ali Ahmed, Hector Efrain Alvarez, and Mauren Morel each pleaded guilty to conspiracy to commit health care fraud and wire fraud and were sentenced to a combined 15 years and 4 months in prison and ordered to pay \$4.2 million in restitution, joint and several.

## 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/>. During this semiannual reporting period, one fugitive was captured.

The following is a case example involving a captured fugitive:

One of OIG's Most Wanted Fugitives, Alejandro Diaz Gonzalez, was captured during this reporting period. Gonzalez was involved in a scheme to fraudulently bill Medicare for services not rendered. Gonzalez has been a fugitive since 2015 and was believed to have absconded to Cuba—he was recently apprehended by authorities attempting to re-enter the United States through the Arizona border.

Gonzalez became the owner of Humanly Home Health Care Agency (Humanly) in December 2014, and a significant increase in billing occurred in conjunction with this change of ownership during 2014 and 2015. In 2014, the Medicare Program reimbursed Humanly approximately \$246,097.61; however, in March 2015, Medicare reimbursed Humanly approximately \$856,478.47. A large percentage of beneficiaries identified in these claims reside outside the service area for Humanly, and numerous complaints were received regarding services not rendered. In November 2019, Gonzalez pleaded guilty to five counts of health care fraud and was sentenced to 2 years and 6 months in prison and ordered to pay \$1.3 million in restitution.

## HHS-OIG Hotline

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 \$21.7 million as a direct result of cases originating from hotline complaints.

## OIG Hotline Activity (10/1/2019–3/31/20)

Contacts to 1-800-HHS-TIPS phone line, including callers seeking information	47,261
Total tips evaluated	16,394
Tips referred for action	11,780
Closed; no basis provided for further action	4,614
Closed; no HHS violation <sup>1</sup>	506

## Sources of tips referred for action

Phone	4,233
OIG website	5,381
Letters or faxes	1,130
Other	1,036

## 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. In this reporting period, OIG certified a new MFCU in North Dakota. 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.

*Medicaid Fraud Control Units Fiscal Year 2019 Annual Report* ([OEI-09-20-00110](#)), March 2020

This annual report highlights statistics on the accomplishments of the 52 MFCUs in operation during FY 2019. OIG found that the number of convictions in FY 2019 (1,527) remained consistent with previous years. Forty-four percent of the 1,111 MFCU fraud convictions involved personal care services attendants and agencies. Fraud cases accounted for 73 percent of the MFCU convictions,

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

while 27 percent involved patient abuse or neglect. MFCUs were responsible for 658 civil settlements and judgments, 25 percent of which involved pharmaceutical manufacturers. MFCUs reported \$1.9 billion in criminal and civil recoveries.

In an appendix to the report, OIG summarizes beneficial practices identified by OIG in its onsite reports that may be useful to other MFCUs.

## 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:

*Missouri Medicaid Fraud Control Unit: 2018 Onsite Inspection* ([OEI-12-18-00490](#)), January 2020

*Montana Medicaid Fraud Control Unit: 2019 Onsite Inspection* ([OEI-12-19-00170](#)), March 2020

## OIG Joint Casework With MFCUs

The following case example involves OIG's joint efforts with MFCUs:

**New York**—Dr. Barry Sloan was convicted of manslaughter in the opioid death of a patient. As part of his guilty plea, Sloan admitted that in August 2014, he issued to L.W. without medical justification, two separate prescriptions for Subsys, a narcotic approved by the FDA to treat intense pain in late-stage cancer patients. Four days later, L.W., an otherwise healthy young man, filled the prescription issued to him by Sloan and died early the next morning after overdosing on fentanyl. Sloan also admitted he knowingly provided false information to Healthfirst, a Medicaid managed care company contracted by the State of New York to cover the cost of medical care and prescriptions. Furthermore, Sloan admitted that between 2012 and 2016, he recklessly issued prescriptions for controlled substances, including highly addictive opioids, to four other patients, and that providing those prescriptions without medical justification caused a significant risk of overdose and death to each of these patients. Sloan pleaded guilty to manslaughter in the second degree, reckless endangerment, and criminal sale of a prescription for a controlled substance by a practitioner and was sentenced to 4 to 9 years in prison. OIG investigated this case with the New York 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 11 requests for advisory opinions and issued 3 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 968 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 903 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:

**Texas**—Dr. Howard Gregg Diamond was excluded for a minimum period of 50 years based on his conviction of conspiracy to possess with the intent to distribute and dispense and distributing and dispensing of controlled substances resulting in death, health care fraud, and aiding and abetting. From approximately January 2010 to about April 2018, Dr. Diamond prescribed controlled medications outside the scope of professional practice by writing prescriptions that contained fentanyl, morphine, oxycodone, oxymorphone,

methadone, hydrocodone, hydromorphone, alprazolam, zolpidem, carisoprodol and diazepam. As a result of his prescribing practices, at least 7 patients died. In addition to his prescribing issues, Dr. Diamond submitted and caused to be submitted, claims to Medicare for services he did not provide. The court sentenced Dr. Diamond to 20 years of incarceration and the Texas Medical Board revoked his license.

**Texas**—Mario Rubio, a massage therapist, was excluded for a minimum period of 50 years based on his conviction of sexual assault. During a massage therapy session, Rubio touched the patient inappropriately to include sexually penetrating her while providing massage therapy services. The court sentenced Rubio to serve 18 years of incarceration and the Texas Department of Licensing and Regulation, Massage therapy program revoked his license.

## 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 Government-wide 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 example involves debarment:

**Illinois**—Thomas Draper was an agent with the Community Support System (CSS), also known as ARC Support Systems. Draper used a credit card belonging to CSS to make purchases for personal transactions totaling over \$74,666. Draper pleaded guilty to one count of Federal program theft and was sentenced to 10 months incarceration and ordered to pay \$74,666.92 in restitution.

## 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 \$16.9 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:

**Florida**—On October 2, 2019, Physicians Group Services, P.A. (PGS) entered into a \$1,128,615.04 CMPL settlement agreement with OIG. The settlement agreement resolves allegations that PGS received remuneration from Millennium Health, LLC f/k/a Millennium Laboratories, Inc. (Millennium), in violation of the anti-kickback statute, 42 U.S.C. § 1320a-7b. Specifically, OIG alleged that PGS received improper remuneration in the form of point-of-care test (POCT) cups, which resulted in prohibited referrals. OIG further alleged that the referrals were prohibited because the remuneration created a financial relationship and PGS caused Millennium to present claims for designated health services that resulted from the prohibited referrals, in violation of the Stark Law, 42 U.S.C. § 1395nn. This is one in a series of cases the OIG has settled regarding the provision of free POCT cups from Millennium. To date, the OIG has recovered over \$2,175,000 as a result of these CMPL settlements.

**New York**—On January 22, 2020, SeniorCare Emergency Medical Services, Inc. (SeniorCare) entered into a \$1,231,854.09 CMPL settlement agreement with OIG. The settlement agreement resolves allegations that SeniorCare knowingly presented claims to Medicare Part B for ambulance transportation to and from skilled nursing facilities (SNFs) where such transportation was already covered by the SNF consolidated billing payment under Medicare Part A.

**Texas**—On October 4, 2019, Ohio River Laboratories, LLC (ORL) entered into a \$49,493.48 CMPL settlement agreement with OIG. The settlement agreement resolves allegations that ORL submitted claims to Medicare for specimen validity testing (SVT), a non-covered service. SVT is a quality control process that evaluates a urine drug screen sample to determine whether it is consistent with normal human urine and to ensure that the sample has not been substituted, adulterated, or diluted. This is one in a series of data-driven cases the OIG has settled concerning SVT. To date, the OIG has recovered over \$2.4 million as a result of these CMPL settlements.

## 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 examples involve EMTALA:

**Georgia**—On November 22, 2019, Rockdale Medical Center (RMC) entered into a \$70,000 settlement agreement with OIG. The settlement agreement resolves allegations that, based on OIG's investigation, RMC violated EMTALA when it failed to provide a medical screening examination, stabilizing treatment or proper transfer to a 79-year-old female. Specifically, the patient presented to RMC's Emergency Department (ED) by ambulance after being involved in a motor vehicle crash with multiple injured individuals. EMS contacted RMC's ED for guidance about disposition of the injured individuals and the ED physician at RMC directed that the patient be taken to a trauma center. When one of the ambulances arrived in RMC's ambulance bay with the patient, a hospital nurse approached the ambulance and told the driver that the patient was supposed to go to the trauma center. The ambulance then transported the patient to the trauma center without the patient receiving a medical screening examination. During the transport, the patient's condition deteriorated, and she ultimately died at the receiving hospital.

**Maryland**—On February 10, 2020, Maryland General Hospital, Inc. d/b/a UM Medical Center Midtown Campus (UMMC), entered into a \$106,965 settlement agreement with OIG. The settlement agreement resolves allegations that UMMC violated EMTALA, when it failed to provide an adequate medical screening examination and stabilizing treatment for a 22-year old female patient. Specifically, the patient presented to UMMC's Emergency Department (ED) on January 9, 2018, via ambulance. The patient was diagnosed with a contusion of the face and lip abrasion, and was discharged. The patient refused to sign the discharge forms, stated that she was homeless, and refused to exit the premises. The patient was escorted by security off of UMMC's property wearing only a hospital gown and socks. The following day, the patient returned to UMMC's ED via ambulance after a bystander called 911. The bystander found the patient at a bus stop outside the hospital in 30-degree weather. A nurse told the patient that she would need to go to a shelter if she did not have a place to stay. The patient was then discharged without receiving a medical screening examination or being stabilized.

**Nevada**—On December 26, 2019, St. Rose Dominican Hospital—Siena Campus (St. Rose) entered into a \$90,000 settlement agreement with OIG. The settlement agreement resolves allegations that, based on OIG's investigation, St. Rose violated EMTALA when it failed to provide an appropriate medical screening examination, stabilizing treatment and transfer for a patient. On May 22, 2016, the patient presented to St. Rose's ED complaining of

dizziness, black stool, yellow skin, and stiff muscles. He was transferred with low blood pressure and without having received any blood products, and went into cardiac arrest and died shortly after arriving at the receiving hospital.

## 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 available only 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 \$27 million in HHS receivables.

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

**California**—After it self-disclosed conduct to OIG, Central Coast In-Patient Consultants, Inc. (CCIC) agreed to pay \$750,000 for allegedly violating the CMPL. OIG alleged that CCIC submitted claims for services provided by physicians to Medicare beneficiaries at a hospital when those physicians were not properly enrolled in Medicare and when the names and National Provider Identifier numbers of physicians who did not furnish the services were used on claims submitted to and paid by Medicare for the services furnished by the non-enrolled physicians.

**Kansas**—After they self-disclosed conduct to OIG, Opti-Vision, LLC (Opti-Vision) and Grene Vision Group, L.L.C. (Grene), (collectively, "Opti-Vision and Grene") agreed to pay \$916,145.39 for allegedly violating the CMPL provision applicable to kickbacks. OIG alleged that Opti-Vision and Grene received remuneration from an optical laboratory for the purchase of membership interests in a group purchasing organization owned, in part, by Opti-Vision in the form of installment payments made to Opti-Vision that were conditioned

on Opti-Vision, through Grene, purchasing a certain amount of items from the optical laboratory through the group purchasing organization.

## 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:

**South Carolina**—After it disclosed conduct to OIG pursuant to its CIA, Drayer Physical Therapy, LLC (Drayer) entered into a \$81,455.97 settlement agreement with OIG. OIG alleged that Drayer billed and received reimbursement from TRICARE for physical therapy services that were provided by physical therapy assistants.

**Texas**—After it disclosed conduct to OIG pursuant to its CIA, Medi-Lynx Cardiac Monitoring, LLC (Medi-Lynx) entered into a \$71,595.27 settlement agreement with OIG. OIG alleged that Medi-Lynx employed an individual that it knew or should have known was excluded from participation in Federal health care programs.

# Public Health and Human Service Agency Reports and Reviews

## Public Health Agency Reports and Reviews

### Food and Drug Administration

*Ownership—But Not Physical Movement—of Selected Drugs Can Be Traced Through the Supply Chain* ([OEI-05-17-00460](#)), February 2020

Drug product tracing records required by the DSCSA do not always include information about the drug's owner or the drug's physical path through the supply chain. Knowing which trading partner owns a drug, where it is in the supply chain, and where it has been can help investigators from FDA do the following: ensure that a potentially dangerous drug is removed the drug supply; identify breaches; and protect patients from harmful, ineffective, and illegitimate drugs. FDA concurred with all of our recommendations, which were:

- Follow up with the wholesale distributor that did not provide tracing information to OIG,
- Provide educational outreach to trading partners about required tracing information for drug products and data standardization guidelines, and
- seek legislative authority to include information about a drug product's complete physical path through the supply chain on drug product tracing information.

### Indian Health Service

*Indian Health Service Has Strengthened Patient Protection Policies but Must Fully Integrate Them Into Practice and Organizational Culture* ([OEI-06-19-00330](#)), December 2019

In recent years, IHS has had a number of cases of health care providers abusing patients under facility care, including a pediatrician who was convicted of multiple counts of child sexual abuse. In early 2019, IHS updated its policies to prevent and address child sexual abuse by providers. We found that IHS policies are consistent with those of other health care organizations, but the policies have coverage gaps and are still early in implementation. IHS concurred with our recommendations, which were:

- Extend policies to address more types of perpetrators, victims, and abuse;
- Ensure that the new incident reporting system is effective and addresses risks identified in the current system;

- Designate a central owner in IHS headquarters to ensure clear roles and responsibilities in implementing patient protection policies, and responding to abuse reports;
- Continue to actively promote an organizational culture of transparency, and work to resolve barriers to staff reporting of abuse; and
- Conduct additional outreach to Tribal communities to inform them of patient rights, solicit concerns, and address barriers to reporting of patient abuse.

## National Institutes of Health

*The National Institutes of Health Submitted OIG Clearance Documents for Just Over One-Half of Its Audit Recommendations, and the Remaining 225 Recommendations Were Unresolved as of September 30, 2016 (A-07-19-03236), January 2020*

NIH did not always resolve OIG audit recommendations in a timely manner during FYs 2015 and 2016. Specifically, NIH resolved 262 of the 487 audit recommendations that were outstanding during FYs 2015 and 2016. However, it did not resolve 166 of the 262 recommendations (63.4 percent) within the required 6-month resolution period. In addition, as of September 30, 2016, NIH had not resolved 225 audit recommendations that were past due for resolution. These 225 recommendations were procedural and did not involve dollar amounts such as recommended disallowances.

NIH had some policies and procedures in place for audit resolution, and those policies and procedures included references to the Federal criteria that require resolution of audit recommendations within 6 months of the audit report's issue date. However, those policies and procedures did not differentiate between issuing a management decision (and submitting a related clearance document) within the required 6-month resolution period and proceeding with corrective action as rapidly as possible.

NIH concurred with our recommendations that it update its policies and procedures related to the audit resolution process, to include issuing management decisions and submitting related clearance documents to OIG—regardless of whether any corrective action has yet been taken—within the required 6-month resolution period and promptly resolve the 225 outstanding audit recommendations that were past due as of September 30, 2016.

*National Institutes of Health Had Information Technology Control Weaknesses Surrounding Its Electronic Health Record System (A-18-19-06003), February 2020*

An outside auditor under contract with OIG, CliftonLarsonAllen LLP (CLA), found that NIH had certain controls in place to secure electronic health record (EHR) information and information systems. However, NIH's information security policies and practices were not operating effectively to preserve the security, confidentiality, integrity, and availability of NIH's EHR information and information systems, resulting in potential risks of unauthorized access, use, disclosure, disruption,

modification, or destruction. At the time of the fieldwork, NIH located its alternative processing site in the same geographic location as its primary site, had delayed software upgrades until completion of system upgrades had been completed, and had not yet fully implemented the automated tool that was intended to ensure that users and inactive accounts were deactivated timely.

NIH concurred with CLA's recommendations that NIH Clinical Center management (1) complete the National Institute of Standards and Technology requirements for implementing an alternative processing site that is a reasonable and viable option and identify, document, and implement actions to mitigate risks of using existing alternative sites until a compliant alternative site is established; (2) implement policies and procedures to ensure all software is upgraded or replaced prior to end of life; and (3) ensure that the automated Clinical Research Information System User Account Management tool is operating so that all changes to user privileges are authorized and properly documented, and that inactive accounts are deactivated.

*NIH Has Acted To Protect Confidential Information Handled by Peer Reviewers, But Could Do More (OEI-05-19-00240)*, March 2020

We found that NIH has policies and procedures to protect the confidentiality of the peer-review process, that it takes action against reviewers who disclose information, and that it actively responds to instances of suspected undue foreign influence in peer review. However, we concluded that NIH can do more to systemically and directly address concerns about foreign threats to the confidentiality of the peer-review process. NIH concurred with all of our recommendations, which were for it to:

- conduct targeted, risk-based oversight of peer reviewers using analysis of information about threats to research integrity;
- update its training materials routinely to include information about breaches of peer reviewer confidentiality and possible undue foreign influence;
- require all peer reviewers to attend periodic trainings about peer review integrity; and
- consult with Federal law enforcement and national security experts to determine what additional steps it might take to identify and address potential risks to confidentiality of the peer-review process, including possible undue foreign influence.

## Substance Abuse and Mental Health Services Administration

*Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder (OEI-12-17-00240)*, January 2020

Among the approximately 1,100 U.S. counties identified by OIG as having the greatest need for opioid use disorder treatment services, 56 percent likely had inadequate capacity to treat patients with buprenorphine in an office setting. This finding indicates that waived providers may not



always be found in the areas where access to treatment is most critical. Furthermore, although the number of providers obtaining waivers to prescribe buprenorphine has increased significantly since 2002, this figure likely overstates the availability of buprenorphine treatment in these settings due to (1) providers not treating up to their approved patient-limit capacity (i.e., up to 30, 100, or 275 patients) and (2) waived providers are not evenly distributed across the nation. MAT couples medication (such as buprenorphine, methadone, or naltrexone) with counseling and behavioral therapies to treat opioid use disorder. The Buprenorphine Waiver Program allows qualified providers to prescribe buprenorphine to patients in office settings rather than limiting this service to specialized opioid treatment programs. SAMHSA concurred with our recommendation to target its efforts to increase the participation of waived providers in high-need counties.

*SAMHSA's Oversight of Accreditation Bodies for Opioid Treatment Programs Did Not Comply With Some Federal Requirements (A-09-18-01007), March 2020*

SAMHSA performed inspections at selected OTPs but did not (1) meet its goal for the number of OTPs it would inspect, (2) take actions to address accreditation bodies' noncompliance with survey requirements, or (3) determine whether OTPs complied with the Federal standards when patient charts were incomplete. In addition, SAMHSA reviewed accreditation bodies' survey reports, but the reports were inconsistent and did not contain sufficient information to determine whether the OTPs met the Federal standards. Finally, SAMHSA's evaluations of accreditation bodies' accreditation elements were not documented or retained. (An example of an accreditation element would be accredited OTPs' commitment to continually improving their organizations and service delivery to the people served.) Without improved oversight and proper documentation of its evaluations, SAMHSA may not be able to adequately evaluate the performance of accreditation bodies and ensure that OTPs are meeting the Federal opioid treatment standards.

SAMHSA concurred with our recommendations that it identify steps it can take to ensure that it meets its goal for the number of OTPs it inspects each year, review the results of its inspections and take action to address accreditation bodies' noncompliance with survey requirements, ensure that its compliance officers follow the Compliance Audit Guidance, work with the accreditation bodies to standardize the survey reports to include not only surveyor teams' information but also OTPs' compliance with each of the Federal opioid treatment standards, and comply with Federal regulations and HHS policy for documenting and retaining its evaluations of accreditation elements.

*States' Use of Grant Funding for a Targeted Response to the Opioid Crisis (OEI-BL-18-00460), March 2020*

More than \$300 million of grant funding for the State Targeted Response to the Opioid Crisis grant program (STR grant program) remained unspent after 2 years. Fourteen States spent less than half of their grant allocations. All but six States requested extensions—known as “no-cost extensions”—that will allow them additional time to use their STR funding. Although States

reported using their STR grants to expand access to treatment, SAMHSA did not track how many patients received MAT, the primary form of evidence-based treatment. With an average of 130 U.S. opioid-overdose deaths per day, it is paramount that SAMHSA and its State partners quickly and effectively use Federal grant dollars to expand access to MAT. Given the lack of data, it is unclear how successful the STR grant program was at achieving its goal of expanded access to MAT.

SAMHSA concurred with all of our recommendations, which were for it to:

- work closely with States and territories during the no-cost extension period to address barriers to timely spending and to ensure that administrative cost caps are not exceeded and
- require States that receive grants for OUD treatment to specifically report how many patients are receiving MAT.

## Human Services Agency Reports and Reviews

### Administration for Children and Families

*New York State Claimed Federal Reimbursement for Unallowable Childcare Subsidies Paid to New York City (A-02-17-02010)*, October 2019

New York State claimed Federal reimbursement for childcare subsidy payments made to New York City that did not comply with Federal and State requirements. Specifically, for 209 of our 210 sampled beneficiary-years, New York State paid New York City for partially unallowable childcare subsidies related to (1) excessive program closure days or (2) the incorrect application of families' calculated contributions toward childcare. On the basis of our sample results, we estimated that New York State claimed Federal reimbursement of \$24.7 million related to these unallowable payments.

During our audit period, New York City did not have controls in place to prevent these unallowable payments. New York City officials stated that they implemented controls to prevent these errors from occurring after our audit period. The officials also stated that, for the final year of our 3-year audit period, they manually corrected claims by applying families' calculated contributions toward childcare subsidies.

New York State, which is responsible for overseeing its Child Care and Development Fund (CCDF) program, did not detect these claiming issues because its childcare subsidy reviews focused on program eligibility, not on New York City's claims for subsidy payments.

New York State concurred with our recommendations that it refund \$24.7 million in unallowable childcare subsidies claimed for Federal reimbursement and ensure that New York City's recently implemented CCDF program controls are properly functioning.

*Wateree Community Actions, Inc., Made Improvements but Still Requires Monitoring*  
*(A-04-19-08069), February 2020*

Our prior audit (A-04-14-04026) of Wateree Community Actions, Inc. (Wateree), for FYs 2012 and 2013, found that Wateree improperly managed some Federal funds related to HHS programs. Wateree continued to experience financial management problems related to its Federal programs because it misallocated funds or claimed duplicate Head Start program costs in violation of Federal requirements, did not meet its non-Federal match requirement for Head Start, and continued to file Federal and non-Federal reports inaccurately or late. However, Wateree resolved one prior OIG audit finding and improved its financial condition.

These deficiencies occurred because Wateree did not have adequate cash management or other controls. As a result, Wateree mismanaged \$354,597 in Federal funds, is subject to a Federal funds disallowance of \$252,591, and may incur other administrative actions from ACF.

Since the end of our audit period, Wateree has taken steps to improve its cash management system. After the initiation of our audit, Wateree repaid the unallowable amount.

Although Wateree did not directly agree or disagree with our recommendations, it described actions taken or processes implemented to (1) monitor the non-Federal match it is receiving throughout the budget year and, if needed, either request a waiver from ACF immediately upon determining that it cannot meet its match requirements or adjust its Federal funds grant expenditures accordingly and (2) ensure adequate controls are in place to prevent invoicing both Head Start and the U.S. Department of Agriculture's Child Nutrition programs for the same expenses. We also made two procedural recommendations.

*Opportunities for Williamson and Burnet Counties Had Ineffective Accounting Controls and Used Unapproved or Questionable Cost Allocation Methods (A-06-18-02002), February 2020*

Opportunities for Williamson and Burnet Counties (Opportunities) did not always account for costs in accordance with Federal regulations. Specifically, Opportunities drew down grant funds without an immediate cash need; did not track expenses in a way that provided for accurate, current, and complete disclosure of the financial results of each Federal program; did not maintain internal controls necessary to provide reasonable assurance that expenses were approved in accordance with internal policies; used unapproved methods to allocate shared costs; and did not allocate indirect costs to programs relative to the benefits received. In addition, Opportunities claimed some unallowable costs.

Opportunities agreed with our recommendations that it (1) implement procedures designed to ensure that Federal funds are drawn down only in the amounts needed to meet the immediate cash requirements of its Community Service Block Grant and Low Income Home Energy Assistance Program-related activities; (2) train its employees to properly use accounting software and follow

policies and procedures for approval of expenses; (3) work with Cost Allocation Services to either be released from the existing indirect cost rate or negotiate a current indirect cost rate for claiming future indirect costs; (4) develop and implement a reasonable basis to allocate meal costs, kitchen salaries, and central office expenses between the Head Start and Senior Nutrition programs in accordance with the benefits received; and (5) refund \$3,207 in unallowable costs.

*Communication and Management Challenges Impeded HHS's Response to the Zero-Tolerance Policy (OEI-BL-18-00510)*, March 2020

Poor interagency communication and internal management decisions that failed to protect children's interests left HHS unprepared for the zero-tolerance policy. This lack of preparation impeded HHS's ability to identify, care for, and reunify separated children. ACF needs to address the management concerns that we identified to improve its operation of the UAC Program. ACF concurred with our recommendations, which were to:

- take steps to ensure that children's interests are prioritized and represented in decisions affecting the UAC Program, both internally and when engaging with interagency partners;
- modify or pursue formal agreements with DHS and the DOJ to ensure that it is receiving information that supports its operation of and ability to provide care for children in the UAC Program;
- improve communication to care provider facilities regarding interim guidance, operational directives, and other instructions that are not immediately available in published policy documents; and
- further improve its ability to identify and track separated children by reducing reliance on manual processes.

# 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, the Health Resources and Services Administration (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.

During this semiannual reporting period, 12 individuals and related entities were excluded because of a PSC referral of their cases to OIG. Individuals who have been excluded because of default may enter into settlement agreements whereby the exclusions are stayed while they pay specified amounts each month to satisfy their debts. If they default on these settlement agreements, they may be excluded until the entire debt is repaid, and they may not appeal the exclusions.

After being excluded for nonpayment of their HEAL debts, 2,823 individuals chose to enter into settlement agreements or completely repay their debts. That figure includes 19 individuals who entered into such settlement agreements or completely repaid their debts. More than \$228.3 million is being repaid through settlement agreements or through complete repayment. Of that amount, almost \$3.6 million is attributable to this semiannual reporting period.

The following examples are settlement agreements. These practitioners entered into settlement agreements to repay the amounts indicated:

- **California**—Drew Danchisin, Chiropractor—\$123,326
- **New Jersey**—Kyunghoon Jung, Dentist—\$146,040

## 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 one criminal action and court-ordered restitution and settlement of \$50,590.

### 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

*Risk Assessment of HHS Grant Closeout Procedures (A-04-19-08072), March 2020*

We determined that an audit of HHS's grant closeout process is not warranted at this time. Overall, the risk that HHS will not meet Federal requirements for grant closeouts is low. The Office of Assistant Secretary for Financial Resources (ASFR) and the HHS OpDivs have responded to the Grants Oversight and New Efficiency Act requirements by taking significant steps to reduce the HHS-wide backlog of open but expired grants and implementing controls to address the risk of a recurrence of the backlog. Nevertheless, HHS still faces some challenges in mitigating the risks associated with grant closeouts. Overall, we identified five sub-risk areas as low risk, three as moderate risk, one as high risk, and zero as critical.

ASFR agreed with our recommendations that it work with Payment Management System (PMS) personnel to improve HHS OpDiv grant management offices' access to timely data; work with OpDivs to ensure that personnel are trained in how to obtain and interpret the PMS reports available to them; continue the grant remediation process to close remaining pooled accounts; work with CMS to implement an electronic grant management system for the Center for Medicaid and Children's Health Insurance Program Services (CMCS) and the Center for Clinical Standards and Quality, assign clear roles and responsibilities related to grant closeout activities at CMCS, and clarify CMCS's ability to close out its grants; and consider revising HHS regulations and the *HHS Grants Policy Administrative Manual* to align closeout time limits for OpDivs with those specified in Federal regulations.

## 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.

### Grant Fraud Investigations

The following case examples relate to misuse of grant funds:



**Michigan**—Van Andel Research Institute (VARI) agreed to pay \$5.5 million to resolve allegations that it violated the False Claims Act by submitting Federal grant applications and progress reports to NIH in which VARI failed to disclose Chinese government grants that funded two VARI researchers. The settlement further resolves allegations that in a December 21, 2018, letter, VARI made certain factual representations to NIH with deliberate ignorance or reckless disregard for the truth regarding the Chinese grants. VARI is an independent research institute in Grand Rapids, Michigan.

**Pennsylvania**—Dr. Melanie Millholland was sentenced for her role in a scheme to misuse Federal grant funds. Between March 2015 and July 2017, Millholland was an employee of Phelix Therapeutics LLC, a company receiving NIH grant funding. From about January 2017 to about June 2017, Millholland embezzled approximately \$383,790 from the company by forging checks and fabricating invoices. Millholland pleaded guilty to embezzlement from an organization receiving Federal benefits and was sentenced to 5 years of probation, which includes 6 months of home detention and 500 hours of community service. Additionally, Millholland was ordered to pay restitution of \$343,790 and a \$100 assessment.

### 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 December 2019 report delivered to the three congressional oversight committees, we reported that OIG spent approximately \$278,733 in salaries on oversight related to 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 any 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, as part of their semiannual report, pursuant to section 5 of the Inspector General Act, information on final completed contract audit reports

issued during the period to the contracting activity. 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 270 reports covering \$471.6 billion in audited costs. Federal dollars covered by these audits totaled \$92.6 billion, of which about \$45.3 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 organization-wide "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, October 1, 2019, Through March 31, 2020

Not requiring changes or having minor changes	255
Requiring major changes	11
Having significant technical inadequacies	4
<b>Total Number of Non-Federal Audits</b>	<b>270</b>

## 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 operating or staff divisions 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
<b>Section 1</b>			
Reports for which no management decisions had been made by the beginning of the reporting period <sup>1</sup>	86	\$2,265,038,000	\$563,160,000
Issued during the reporting period	40	\$288,390,000	\$0
<b>Total Section 1</b>	<b>126</b>	<b>\$2,553,428,000</b>	<b>\$563,160,000</b>
<b>Section 2</b>			
Reports for which management decisions were made during the reporting period <sup>2, 3</sup>			
Disallowed costs	53	*\$605,182,000	\$7,020,000
Costs not disallowed	2	\$13,078,000	\$0
<b>Total Section 2</b>	<b>55</b>	<b>\$618,260,000</b>	<b>\$7,020,000</b>

\* Audit receivables (expected recoveries)

### Section 3

Reports for which no management decisions had been made by the end of the reporting period (Section 1 minus Section 2)	71	\$1,935,168,000	\$556,140,000
<b>Section 4</b>			
Reports for which no management decisions were made within 6 months of issuance <sup>4</sup>	37	\$1,661,273,000	\$556,140,000

## Table 1 End Notes

<sup>1</sup> The opening balance was adjusted upward by \$59.1 million because of a reevaluation of previously issued recommendations.

<sup>2</sup> Revisions to previously reported management decisions:

- A-05-07-00036, *Wisconsin Improperly Claimed Federal Medicaid Reimbursement for Most Residential Care Center Payments*. Subsequent review by CMS determined that the original finding amount was allowable resulting in a decreased previously sustained amount by \$22,839,628.
- A-06-15-00041, *Texas Did Not Appropriately Spend Some State Balancing Incentive Payments Program Funds*. Subsequent review by CMS determined that the original finding amount was allowable resulting in a decreased previously sustained amount by \$11,982,826.
- A-03-17-00005, *University of Wisconsin Hospital and Clinics Authority Incorrectly Billed Medicare Inpatient Claims With Severe Malnutrition*. Subsequent review by CMS determined that the original finding amount was partially allowable resulting in a decreased previously sustained amount by \$1,873,716.
- A-05-15-00044, *Medicare Compliance Review of NorthShore University Health System For 2013 And 2014*. Due to subsequent review by CMS and the OIG, the amount sustained was reduced by \$1,007,913.
- **Not detailed are reductions to previously disallowed management decisions totaling \$976,000.**

<sup>3</sup> Included are management decisions to disallow \$33 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.

<sup>4</sup> Because of administrative delays, some of which were beyond management control, resolution of the following 37 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-02-16-01022	<i>New York May Not Have Complied With Federal and State Requirements Prohibiting Medicaid Payments for Inpatient Hospital Services Related to Provider-Preventable Conditions, May 2019, \$50,256,025</i>
A-09-17-03035	<i>Medicare Improperly Paid Suppliers for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Provided to Beneficiaries During Inpatient Stays, November 2018, \$34,014,796</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, \$19,979,573</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-05-18-00030	<i>Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs, June 2019, \$4,065,188</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-02-17-02009	<i>New York Did Not Provide Adequate Stewardship of Substance Abuse Prevention and Treatment Block Grant Funds, March 2019, \$1,800,212</i>
A-07-19-00564	<i>National Government Services, Inc., Claimed Some Unallowable Medicare Pension Costs Through Its Incurred Cost Proposals, September 2019, \$1,780,718</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-01-18-02501	<i>Vermont's Office of Child Support Needs Better Oversight of Its Administrative Costs Claimed, September 2019, \$1,058,309</i>
A-07-19-00572	<i>National Government Services, Inc., Claimed Some Unallowable Medicare Nonqualified Plan Costs Through Its Incurred Cost Proposals, September 2019, \$971,820</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-05-16-00038	<i>Heartland Human Care Services, Inc. Generally Met Safety Standards, but Claimed Unallowable Rental Costs, September 2018, \$768,460</i>
A-06-16-07007	<i>BCFS Health and Human Services Did Not Always Comply With Federal Requirements Related to Less-Than-Arm's-Length Leases, February 2018, \$658,248</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-07-19-00561	<i>Group Health Incorporated Understated Its Emblem Health Services Company, LLC, Employees' Retirement Plan Medicare Segment Pension Assets as of January 1, 2015, July 2019, \$432,584</i>
A-07-19-00563	<i>National Government Services, Inc., Claimed Some Unallowable Medicare Nonqualified Plans Costs Through Its Final Administrative Cost Proposals, September 2019, \$426,123</i>
A-07-19-00557	<i>Group Health Incorporated Understated Its Cash Balance Pension Plan Medicare Segment Pension Assets as of January 1, 2011, July 2019, \$366,763</i>
A-04-13-01024	<i>The University of North Carolina at Chapel Hill Did Not Always Claim Selected Costs Charged Directly to Department of Health and Human Services Awards in Accordance With Federal Requirements, June 2014, \$352,843</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-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-07-19-00565	<i>National Government Services, Inc., Claimed Some Unallowable Medicare Supplemental Executive Retirement Plan Costs Through Its Incurred Cost Proposals, September 2019, \$268,633</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-06-11-00058	<i>Crowley's Ridge Development Council, Inc., Claimed Unallowable Costs Under a</i>



	<i>Recovery Act Grant, August 2012, \$115,420</i>
A-04-17-07069	<i>Medicare Payments to Providers for Polysomnography Services Did Not Always Meet Medicare Billing Requirements, June 2019, \$56,668</i>
A-07-18-00551	<i>National Government Services, Inc., Claimed Some Unallowable Supplemental Executive Retirement Plan Costs Through Its Final Administrative Cost Proposals, September 2019, \$36,524</i>
<b>TOTAL CINS: 37</b>	
<b>TOTAL AMOUNT: \$1,661,273,000</b>	

## 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
<b>Section 1</b>		
Reports for which no management decisions had been made by the beginning of the reporting period	9	\$15,625,113,000
Reports issued during the reporting period	8	\$911,270,000
<b>Total Section 1</b>	<b>17</b>	<b>\$16,536,383,000</b>
<b>Section 2</b>		
Reports for which management decisions were made during the reporting period		
Value of recommendations agreed to by management		
Based on proposed management action	4	\$144,131,000
Based on proposed legislative action	0	\$0
Value of recommendations not agreed to by management		\$0
<b>Total Section 2</b>	<b>4</b>	<b>\$144,131,000</b>
<b>Section 3</b>		
Reports for which no management decisions had been made by the end of the reporting period <sup>1</sup> (Sec. 1 minus Sec. 2)	13	\$16,392,252,000

### Table 2 End Notes

<sup>1</sup>Because of administrative delays, some of which were beyond management control, 5 of the 13 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	<i>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</i>
A-04-17-07069	<i>Medicare Payments to Providers for Polysomnography Services Did Not Always Meet Medicare Billing Requirements, June 2019, \$269,768,285</i>
A-06-17-08004	<i>Medicare Part D Is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit, August 2019, \$160,800,000</i>
A-03-13-03002	<i>HHS Did Not Identify and Report Antideficiency Act Violations, May 2017, \$49,445,025</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>
<b>TOTAL CINS: 5</b>	
<b>TOTAL AMOUNT: \$15,480,982,000</b>	

## Appendix B: 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
	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, no peer reviews involving OEI were completed. Information concerning OEI's peer-review activity during a prior reporting period is also listed below.

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 C: 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 3 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 3 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 3 times the amount of funds at issue: (1) for each instance of knowingly making a false statement in a document required to be submitted in order 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 3 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 not only the traditional definition but 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 again amended 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 D: 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
<b>Section 4</b>		
(a)(2)	Review of legislation and regulations	"Other HHS-Related Reviews and Investigations" section
<b>Section 5</b>		
(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	Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs: Top Unimplemented Recommendations (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.	None for this reporting period
(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 B
(a)(17)	Investigative statistical tables	Appendix E
(a)(18)	Metrics description for statistical tables	Appendix E
(a)(19)	Investigations on senior Government employees	Appendix E
(a)(20)	Description of whistleblower retaliation instances	Appendix E
(a)(21)	Description of attempts to interfere with OIG independence	Appendix E
(a)(22)	Description of closed and nondisclosed reports and investigations regarding senior Government employees	Appendix E

## 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 F

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 E: 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 six-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, inspection, and evaluation reports issued from FY 2011 through FY 2020, OIG had a total of 113 reports with overdue final management decisions (FMD) as of the end of this reporting period.<sup>2</sup> The breakdown of those 113 reports by HHS operating division is as follows:

Operating Division	Overdue FMDs
ACF	17
ACL	2
ASPR	1
CDC	4
CMS	48
FDA	2
IHS	12
NIH	7
OASH	1
OS	17
SAMHSA	2

<sup>2</sup> 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, one OS) with overdue management decisions from FY 1990 through FY 2010.

OIG is unable to provide reasons and timetables for each of these overdue management decisions, due to 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 with comments exceeding 60 days.

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

OIG is actively tracking 1,253 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)	Number of Reports With Unimplemented Recommendations	Number of Unimplemented Recommendations	Dollar Value of Aggregate Potential Cost Savings
2011	13	20	\$446,994,129
2012	24	29	\$397,437,195
2013	31	48	\$235,963,777
2014	33	56	\$15,142,396,350
2015	29	47	\$333,957,018
2016	31	77	\$191,370,339
2017	41	124	\$1,116,136,306
2018	59	189	\$2,214,327,855
2019	104	401	\$1,263,918,211
2020	76	262	\$1,007,060,034
<b>Totals</b>	<b>441</b>	<b>1,253</b>	<b>\$22,349,561,214</b>

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	<b>0</b>
Total number of persons referred <sup>3</sup> to Federal prosecuting authorities for criminal prosecution during the reporting period <sup>4</sup>	<b>1,659</b>
Total number of persons referred to State and local prosecuting authorities for criminal prosecutions during the reporting period	<b>203</b>
Total number of Federal indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities	<b>370</b>
Total number of State and local indictments and criminal information during the reporting period that resulted from any prior referral to prosecuting authorities	<b>150</b>

*(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

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

<sup>4</sup> 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 Staff Division, 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 employees 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 October 1, 2019, through March 31, 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, October 1, 2019, Through March 31, 2020

Category/Description	Number of Reports
IT security reviews (involve IT systems, e.g., penetration test audits)	1
Homeland security issues (involve particularly sensitive topics, e.g., bioterrorism, emergency preparedness, and classified or potentially classified information)	0
Recipient Capability Audits (primarily in Head Start/Early Head Start programs)	0
Reimbursable audits performed for other Federal agencies (primarily contract audits)	0
Confidential or proprietary information (e.g., Medicare Part B drug claims/imaging services, Medicare investment income)	0
Medicare Adverse Event Reviews (required by law not to disclose)	0
Medicare Prescription Drug Event Reviews	0
Other	0
HHS technical assistance reports <sup>5</sup>	0
Finance-related attestation reviews	1
<b>Total</b>	<b>2</b>

*(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

<sup>5</sup> 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 four 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
Complaint alleged that a Senior Executive Service (SES) employee and members of his staff, which included another SES, violated FAR when the SES instructed contracting companies to engage in prohibited personnel practices when the SES improperly used Schedule A Excepted Service Appointments to hire family and friends, and the SES violated a court order when the SES instructed their staff to not track children that fell with the court-ordered definition of an Unaccompanied Minor.	Closed.	No evidence to support allegations.	N/A	N/A	N/A	N/A
A complaint alleged that a senior	Closed.	Allegations determined	N/A	N/A	N/A	N/A

Government employee had inappropriate sexual contact with a female patient.		to be unfounded and un-proveable.				
The Complaint alleged that a senior Government employee was caught in 2011 or 2012 having sexual contact with a juvenile female while employed in the private sector. The senior Government employee then resigned his employment and began working for the Government. No current sexual abuse allegation was received regarding the senior Government employee while employed by the Government.	Closed.	No current criminal allegations received, or actionable information discovered.	N/A	N/A	N/A	N/A

## Appendix F: 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*.<sup>6</sup> 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.<sup>7</sup> 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

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<sup>6</sup> 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>.

<sup>7</sup> 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](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 information technology, 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).<sup>8</sup> 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, among other ways, 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;

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<sup>8</sup> 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>.



- 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(jj)) for donations of cybersecurity technology and services;
- proposed modifications to the existing safe harbor for 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 provide only 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.