

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

Semiannual Report to Congress

April 1, 2019–September 30, 2019



A Message From Joanne M. Chiedi, Acting Inspector General

I am pleased to submit this *Semiannual Report to Congress* summarizing the activities of the Department of Health and Human Services (HHS) Office of Inspector General (OIG) for the 6-month period ending on September 30, 2019.

In this reporting period, OIG continued to produce outstanding results for the American people through independent, objective oversight. OIG's work safeguarded taxpayer funds and helped improve the quality, safety, and value of HHS programs. For example, our work included a first-of-its-kind investigation of a major genetic testing fraud scheme and a report on challenges meeting the mental health needs of unaccompanied children in HHS custody. We furthered our work on combating the devastating opioid epidemic and helped dismantle a massive healthcare fraud scheme involving fraudulent telemedicine companies with over \$1.2 billion in losses for medically unnecessary orthotic braces.



We made a range of recommendations to improve program operations in areas such as reporting and preventing elder abuse, recovery of overpayments, state oversight of Medicaid, monitoring of independent living programs, and quality of care in Indian Health Service hospitals. Touching on the breadth of our work in the reporting period, we provided testimony at six congressional hearings that addressed the Unaccompanied Alien Children Program, elder justice, prescription drug prices, and foreign threats to taxpayer-funded medical research. In short, OIG continued its enterprise-wide oversight of HHS's over \$1 trillion portfolio and its bold pursuit of those who cheat HHS programs or harm HHS beneficiaries.

OIG's talented and dedicated workforce uses multidisciplinary approaches, cutting-edge data and technology, and collaborations at the Federal, State, and local levels to achieve our mission. OIG is preparing to oversee emerging technology-enriched, value-driven health and human services programs with investments in the expertise of our people, as well as proven technologies and data capabilities. Our work demonstrates that promising technology that can help patients, such as genetic testing, can also be misused for fraud and put patients at risk. At this transformational time in healthcare, OIG will be vigilant and innovative in advancing program integrity. Currently, OIG is collecting public comments on a proposed rule designed to accelerate the transformation of the healthcare system into one that better pays for value and promotes care coordination for patients.

OIG is ready to address complex, fast-moving changes in health and human services programs with consistent, assertive, objective, and fearless oversight. With an eye on the future and a steady focus on the people served by HHS, OIG will continue to be resolute in catching and holding accountable perpetrators of fraud, identifying misspent funds, and making systemic recommendations to promote the economy, efficiency, and effectiveness of the Nation's health and human services programs.

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

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OIG's Approach to Driving Positive Change

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) Office of Inspector General (OIG) provides independent and objective oversight that promotes economy, efficiency, and effectiveness in HHS programs and operations. OIG's program integrity and oversight activities are shaped by legislative and budgetary requirements and adhere to professional standards established by the Government Accountability Office (GAO), the Department of Justice (DOJ), and the Inspector General community. Through a nation-wide 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 assessments 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 (FCA), 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 healthcare 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

OIG Work Plan

OIG’s [Work Plan](#) sets forth various 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).

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 entire FY 2019. We also highlight some of our work completed during this semiannual reporting period, April 1, 2019, through September 30, 2019.

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.

Highlights of OIG Accomplishments

HHS-OIG’S SEMIANNUAL REPORT TO CONGRESS (Semiannual Report) describes OIG’s work identifying significant risks, problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations that were disclosed during the semiannual reporting period, April 1, 2019, through September 30, 2019. In this highlights section, we present data on OIG reports issued, expected recoveries, criminal and civil actions, and other statistics resulting from our work for both the semiannual reporting period and the entirety of fiscal year (FY) 2019. We then highlight significant results from selected audits, evaluations, and enforcement activities completed during the reporting period.

Fiscal Year 2019 At-a-Glance Highlights

Statistic	FY 2019 (10/1/2018–9/30/2019)
Audit Reports Issued	163
Evaluations Issued	46
Expected Audit Recoveries	\$819,151,000
Questioned Costs	\$913,475,000
Potential Savings	\$836,422,000
New Audit and Evaluation Recommendations	582
Recommendations Implemented by HHS Operating Divisions	341
Expected Investigative Recoveries	\$5.04 billion
Criminal Actions	809
Civil Actions	695
Exclusions	2,640

Results for the Semiannual Reporting Period

During this semiannual reporting period (April through September 2019), we issued 91 audit reports and 36 evaluation reports. Our audit work identified \$322,724,000 in expected recoveries, as well as \$666,549,000 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 \$573,037,000 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 367 new audit and evaluation recommendations, which are crucial to encourage positive change in HHS programs. Meanwhile, HHS operating divisions implemented 142 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, State 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 \$2.74 billion in expected investigative recoveries and 388 criminal actions during this reporting period. OIG also took civil actions, such as assessing monetary penalties, against 364 individuals and entities, and excluded 1,347 individuals and entities from Federal health care programs.

OIG continues to focus on the most significant and high-risk issues in healthcare and human services. Our mission is to protect the health and welfare of beneficiaries and to protect the integrity of HHS programs. Below we highlight results from selected OIG oversight and enforcement activities from the semiannual reporting period April 1, 2019, through September 30, 2019, 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 (IG Act).

Protecting Unaccompanied Children in the Department’s Care

HHS, through the ACF Office of Refugee Resettlement (ORR), is responsible for ensuring the shelter and care of thousands of unaccompanied alien children (UAC) 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), including children who arrived in the United States unaccompanied and those who were separated from their parents or legal guardians by 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 ORR’s care provider facilities faced challenges in addressing the mental health needs of children. ORR facilities reported several challenges in addressing children’s mental health needs, especially for children who have experienced significant trauma. Facility staff described challenges such as difficulty recruiting and retaining clinicians and resulting high caseloads, trouble accessing external mental health care providers, and difficulty transferring children to facilities within ORR’s network that provide specialized treatment. Policy changes in 2018 exacerbated these concerns, as they resulted in a rapid increase in the number of children separated from their parents after entering the United States, many of whom were younger, and longer stays in ORR custody. ACF agreed with OIG’s recommendations for practical steps that ORR can take to assist facilities care for children and minimize barriers to appropriate mental health treatment. (See report [OEI-09-18-00431](#).)

OIG found that ORR’s care provider facilities faced challenges in hiring, screening, and retaining employees. In general, facilities met a range of background checks and qualification requirements designed to keep individuals who may pose a risk to the safety and well-being of children from having

direct access to children. However, some facilities did not have evidence of the required background check results, and over half of the facilities we reviewed allowed employees to begin employment before receiving background check results. In addition, facilities had difficulty maintaining required staffing ratios because of challenges experienced in screening, hiring, and retaining qualified employees. ACF agreed to OIG's several recommendations to improve ORR program operations related to background checks, education requirements, and staffing ratios. (See report [A-12-19-20001](#).)

OIG found that one of ORR's largest grantees did not adequately protect children's information and did not always document meeting safety standards for the care and release of children. Southwest Key, which operates multiple care provider facilities for unaccompanied children in ORR's custody, had not implemented an adequate information systems security program to protect the personally identifiable information of children in its care as required by Federal regulations. OIG also found that Southwest Key did not always meet or properly document that it met certain safety standards for the care or release of some children in its custody. Without adequate documentation, ORR could not be assured that Southwest Key had followed ORR policies regarding background checks, prompt care, or that DHS was notified about the child's release to a sponsor. OIG made a number of recommendations to Southwest Key to address these issues. (See reports [A-18-18-06001](#) and [A-06-17-07005](#).)

OIG testified about ORR oversight work at two congressional hearings. In September, Ann Maxwell, Assistant Inspector General for Evaluation and Inspections, testified at two congressional hearings. Once before the House Committee on Appropriations and again before the House Committee on Energy and Commerce, Oversight and Investigations Subcommittee. Both testimonies focused on OIG's oversight of the Unaccompanied Alien Children (UAC) Program. (See [OIG congressional testimony](#).)

Preventing Opioid Misuse and Promoting Access to Treatment

OIG has an extensive history of work focused on the national opioid epidemic, and we continued to expand that body of work through our investigations, evaluations, and audits during this reporting period. As advanced data analytics allow us to assess broad usage patterns and detect potential problems with increasing sophistication, we have worked to ensure that HHS program data are of sufficient quality to realize the full potential of those capabilities. Additionally, we have expanded our work related to treatment of substance use disorder—to ensure appropriate access for beneficiaries and to prevent fraud, waste, or misuse of funding for treatment. Significant OIG work during this semiannual reporting period includes the following:

Over 50 individuals in Texas, including medical professionals, were charged with illegally diverting prescription opioids through "pill mill" clinics. In September 2019, OIG and Federal and State law enforcement partners announced an enforcement operation across Texas, involving charges against a total of 58 individuals across all four Federal districts for their alleged involvement in fraud schemes and networks of "pill mill" clinics resulting in \$66 million in losses to public and private insurers and 6.2 million pills. Of those charged, 16 were doctors or medical professionals, and 20 were charged for their role in diverting opioids. This operation exemplifies OIG's continued targeting of schemes to bill Medicare,

Medicaid, and other public and private insurers for medically unnecessary prescription drugs and compounded medications that often are never even purchased and/or distributed to beneficiaries. The operation also reflects OIG's aggressive pursuit of individuals contributing to the opioid epidemic, with a particular focus on medical professionals allegedly involved in the unlawful distribution of opioids and other prescription narcotics.

A pharmaceutical company agreed to pay \$700 million to settle allegations that it illegally marketed an opioid treatment drug. A pharmaceutical company entered into a \$700 million FCA settlement with the United States to resolve allegations that it illegally marketed and promoted the opioid treatment drug Suboxone. The allegations included knowing promotion of Suboxone to physicians who were prescribing it in an unsafe manner, as well as making false and misleading claims to physicians, State Medicaid agencies, and the Food and Drug Administration to increase sales and delay generic competition.

OIG found that opioid use has declined in Medicare Part D while use of opioid treatment drugs has increased. OIG's most recent national data brief on opioid use in Medicare's Part D program showed decreases in both the number of beneficiaries receiving opioids and the number of beneficiaries at serious risk of opioid misuse or overdose. At the same time, the number of beneficiaries receiving drugs for medication-assisted treatment of opioid use disorder and the number of beneficiaries receiving naloxone (a drug that can reverse the effects of an opioid overdose) grew. (See report [OEI-02-19-00390](#).)

OIG found that incomplete Medicaid data prevent a national review of opioid prescribing. Although the Department has made progress in building a single, nation-wide Medicaid dataset, we found that the dataset cannot yet be used to conduct a nation-wide analysis of opioid use and prescribing patterns in Medicaid. This type of review is essential to identifying patterns and linkages that might not be discernable from analysis of individual States' Medicaid data. CMS agreed with our recommendations to help ensure the identification of at-risk beneficiaries and providers who may be overprescribing. (See report [OEI-05-18-00480](#).)

OIG found that Indian Health Service (IHS) hospitals did not always follow protocols for prescribing and dispensing opioids. OIG's patient record review for five IHS hospitals found that they did not always take actions as required or recommended—such as reviewing patients' health records or treatment histories and performing urine drug screens within specified timeframes—when prescribing and dispensing opioids. OIG also found that the IHS hospitals reviewed did not fully use their States' prescription drug monitoring programs. IHS agreed with our recommendations to help ensure that it follows the Indian Health Manual when prescribing and dispensing opioids and other vulnerabilities identified in the report. (See report [A-18-17-11400](#).)

Fighting Fraud To Protect the Medicare and Medicaid Programs

Medicare and Medicaid are among the largest Federal programs in the United States, both in terms of expenditures and individuals served. In 2018, Medicare spent nearly \$741 billion, and provided health coverage to 59.9 million beneficiaries. The Medicaid program serves more people than any other Federal

health care program. One in five Americans—approximately 73 million people—receive care through Medicaid at a cost of \$560 billion per year.

OIG's sustained efforts to root out illegal activity that can unnecessarily raise costs for the Medicare and Medicaid programs or put beneficiaries at risk is as important as ever. Significant OIG work during this semiannual reporting period includes the following:

[OIG helped shut down a vast fraud scheme involving telemedicine and orthotic braces.](#) In April 2019, OIG and our law enforcement partners announced an investigation (known as Operation Brace Yourself) that dismantled a healthcare fraud scheme involving over \$1.2 billion in losses. In the alleged scheme, medical professionals working with fraudulent telemedicine companies received illegal kickbacks and bribes from medical equipment companies. In exchange, the medical equipment companies obtained prescriptions for medically unnecessary orthotic braces and used them to fraudulently bill Medicare. The operation led to charges against 24 defendants across 17 Federal districts.

[OIG helped lead a multidistrict takedown targeting a massive genetic testing fraud scheme.](#) In September 2019, OIG and Federal and State law enforcement partners announced efforts to dismantle one of the largest healthcare fraud schemes ever charged. The takedown resulted in charges in 5 Federal districts against 35 defendants—including 9 doctors—associated with dozens of telemedicine companies and laboratories. The defendants are charged with fraudulently billing Medicare more than \$2.1 billion for cancer-related genetic tests as part of a scheme involving payment of illegal kickbacks and bribes.

[Two Florida residents were convicted in the largest healthcare fraud scheme ever charged by Federal authorities.](#) The fraud scheme involved a record \$1.3 billion in fraudulent claims. According to the investigation, the leader of the scheme bribed physicians to admit patients into care facilities he owned, and then cycled the patients through facilities in his network. In addition to billing Medicare and Medicaid for services and prescription drugs that were unnecessary or not provided, witnesses testified that the facilities were in poor condition and provided inadequate care—information that was concealed by bribing a State regulator for advance notice of surprise inspections. The leader of the scheme was sentenced to 20 years in prison, and his accomplice was sentenced to over 6 years in prison.

[An inpatient rehabilitation company settled allegations of submitting false patient diagnoses and admitting patients unnecessarily to bolster Medicare payments.](#) The company allegedly provided false diagnoses on patient assessments to keep its facilities eligible for a special Medicare status that pays a higher rate. The company also allegedly admitted and billed for Medicare patients that did not need the care they were provided. The company paid \$48 million to resolve the allegations.

[Three pharmaceutical companies settled allegations of using nonprofit foundations to increase their proceeds from Medicare.](#) The companies agreed to pay over \$120 million to resolve allegations that they illegally paid beneficiaries' copays through purportedly independent nonprofit foundations. Federal law prohibits pharmaceutical companies from paying Medicare beneficiaries to induce the purchase of the

companies' drugs, which can increase costs for the program. Two of the companies also entered into CIAs in connection with the settlements.

OIG found that not all States are conducting criminal background checks for high-risk Medicaid providers. Thirteen States had not implemented fingerprint-based criminal background checks for their high-risk Medicaid providers as of January 1, 2019. Unscrupulous providers could exploit loopholes in the enrollment process to avoid undergoing these checks, leaving the Federal and State governments vulnerable to fraud risks. OIG recommended that CMS ensure State compliance with background check requirements for Medicaid providers and take actions to close the identified loopholes. (See report [OEI-05-18-00070](#).)

Ensuring Appropriate Use of Medicaid Funds

OIG reviews of CMS and States' administration of Medicaid are critical to ensuring that Federal and State 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 that Florida made hundreds of millions of dollars in unallowable Medicaid payments to a hospital under a waiver program. As part of its Medicaid reform waiver, Florida established the Low Income Pool (LIP) program to compensate hospitals for providing care to low-income patients. OIG found that during State FYs 2010 through 2014, Florida paid \$686 million to Jackson Memorial Hospital under the LIP program in excess of the hospital's allowable costs. OIG recommended that Florida refund the \$412 million Federal share of the unallowable payments, improve its oversight of the LIP program, and make other procedural changes. (See report [A-04-17-04058](#).)

OIG found that New York incorrectly treated some beneficiaries as eligible for Medicaid. Although New York correctly determined Medicaid eligibility for the majority of sampled beneficiaries, it incorrectly determined that some beneficiaries were eligible for the program and did not provide documentation to confirm eligibility for others. OIG estimated that the Federal share of New York's payments was \$520 billion for ineligible beneficiaries and \$1.3 billion for potentially ineligible beneficiaries. OIG also found that New York's enrollment system did not always query all electronic data sources to confirm beneficiaries' reported income. OIG made recommendations to New York State to address these findings, including that New York redetermine, as appropriate, the eligibility status for the individuals we identified as ineligible. (See report [A-02-16-01005](#).)

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 the elderly, the terminally ill, and other vulnerable populations. Significant OIG work during this semiannual reporting period includes the following:

OIG found that potential abuse and neglect at nursing facilities was not always reported and investigated, and that CMS could better use Medicare data to identify instances of potential abuse and neglect. An estimated one in five high-risk emergency room visits by Medicare beneficiaries in 2016 resulted from potential abuse or neglect at skilled nursing facilities (SNFs). OIG determined that SNFs did not report many of these incidents to State Survey Agencies, and that some Survey Agencies failed to report substantiated abuse to local law enforcement. In addition, OIG found that a data extract containing diagnosis codes indicative of abuse or neglect could help ensure that incidents of potential abuse or neglect are detected and investigated. OIG recommended that CMS work with Survey Agencies and SNFs to improve staff training and clarify guidance on identifying and reporting abuse and neglect. OIG also recommended that CMS use diagnosis codes in Medicare claims data to better monitor potential abuse and neglect incidents. (See reports [A-01-16-00509](#) and [A-01-17-00513](#).)

OIG found that the ACL did not appropriately oversee the activities of two independent living programs. Although ACL conducted some monitoring activities, such as desk reviews, it had not conducted any onsite compliance reviews of two independent living programs since beginning its oversight of the programs in July 2014. ACL officials said that they were unable to conduct onsite compliance reviews because of limited travel funding. OIG recommended that ACL determine whether it can allocate funds differently or seek additional funding to enable onsite compliance reviews. (See report [A-05-18-00034](#).)

OIG found that New York did not adequately oversee life safety and emergency preparedness requirements in 20 nursing homes. OIG identified deficiencies in areas related to life safety and emergency preparedness at all 20 nursing homes OIG reviewed. These deficiencies left residents at increased risk of injury or death during a fire or other emergency. The identified areas of noncompliance occurred because of inadequate management oversight and staff turnover at the nursing homes, but gaps in New York's oversight—such as not having a standard life safety training program for all nursing home staff—also existed. New York agreed with our recommendations to improve its oversight of the nursing homes' compliance with Federal requirements for life safety and emergency preparedness. (See report [A-02-17-01027](#).)

Promoting Access to High-Quality Care

HHS programs provide critical health and human services to vulnerable populations in many different settings. Therefore, HHS must ensure that the individuals in HHS programs have access to and receive high-quality care and services. Significant OIG work during this semiannual reporting period includes the following:

OIG highlighted the prevalence of quality-of-care deficiencies among hospice providers and gaps in Medicare protections for hospice patients. Three out of four hospices inspected in 2016 were cited with at least one deficiency, such as poor care planning or inadequate patient assessments. Additionally, over 300 hospices had at least one serious deficiency or at least one substantiated severe complaint. OIG also described cases of serious harm that reveal gaps and vulnerabilities in Medicare's protections for hospice

patients. OIG recommended that CMS take a number of actions to more effectively protect hospice beneficiaries from harm. (See reports [OEI-02-17-00020](#) and [OEI-02-17-00021](#).)

OIG found that many Medicaid-enrolled children who were treated for attention deficit hyperactivity disorder (ADHD) did not receive recommended followup care. Followup care is an important part of treatment for ADHD as the disorder can affect all aspects of a child's academic and health outcomes. OIG found that over 500,000 Medicaid-enrolled children who were newly prescribed an ADHD medication and over 3,500 children hospitalized with a primary diagnosis of ADHD did not receive followup care within the timeframes outlined in the national quality measures. CMS agreed with our recommendations to work toward improving health outcomes by developing strategies to increase the number of children who receive timely followup care for ADHD. (See report [OEI-07-17-00170](#).)

OIG identified organizational challenges to improving quality of care at IHS hospitals along with longstanding difficulties in recruiting and retaining staff. In two reports, we examined challenges and identified strategies for improving quality of care at IHS hospitals. In one report, we analyzed IHS's management of the closure (due to serious quality problems and staffing shortages) and reopening of the emergency department at its Rosebud Hospital. In the other report, we outlined strategies for IHS to address core organizational challenges that have limited its ability to improve hospital operations and quality of care. (See reports [OEI-06-17-00270](#) and [OEI-06-16-00390](#).)

OIG found limited availability of behavioral health services in New Mexico's Medicaid managed care program. Shortages of providers and difficulty arranging services has resulted in limited availability of behavioral health care for New Mexico's Medicaid managed care enrollees. The challenges faced by New Mexico are likely shared by other States, and require both State and national attention. Both CMS and New Mexico agreed with OIG's recommendations to help address these challenges, including expanding the behavioral health workforce, improving transportation options for enrollees, and expanding the use of telehealth. (See report [OEI-02-17-00490](#).)

OIG found that beneficiaries face avoidable extra steps that can limit their access to prescribed drugs in Medicare Part D. In 2017, Part D plan sponsors rejected millions of prescriptions that beneficiaries tried to fill at pharmacies, and overturned a large number of drug-coverage denials when beneficiaries appealed. Some of these rejections and denials were avoidable or inappropriate, creating extra steps that can delay or deter access to medications if beneficiaries are unable or unwilling to spend time navigating the approval process. CMS agreed with OIG's recommendations that CMS address these issues through improved electronic communication between sponsors and prescribers, additional action to reduce inappropriate pharmacy rejections and coverage denials, and more accessible information for beneficiaries. (See report [OEI-09-16-00411](#).)

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 2019, 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 has improved its review of financial conflicts of interest (FCOIs) that institutions report to it, but it has limited controls in place to ensure that institutions report everything that they should. OIG found that NIH has made strides in its oversight of FCOIs reported by institutions. Specifically, NIH has strengthened its reporting requirements and developed an online system for collecting, reviewing, and storing the FCOIs that institutions report. However, NIH could do more to ensure the quality of the reviews of FCOIs that its staff performs. In another review, OIG found that NIH has limited policies, procedures, and controls in place to ensure that institutions report all sources of research support, financial interests, and affiliations. More than half of the 1,875 institutions that received NIH funding in FY 2018 and were required to have FCOI policies did not have such policies posted on their websites. NIH agreed with OIG's recommendations to help address these issues. (See reports [A-03-19-03003](#) and [OEI-03-19-00150](#).)

OIG found strengths and limitations in NIH's vetting of peer reviewers. NIH's process for vetting peer reviewer nominees has a number of strengths, including robust verification of scientific expertise, consideration of ability to be an effective peer reviewer, and checks for prior research misconduct. However, OIG found that NIH generally limits the sources it uses to vet other concerns and gives little attention to foreign affiliation in its vetting of peer reviewer nominees. NIH agreed with OIG's recommendation that NIH, in consultation with national security experts and the HHS Office of National Security, update its guidance to identify potential foreign threats and develop a risk-based approach for additional vetting. (See report [OEI-01-19-00160](#).)

OIG Participation in Congressional Hearings

<i>Date</i>	<i>Witness</i>	<i>Testimony/Committee</i>
9/19/2019	Ann Maxwell, Assistant Inspector General for Evaluation and Inspections	<u>"HHS-OIG Oversight of the Unaccompanied Alien Children Program,"</u> House Committee on Energy and Commerce
9/18/2019	Ann Maxwell, Assistant Inspector General for Evaluation and Inspections	<u>"HHS-OIG Oversight of the Unaccompanied Alien Children Program,"</u> House Committee on Appropriations
7/23/2019	Megan H. Tinker, Senior Advisor for Legal Affairs	<u>"Promoting Elder Justice: A Call for Reform,"</u> Senate Committee on Finance
7/12/2019	Ann Maxwell, Assistant Inspector General for Evaluation and Inspections	<u>"HHS-OIG Oversight of the Unaccompanied Alien Children Program,"</u> House Committee on Oversight and Reform
6/19/2019	Vicki L. Robinson, Senior Counselor for Policy	<u>"The Complex Web of Prescription Drug Prices, Part III: Examining Agency Efforts to Further Competition and Increase Affordability,"</u> Senate Special Committee on Aging
6/5/2019	Leslie W. Hollie, Chief of Investigative Operations	<u>"Foreign Threats to Taxpayer-Funded Medical Research: Oversight Opportunities and Policy Solutions,"</u> Senate Committee on Finance

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
FCA	False Claims 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

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Financial Management and Improper Payments

Trends in Deficiencies at Nursing Homes Show That Improvements Are Needed To Ensure the Health and Safety of Residents (A-09-18-02010), April 2019

Our objective in this data brief was to analyze trends in the deficiencies that State agencies identified in nursing home surveys across the Nation. Our data analysis showed the following:

- The number of nursing home surveys and deficiencies slightly increased each year from 2013 through 2016, then slightly decreased in 2017.
- Ninety-four percent of deficiencies had “less serious” ratings, and 6 percent of deficiencies had “more serious” ratings.
- About 31 percent of nursing homes had a deficiency type that was cited at least five times during our review period.
- Ten States accounted for half of the deficiencies identified.
- The top 10 of 340 deficiency types accounted for more than 40 percent of deficiencies.

The results of our analysis do not clearly indicate whether the quality of care and the safety of nursing home residents improved during our review period.

We made several recommendations to CMS in our previous report to help ensure the health and safety of nursing home residents. Implementing those recommendations and considering the information in this data brief may help CMS and other stakeholders to identify areas for improvement in the nursing home survey and certification process, ensure that deficiencies recur less frequently at nursing homes, and improve the quality of care and the safety of residents at nursing homes across the Nation.

New York Should Improve Its Oversight of Selected Nursing Homes’ Compliance With Federal Requirements for Life Safety and Emergency Preparedness (A-02-17-01027), August 2019

New York did not ensure that selected nursing homes in the State that participated in the Medicare or Medicaid programs complied with CMS requirements for life safety and emergency preparedness. As a result, residents at the 20 nursing homes we reviewed were at increased risk of injury or death during a fire or other emergency.

The identified areas of noncompliance occurred because of inadequate management oversight and staff turnover at the nursing homes. In addition, New York did not have a standard life safety training program for all nursing home staff (not currently required by CMS), generally performed

comprehensive life safety surveys no more frequently than once every 9 to 15 months, and did not check to see whether carbon monoxide detectors were installed.

New York generally agreed with our recommendations to improve its oversight of the nursing homes' compliance with Federal requirements for life safety and emergency preparedness. New York also described steps it has taken or plans to take to address those recommendations.

Quality of Care, Safety, and Access

Concerns About Opioid Use in Medicare Part D in the Appalachian Region ([OEI-02-18-00224](#)), April 2019

We found that 36 percent of beneficiaries in five States in the Appalachian region—Alabama, Kentucky, Ohio, Tennessee, and West Virginia—received a prescription opioid through Medicare Part D in 2017. Almost 49,000 beneficiaries in these States received high amounts of opioids, far exceeding levels the CDC says to avoid. Of these, nearly 6,000 beneficiaries were at serious risk of opioid misuse or overdose. These 6,000 beneficiaries received extreme amounts of opioids or appeared to be doctor shopping. Ensuring the appropriate use and prescribing of opioids is essential to protecting the health and safety of beneficiaries and the integrity of Part D. The severity of the crisis makes it imperative that the HHS, including CMS and OIG, continue to work with its partners to address this epidemic.

Using Health IT for Care Coordination: Insights from Six Medicare Accountable Care Organizations ([OEI-01-16-00180](#)), May 2019

The six Accountable Care Organizations (ACOs) we visited have used health IT tools to better coordinate care for their patients. However, the promise of seamless integration and coordination across providers and care settings has not yet been realized. This work showcases some of the advances ACOs have made as well as challenges that remain for fulfilling that promise.

Incidents of Potential Abuse and Neglect at Skilled Nursing Facilities Were Not Always Reported and Investigated ([A-01-16-00509](#)), June 2019

An estimated one in five high-risk hospital ER Medicare claims for treatment provided in 2016 were the result of potential abuse or neglect, including injury of unknown source, of beneficiaries residing in a SNF. We determined that SNFs failed to report many of these incidents to the State Survey Agencies in accordance with applicable Federal requirements. We also determined that several Survey Agencies failed to report some findings of substantiated abuse to local law enforcement. Lastly, we determined that CMS does not require all incidents of potential abuse or neglect and related referrals made to law enforcement and other agencies to be recorded and tracked. Preventing, detecting, and combating elder abuse requires CMS, Survey Agencies, and SNFs to meet their responsibilities.

CMS concurred with our recommendations that it take action to ensure that incidents of potential abuse or neglect of Medicare beneficiaries residing in SNFs are identified and reported. Specifically, we recommended that CMS work with the Survey Agencies to improve training for staff of SNFs on how to identify and report incidents of potential abuse or neglect of Medicare beneficiaries, clarify guidance to define and provide examples of incidents of potential abuse or neglect, require the Survey Agencies to record and track all incidents of potential abuse or neglect in SNFs and referrals made to local law enforcement and other agencies, and monitor the Survey Agencies' reporting of findings of substantiated abuse to local law enforcement.

CMS Could Use Medicare Data To Identify Instances of Potential Abuse or Neglect (A-01-17-00513), June 2019

We estimated that, of 34,664 Medicare claims for our audit period that contained diagnosis codes indicating the treatment of injuries potentially caused by abuse or neglect of Medicare beneficiaries, 2,574 were allegedly perpetrated by a healthcare worker, 3,330 were related to incidents that occurred in a medical facility, and 9,294 were related to incidents that were not reported to law enforcement.

CMS did not identify the Medicare claims that indicate potential abuse or neglect because, according to CMS officials, it did not extract data consisting of Medicare claims containing the 17 diagnosis codes related to abuse or neglect. The lack of a data extract impeded the ability of CMS or of public and patient safety organizations to pursue legal, administrative, and other appropriate remedies to ensure the safety, health, and rights of Medicare beneficiaries.

CMS concurred with our recommendations that it assess the sufficiency of existing Federal requirements to report suspected abuse and neglect of Medicare beneficiaries and strengthen those requirements or seek additional authorities as appropriate. CMS did not concur with our recommendations that it (1) compile a complete list of diagnosis codes that indicate potential physical or sexual abuse and neglect, (2) use that list to conduct periodic data extracts of all Medicare claims containing at least one of those codes, and (3) inform States that the extracted Medicare claims data are available to help States ensure compliance with their mandatory reporting laws.

Part D Plans Generally Include Drugs Commonly Used by Dual Eligibles: 2019 (OEI-05-19-00220), June 2019

We found that overall, the rate at which Part D plan formularies include the drugs commonly used by dual eligibles (i.e., individuals who are eligible for both Medicare and Medicaid) is high, with some variation. The 401 unique formularies used by the 4,073 Part D plans include 97 percent of the 196 drugs most commonly used by dual eligibles and covered by Part D. In addition, 72 percent of the commonly used drugs are included by all Part D plan formularies. On average,

formularies applied utilization management tools to 28 percent of the unique drugs we reviewed in 2019.

Because some variation exists in formularies' inclusion of these drugs and in their application of utilization management tools to the drugs, some dual eligibles may need to use alternative methods to access the drugs they take.

Opioid Use Decreased in Medicare Part D, While Medication-Assisted Treatment Increased
([OEI-02-19-00390](#)), July 2019

We found that nearly 3 in 10 Medicare Part D beneficiaries received opioids in 2018, a decrease from the previous 2 years. At the same time, the number of beneficiaries receiving drugs for medication-assisted treatment for opioid use disorder steadily increased and reached almost 174,000 in 2018. In addition, the number of beneficiaries receiving prescriptions through Part D for naloxone—a drug that can reverse the effects of an opioid overdose—more than doubled from 2017 to 2018. Nearly 354,000 beneficiaries received high amounts of opioids in 2018, with about 49,000 of them at serious risk of opioid misuse or overdose; this was fewer than in the previous 2 years. About 200 prescribers had questionable opioid prescribing for the beneficiaries at serious risk. Although progress has been made in decreasing opioid use in Part D and increasing the use of medication-assisted treatment and the availability of naloxone, it is imperative for the Department to continue to implement effective strategies and develop new ones to address this epidemic.

Hospice Deficiencies Pose Risks to Medicare Beneficiaries ([OEI-02-17-00020](#)), July 2019

Over 80 percent of hospices had at least one deficiency. The most common types of deficiencies involved poor care planning, mismanagement of aide services, and inadequate assessments of beneficiaries. Further, one-third of hospices had complaints filed against them. Over 300 hospices were poor performers in that each had at least one serious deficiency or at least one substantiated severe complaint in 2016. The findings make clear the need for CMS to strengthen its oversight of the Medicare hospice program to better protect both the program and its beneficiaries.

CMS concurred or partially concurred with the following recommendations:

- Expand the deficiency data that accrediting organizations report to CMS and use the data to strengthen its oversight of hospices;
- Take the steps necessary to seek statutory authority to include information from accrediting organizations on Hospice Compare;
- Include on Hospice Compare the survey reports from accrediting organizations, once authority is obtained;
- Educate hospices about common deficiencies and those that pose particular risks to beneficiaries; and
- Increase oversight of hospices with a history of serious deficiencies.

CMS did not concur with the remaining recommendation:

- Include on Hospice Compare the survey reports from State agencies.

Safeguards Must Be Strengthened To Protect Medicare Hospice Beneficiaries From Harm
([OEI-02-17-00021](#)), July 2019

Some beneficiaries have been seriously harmed when hospices provided poor care or failed to take action in cases of abuse. These cases reveal vulnerabilities in beneficiary protections that CMS must address, including strengthening reporting requirements, to better ensure that beneficiary harm is identified, reported, addressed, and, ultimately, prevented.

There is one existing recommendation from prior OIG work that addresses these findings:

- CMS should seek statutory authority to establish additional, intermediate remedies for poor hospice performance.

In addition, CMS concurred with the first four of the following new recommendations and partially concurred with the fifth:

- Strengthen requirements for hospices to report abuse, neglect, and other harm;
- Ensure that hospices are educating their staff to recognize signs of abuse, neglect, and other harm;
- Strengthen guidance for surveyors to report crimes to local law enforcement;
- Monitor surveyors' use of immediate jeopardy citations; and
- Improve and make user-friendly the process for beneficiaries and caregivers to make complaints.

ACOs' Strategies for Transitioning to Value-Based Care: Lessons From the Medicare Shared Savings Program ([OEI-02-15-00451](#)), July 2019

As part of their transition to value-based care, Medicare Shared Savings Program ACOs reported a number of successful strategies in reducing Medicare spending and improving quality of care for patients. These strategies should inform CMS's broader efforts to transform the healthcare system from fee-for-service to value-based care.

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

- review the impact of programmatic changes on ACOs' ability to promote value-based care;
- expand efforts to share information about strategies that reduce spending and improve quality among ACOs and more widely with the public;
- adopt outcome-based measures and better align measures across programs;
- assess and share information about ACOs' use of the 3-day waiver and apply these results when making changes to the Shared Savings Program or other programs;

- identify and share information about strategies that integrate physical and behavioral health services and address social determinants of health;
- identify and share information about strategies that encourage patients to share behavioral health data; and
- prioritize ACO referrals of potential fraud, waste, and abuse.

Opioid Use in Medicare Part D in Missouri ([OEI-02-19-00391](#)), September 2019

We found that one-third of beneficiaries in Missouri received an opioid through Part D in 2018, which is higher than the national rate. In addition, almost 10,000 beneficiaries in Missouri received high amounts of opioids. About 1,400 beneficiaries in Missouri are at serious risk of opioid misuse or overdose. The severity of the national opioid crisis makes it imperative that States, including Missouri, take effective steps to address the epidemic. OIG supports State and Federal efforts to combat the opioid crisis. Notably, OIG supports States' efforts to implement and enforce strong prescription drug monitoring programs that require prescribers and pharmacies to check a database before prescribing and dispensing opioids.

Some Medicare Part D Beneficiaries Face Avoidable Extra Steps that Can Delay or Prevent Access to Prescribed Drugs ([OEI-09-16-00411](#)), September 2019

In 2017, Part D insurance companies (called "sponsors") rejected millions of prescriptions that beneficiaries tried to fill at pharmacies, and overturned a large number of drug-coverage denials when beneficiaries appealed. Some of these rejections and denials were avoidable or inappropriate, creating unnecessary extra steps for beneficiaries to obtain needed medications. Extra steps can delay or deter beneficiaries' access to medications if those beneficiaries are unable or unwilling to spend time navigating the approval process.

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

- take additional steps to improve electronic communication between Part D sponsors and prescribers to reduce avoidable pharmacy rejections and coverage denials;
- take action to reduce inappropriate pharmacy rejections;
- take action to reduce inappropriate coverage denials; and
- provide beneficiaries with clear, easily accessible information about sponsor performance problems, including those related to inappropriate pharmacy rejections and coverage denials.

Medicare's Oversight of Ambulatory Surgical Centers ([OEI-01-15-00400](#)), September 2019

We found that CMS has made progress in strengthening oversight of ambulatory surgery centers (ASCs) and addressing vulnerabilities that we previously identified, and more can be done. Most ASCs—known as nondeemed ASCs—undergo a State agency survey to demonstrate they meet Medicare requirements; others—known as deemed ASCs—undergo a survey from an approved

accreditor. States largely met Medicare’s requirement to survey 25 percent of nondeemed ASCs in FY 2017, and nearly half met its requirement to have surveyed all ASCs within the prior 6 years. However, infection control deficiencies found in State surveys continue to be a concern. We also found that from FYs 2013 to 2017, States received complaints for fewer than 4 percent of all ASCs (deemed and nondeemed) each year, but the share of those complaints requiring an onsite survey more than tripled. The results of this new analysis can support CMS in further strengthening its oversight—particularly of the few States that are falling short of meeting its requirements. It can also help CMS focus on ASCs’ recurring challenges in meeting health and safety requirements, especially for infection control.

Wisconsin Physicians Service Needs Enhanced Guidance and Provider Education Related to Phlebotomy Travel Allowances (A-06-17-04005), September 2019

Payments made by Wisconsin Physicians Service (WPS) to providers for travel allowances for clinical diagnostic laboratory tests did not always comply with Medicare requirements. Specifically, 76 of the 109 claim lines in our stratified random sample that were reviewed complied with Medicare requirements, but 33 claim lines did not (some lines had multiple deficiencies). WPS made payments to providers for (1) claims with incorrectly calculated prorated mileage, (2) claims using the incorrect clinical laboratory fee schedule rate, and (3) claims without sufficient documentation to support payment. On the basis of our sample results, we estimated that WPS paid providers \$353,755 in travel allowances for clinical laboratory services that were not in accordance with Medicare requirements.

WPS agreed to implement our recommendations that it (1) work with CMS to clarify guidance to providers, which could have resulted in savings totaling an estimated \$353,755 during our audit period; (2) educate providers on how to correctly calculate the prorated mileage for phlebotomy travel allowance payments; (3) educate providers on their responsibility to bring any previously paid claims to their MAC’s attention if they were paid using the wrong rate; and (4) educate providers on their responsibility to maintain adequate documentation to support payment for phlebotomy travel allowance payments.

Program Integrity

2018 Performance Data for the Senior Medicare Patrol Projects (OEI-02-19-00280), May 2019

The Senior Medicare Patrol (SMP) projects receive grants from the Administration for Community Living to recruit and train retired professionals and other older adults and community members to prevent, recognize, and report healthcare fraud, errors, and abuse. In 2018, the 61 SMP projects had a total of 6,935 total active team members who conducted a total of 26,932 group outreach and education events, reaching an estimated 1.7 million people. In addition, the projects had 278,761 individual interactions with, or on behalf of, a Medicare beneficiary. The projects reported

\$15,136 in expected Medicare recoveries and \$5,734 in expected Medicaid recoveries. Cost avoidance totaled \$602,063, while savings to beneficiaries and others totaled \$27,689.

The Centers for Medicare & Medicaid Services Could Use Comprehensive Error Rate Testing Data To Identify High-Risk Home Health Agencies (A-05-17-00035), September 2019

CMS could use Comprehensive Error Rate Testing (CERT) data to identify high-risk home health agencies (HHAs) as a part of a multifaceted approach that includes targeted probe-and-educate reviews as well as aspects of its Fraud Prevention System to further reduce improper payments and the error rate for claims paid to HHAs. Using nationally reported CERT program data for FYs 2014 through 2017, we identified 87 high-risk HHAs, which in the CERT sample had an improper payment rate of about 78 percent and approximately \$1 million in actual improper payments. Using Medicare program data during this same period, we determined that Medicare paid these 87 HHAs more than \$4 billion for services.

Given the amount of Medicare dollars paid to these providers and the high error rate observed in the CERT sample, focusing oversight on high-risk HHAs and the prevalent types of errors could significantly improve the effectiveness of CMS's efforts to reduce both HHA improper payments and the CERT error rate.

In written comments on our data brief, CMS recognized that HHA claims are a major source of improper payments and described past and future corrective actions that address this issue.

Drug Pricing and Reimbursement

Medicare Part D Rebates for Prescriptions Filled at 340B Contract Pharmacies (A-03-16-00002), July 2019

We determined that tens of millions of dollars in rebates could have been generated had manufacturers and sponsors agreed that eligible prescriptions filled at 340B contract pharmacies would receive rebates. If the Part D prescriptions for the sponsors in our review had been filled at non-340B pharmacies, sponsors calculated that manufacturers would have paid rebates of up to \$74.7 million for 554,549 claims in 2014. The manufacturers did not pay these rebates because, as sponsors reported, rebate agreements did not require manufacturers to pay rebates for Part D drugs filled at a 340B contract pharmacy.

We also found that because there are no 340B identifiers on claims and PDE records, sponsors do not have the data to distinguish whether prescriptions dispensed at a 340B contract pharmacy were filled using 340B drugs. Therefore, the possible additional rebate amount of up to \$74.7 million is for both 340B and non-340B drugs filled at a 340B contract pharmacy for Part D beneficiaries.

There is an opportunity to potentially reduce Part D costs if sponsors were to negotiate similar net prices for both non-340B drugs dispensed by 340B contract pharmacies and drugs dispensed by non-340B pharmacies.

This report contains no recommendations. We provide this report to inform congressional and administration decisionmakers of the impact that drugs dispensed at 340B contract pharmacies may have on the Part D program.

Medicare Part D Is Still Paying Millions for Drugs Already Paid for Under the Part A Hospice Benefit (A-06-17-08004), August 2019

Medicare Part D paid for drugs during 2016 that hospices should have paid for under the Medicare Part A hospice benefit. On the basis of our sample results, we estimated that the Part D total cost was \$160.8 million for drugs that hospice organizations should have paid for. Additionally, although hospices told us they should not have paid for the drugs associated with the remaining \$261.9 million of the \$422.7 million total cost, a review of CMS communications with hospices and sponsors between 2012 and 2016 indicates otherwise—hospice organizations or hospice beneficiaries likely should have paid for many of these drugs, not Part D.

CMS must do more to avoid paying twice for the same drugs. As we have previously recommended, CMS should work directly with hospices to ensure that they are providing drugs covered under the hospice benefit. In addition, we recommend that CMS should develop and execute a strategy to ensure that Part D does not pay for drugs that should be covered by the Part A hospice benefit.

CMS stated that its current efforts will address the issue and help ensure that there is no disruption in beneficiary access. We disagree with CMS's assertion that its current activities will adequately address the issue, and we continue to recommend that CMS develop controls to stop the duplicate hospice drug payments.

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2017 Average Sales Prices (OEI-03-19-00260), August 2019

On the basis of 2017 data, CMS lowered Medicare Part B reimbursement for 14 drugs, saving Medicare and its beneficiaries \$7 million over 1 year. This finding highlights the success of OIG's mandated quarterly comparisons of average sales prices (ASPs) with average manufacturer prices (AMPs) and implementation of CMS's current price-substitution policy. (If OIG finds that the ASP for a drug exceeds the AMP by a certain percentage—currently, 5 percent—the ASP-based payment amount is substituted with a lower calculated rate. This serves as a mechanism for monitoring market prices and limiting potentially excessive payment amounts.)

OIG continues to recommend that CMS expand the price-substitution criteria. CMS did not concur with this recommendation and believes that more experience with the price-substitution policy is needed before it can be expanded.

Rebates for Brand-Name Drugs in Part D Substantially Reduced the Growth in Spending from 2011 to 2015 ([OEI-03-19-00010](#)), September 2019

Overall, we found that increases in rebates substantially reduced the percentage increase in reimbursement for brand-name drugs in Part D from 2011 to 2015. Although rebates reduced the growth of total Part D spending, they did not prevent increased overall Part D spending for brand-name drugs from 2011 to 2015, as Medicare still spent \$2 billion more for brand-name drugs with rebates in 2015 than in 2011. At a drug-by-drug level, unit rebates did not always increase as unit reimbursement increased for brand name drugs reviewed. In fact, although unit reimbursement increased for nearly all drugs, rebates declined as unit reimbursement grew for 39 percent of drugs reviewed.

Medicaid Program Reports and Reviews

Financial Management and Improper Payments

California Medicaid Managed Care Organizations Received Capitation Payments After Beneficiaries' Deaths ([A-04-18-06220](#)), May 2019

Georgia Medicaid Managed Care Organizations Received Capitation Payments After Beneficiaries' Deaths ([A-04-15-06183](#)), August 2019

Illinois Medicaid Managed Care Organizations Received Capitation Payments After Beneficiaries' Deaths ([A-05-18-00026](#)), August 2019

Previous OIG reviews found that States had improperly paid Medicaid Managed Care Organizations (MCOs) capitation payments on behalf of deceased beneficiaries. We reviewed MCOs' capitation payments in three States.

We estimated that California made unallowable payments totaling \$70.9 million (\$53.4 million Federal share) to MCOs during our audit period. The unallowable payments occurred because California did not (1) disenroll beneficiaries after their dates of death were identified; (2) identify inconsistencies between dates of death and other data; or (3) regularly use additional sources or alternative procedures to identify, verify, or determine dates of death.

We estimated that Georgia made payments totaling nearly \$2.2 million (\$1.6 million Federal share) after a beneficiary's death to MCOs during our audit period.

We estimated that Illinois did not recover unallowable MCO payments made on behalf of deceased beneficiaries during our audit period, totaling at least \$4.6 million (\$3.2 million Federal share). Illinois did not enter the dates of death in the Medicaid Management Information System (MMIS) for the majority of our sampled beneficiaries.

California generally concurred with our recommendations that it refund \$53.4 million to the Federal Government and identify and recover unallowable payments made to MCOs during our audit period on behalf of deceased beneficiaries, which we estimate to be at least \$70.9 million, and with our other procedural and administrative recommendations.

Georgia generally concurred with our findings and described actions it has taken or plans to take to address our recommendations that it (1) use additional sources of date of death, (2) implement additional controls to more effectively detect payments involving deceased, and (3) continue to identify payments made after a beneficiary's death to prevent additional payments.

Illinois accepted our recommendations that it (1) refund \$3.2 million to the Federal Government; (2) identify and recover unallowable payments made to MCOs during our audit period on behalf of deceased beneficiaries, which we estimate to be at least \$4.6 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; and (4) ensure that dates of death are added to the MMIS for deceased beneficiaries that were previously marked as "inactive."

New York May Not Have Complied With Federal and State Requirements Prohibiting Medicaid Payments for Inpatient Hospital Services Related to Provider-Preventable Conditions (A-02-16-01022), May 2019

Massachusetts Did Not Ensure Its Managed-Care Organizations Complied With Requirements Prohibiting Medicaid Payments for Services Related to Provider-Preventable Conditions (A-01-17-00003), May 2019

Pennsylvania Did Not Ensure That Its Managed-Care Organizations Complied With Requirements Prohibiting Medicaid Payments for Services Related to Provider-Preventable Conditions (A-03-16-00205), August 2019

Federal regulations prohibit Medicaid payments for inpatient hospital services related to provider-preventable conditions (PPCs). We reviewed three States to determine whether they ensured that their Medicaid MCOs complied with these regulations.

New York did not provide sufficient evidence that it prevented or reduced any payments for PPCs. In addition, New York did not provide documentation of the PPCs in its claim payment processing system or its policies and procedures to identify and update PPCs. Therefore, we have set aside payments for these services for resolution by CMS and New York.

Massachusetts MCOs paid providers approximately \$10 million for 533 claims that contained PPCs. In addition, the MCOs did not have policies or procedures to identify PPCs on claims for inpatient hospital services or determine whether payments for claims containing PPCs should have been reduced.

Pennsylvania MCOs paid providers approximately \$43.5 million for 576 claims that contained PPCs. As a result, unallowable payments for services related to treating PPCs might have been included in the calculation of capitation payment rates.

New York generally agreed with our recommendations that it provide CMS with sufficient documentation to determine whether any portion of the \$50.3 million Federal Medicaid reimbursement was unallowable and refund to the Federal Government the unallowable amount.

Massachusetts did not address our recommendations that it (1) work with the MCOs to determine the portion of the \$10 million that was unallowable, (2) enforce the requirement that makes MCO compliance with the PPC provisions a condition of their payment, (3) enforce the requirement that allows intermediate sanctions to be imposed upon MCOs for failure to comply with applicable requirements, (4) require the MCOs to implement internal controls, and other procedural recommendations. Massachusetts said it will work with the MCOs to further review the 533 claims and to improve its MCOs' data, reporting, and related processes but disagreed with the amount of our finding and its impact on future capitation rates.

Pennsylvania concurred with all of our recommendations, including that it (1) work with the MCOs to determine the portion of the \$43.5 million that was unallowable for claims containing PPCs and its impact on capitation payment rates, (2) include a clause in its agreements with the MCOs that would allow Pennsylvania to recoup funds when contract provisions and Federal and State requirements are not met, and (3) enforce the provisions in its agreements that allow sanctions or penalties to be imposed for noncompliance with or failure to meet performance and program standards.

New York Claimed Federal Reimbursement for Some Payments to Health Home Providers That Did Not Meet Medicaid Requirements (A-02-17-01004), July 2019

For 22 of 100 sampled payments, New York improperly claimed Federal Medicaid reimbursement for payments made to health home providers that did not comply with Federal and State requirements. Specifically, New York's health home providers did not provide services according to a comprehensive individualized patient-centered care plan, ensure that beneficiaries participated in the development and execution of their care plan, maintain documentation to support services billed, bill correctly for services, and bill only for services actually provided. New York also claimed reimbursement for services that duplicated similar ones provided under a different Medicaid-funded program.

The deficiencies occurred because New York did not adequately monitor health home providers for compliance with certain Federal and State requirements for providing, documenting, and billing services. Based on our sample results, we estimated that New York improperly claimed at least \$65.5 million in Federal Medicaid reimbursement for payments made to health home providers.

New York did not indicate concurrence or nonconcurrence with our recommendations that it refund \$65.5 million to the Federal Government and that it improve its monitoring of the health home program to ensure that providers comply with Federal and State requirements for (1) providing services according to a care plan and ensuring beneficiary participation in the development and execution of the care plan, (2) maintaining documentation to support services billed, (3) billing correctly for services, (4) billing only for services actually provided, and (5) not billing for services that duplicate those provided under a different Medicaid-funded program.

New York Did Not Correctly Determine Medicaid Eligibility for Some Non-Newly Eligible Beneficiaries (A-02-16-01005), July 2019

For our sample of 130 beneficiaries, New York correctly determined Medicaid eligibility for 110 beneficiaries but incorrectly determined Medicaid eligibility for 6 beneficiaries. New York did not provide supporting documentation to verify that the remaining 14 beneficiaries were Medicaid-eligible. Additionally, New York's enrollment system did not always query all electronic data sources to ensure that individuals were reporting all sources of countable income when applying for Medicaid. Lastly, New York did not always maintain documentation to support eligibility determinations.

On the basis of our sample results, we estimated that New York made Federal Medicaid payments of \$520.3 million on behalf of 383,893 ineligible beneficiaries and \$1.3 billion on behalf of 618,057 potentially ineligible beneficiaries during our 6-month audit period.

New York did not specifically indicate concurrence or nonconcurrence with our recommendations that it (1) redetermine, as appropriate, the current Medicaid eligibility status of the sampled beneficiaries who did not meet Federal and State eligibility requirements; (2) take the necessary steps to ensure that local district and marketplace staff consider all available, relevant information and data sources, as well as all Federal and State requirements, when determining Medicaid eligibility; and (3) maintain the necessary documentation to determine whether it enrolled individuals who did not meet Federal and State Medicaid eligibility requirements, which could have resulted in up to \$1.3 billion in potentially improper Federal Medicaid payments over the 6-month audit period.

New York Incorrectly Claimed Enhanced Federal Medicaid Reimbursement for Some Beneficiaries (A-02-15-01023), August 2019

New York incorrectly enrolled beneficiaries in eligibility categories for which services were reimbursed at an enhanced Federal medical assistance percentage (FMAP) rate despite case file documentation indicating that the beneficiaries should have been enrolled in a group for which services qualified under the standard FMAP or were not eligible for reimbursement.

On the basis of our sample results, we estimated that New York incorrectly claimed enhanced Federal Medicaid reimbursement of \$116.9 million on behalf of 184,590 Medicaid beneficiaries enrolled in the new adult group during our 6-month audit period.

New York did not indicate concurrence or nonconcurrence with our recommendations that it (1) redetermine, as appropriate, the current Medicaid coverage group of the sampled beneficiaries for which services were incorrectly reimbursed at an enhanced FMAP rate; (2) ensure that it claims Medicaid reimbursement at the correct FMAP rate by taking the necessary steps to ensure that its staff considers all relevant documentation and Federal and State requirements during the enrollment process, which could have reduced or eliminated an estimated \$116.9 million in overpayments caused by eligibility errors over the 6-month audit period; and (3) maintain the necessary documentation to determine whether it enrolled individuals who did not meet Federal and State Medicaid eligibility requirements in the new adult group.

Colorado Did Not Correctly Determine Medicaid Eligibility for Some Newly Enrolled Beneficiaries (A-07-16-04228), August 2019

Colorado made Medicaid payments on behalf of newly eligible beneficiaries who did not meet, or who may not have met, Federal and State eligibility requirements. Colorado correctly determined eligibility and, therefore, correctly claimed Federal Medicaid reimbursement, on behalf of 43 of the 60 beneficiaries in our statistical sample. However, of the remaining 17 beneficiaries whom Colorado determined to be newly eligible for Medicaid, 14 were ineligible and 4 may have been ineligible. We estimated that the financial impact of the incorrect eligibility determinations made by Colorado totaled at least \$66.5 million on behalf of 85,085 ineligible beneficiaries and at least \$26.8 million on behalf of 13,372 potentially ineligible beneficiaries.

These deficiencies occurred because Colorado did not always follow written policies and procedures when making eligibility determinations and because of system and procedural errors related to eligibility determinations, as well as human errors made by Colorado staff and caseworkers.

Colorado agreed with our recommendations that it redetermine, as appropriate, the current Medicaid eligibility status of the sampled beneficiaries. We also make other procedural

recommendations regarding improvements to the design, functionality, and accuracy of Colorado’s eligibility determination system.

Florida Medicaid Paid Hundreds of Millions in Unallowable Payments to Jackson Memorial Hospital Under Its Low Income Pool Program (A-04-17-04058), August 2019

Florida paid hundreds of millions of dollars to Jackson Memorial Hospital (the Hospital) under the Low Income Pool (LIP) program that were not in accordance with its Research and Demonstration Waiver for Medicaid reform and Federal regulations. Of the \$1.8 billion in LIP payments made to the Hospital during our audit period, Florida claimed Medicaid reimbursement of \$686 million (\$412 million Federal share) in excess of the Hospital’s allowable costs, including \$132 million (\$64 million Federal share) of net Hospital-reported overpayments and \$554 million (\$348 million Federal share) of unallowable costs identified during this audit.

We recommend that Florida (1) refund \$412 million to the Federal Government, including \$64 million of hospital-reported net overpayments and \$348 million of unallowable costs identified during this audit; (2) instruct hospitals to establish procedures to return the Federal share of any overpayments in their LIP cost-limit calculations; (3) establish procedures to ensure that it returns to the Federal Government the Federal share of overpayments reported by hospitals; and (4) improve its oversight of the LIP program. We also made other procedural recommendations.

Both the Hospital and Florida disagreed with our findings. Most significantly, the Hospital and Florida contended that we incorrectly determined that the Hospital should offset Medicare and commercial insurance payments against costs for dual-eligible patients. After reviewing both the Hospital’s and Florida’s comments, we maintain that our findings and recommendations are correct but reduced the recommended refund from \$436 million to \$412 million based on additional information that Florida provided.

CMS Paid Over \$277 Million in Unallowable CHIPRA Bonus Payments Based on Incorrect Enrollment Data (A-04-17-08061), September 2019

Our previous audits of Children’s Health Insurance Program Reauthorization Act of 2009 (CHIPRA) bonus payments identified over \$277 million in unallowable payments from \$645 million that CMS paid to 12 States, representing approximately 43 percent of all bonus payments made to those States. CMS has taken significant action to recover these overpayments. Three States voluntarily returned overpayments totaling approximately \$37 million to CMS, and CMS withheld almost \$51 million from States with unspent bonus payment funds. Additionally, CMS issued letters to States initiating recovery of the remaining \$189 million in unallowable payments our audits identified.

These unallowable payments occurred because the CMS CHIPRA bonus program had internal control weaknesses that allowed States to submit incorrect current enrollment numbers to CMS.

Additionally, CMS did not use available data to conduct postaward reviews to verify the accuracy of the current enrollment that the States reported for their bonus payments.

CMS concurred with our findings and described actions it has taken or plans to take to address our recommendations that it continue to work with States to collect the remaining \$189 million in unallowable payments from the over \$277 million that we identified in 12 previously issued reports and consider the results of these reviews when designing internal controls for similar programs to ensure that timely and accurate data are available for adequate oversight, followup, and verification.

Ohio Made Medicaid Capitation Payments That Were Duplicative or Were Improper Based on Beneficiary Eligibility Status or Demographics (A-05-16-00061), September 2019

Ohio did not always make capitation payments for its Medicaid Managed Care program in accordance with Federal and State requirements. For 135 of 200 sampled beneficiary-months, Ohio either made proper capitation payments or canceled the capitation payments before we selected the sample. Capitation payments for the remaining 65 beneficiary-months were improper. On the basis of our sample results, we estimated that Ohio claimed net overpayments totaling at least \$10.6 million (\$6.7 million Federal share) for beneficiary-months in the sampling frame. Generally, Ohio made these improper payments because eligibility system controls did not prevent them, payment system controls did not adjust them, or users entered incorrect data in the eligibility systems.

Ohio concurred with our recommendation that it refund \$6.7 million to the Federal Government. Ohio concurred with one of our procedural recommendations about controls to prevent improper capitation payments in the future but did not concur with the other two. However, Ohio described actions it has taken or planned to take in response to all three procedural recommendations.

Quality of Care, Safety, and Access

National Background Check Program for Long Term Care Providers: Assessment of State Programs Concluded Between 2013 and 2016 (OEI-07-16-00160), April 2019

The National Background Check Program (Program) provides grants to States to develop systems to conduct background checks of State and Federal criminal history records for prospective long-term-care employees. The 10 States that had concluded their participation in the Program by 2016 varied in the extent to which they achieved implementation of Program requirements. Seven of these 10 States implemented all or most of the selected requirements. Three States did not have the necessary authority through State legislation and could not fully implement background check programs.

CMS concurred with our recommendation to take appropriate action to encourage participating States to obtain necessary authorities to fully implement Program requirements.

Four States Did Not Comply With Federal Waiver and State Requirements in Overseeing Adult Day Care Centers and Foster Care Homes (A-05-19-00005), May 2019

Four States (Minnesota, Illinois, Wisconsin, and Mississippi) did not comply with Federal waiver and State requirements in overseeing adult day service centers (centers) and adult foster care homes (homes). Our reviews found 1,141 instances of noncompliance with health and safety and administrative requirements at 96 of the 100 centers and homes reviewed.

State officials in Minnesota, Wisconsin, and Mississippi said that most instances of noncompliance occurred because of low staffing levels that limited the States' oversight and monitoring of facilities and because of insufficient training on State requirements. State officials in Illinois and Minnesota said that the absence of templates for State-required administrative records and unclear State requirements contributed to noncompliance with numerous health and safety and administrative requirements.

CMS concurred with our recommendations that it work with the States reviewed to ensure that the instances of noncompliance with health and safety and administrative requirements identified in this report are corrected; assist all States in ensuring the health and safety of vulnerable adults by offering technical assistance on staffing models in centers, homes, and other home and community-based services (HCBS) settings; review current training the States provide to centers and homes; and ensure the health and safety of vulnerable adults by offering technical assistance on possible templates for administrative records in centers, homes, and other HCBS settings.

Alaska Did Not Fully Comply With Federal and State Requirements for Reporting and Monitoring Critical Incidents Involving Medicaid Beneficiaries With Developmental Disabilities (A-09-17-02006), June 2019

Alaska did not fully comply with Federal Medicaid waiver and State requirements for reporting and monitoring critical incidents involving Medicaid beneficiaries with developmental disabilities residing in community-based settings. For the 303 judgmentally selected claims we reviewed, 68 percent (205 claims) were not reported to Alaska as critical incidents.

Alaska did not have a process, such as performing analytical procedures on Medicaid claims data, to determine whether there were unreported critical incidents. Alaska cannot investigate and take appropriate action to protect the health and welfare of Medicaid beneficiaries with developmental disabilities when community-based providers do not report critical incidents. As a result of not ensuring that providers reported all critical incidents, Alaska did not ensure proper responses to critical incidents or events as outlined in the safeguard assurances it provided to CMS in the Federal Medicaid waivers.

Alaska did not indicate concurrence or nonconcurrence with our recommendations that it (1) work with community-based providers on processes to identify and report all critical incidents, and (2) perform analytical procedures, such as data matches, on Medicaid claims data to identify potential critical incidents that have not been reported and investigate as needed.

Kentucky Did Not Comply With Federal Waiver and State Requirements at 14 of 20 Adult Day Health Care Facilities Reviewed (A-04-18-00123), July 2019

Kentucky did not fully comply with Federal waiver and State requirements in overseeing providers that serve vulnerable adults receiving adult day healthcare services through the program. Of the 20 providers that we reviewed, 12 did not comply with 1 or more health and safety requirements, and 10 did not comply with 1 or more administrative requirements. We found 63 instances of provider noncompliance, including 26 instances of noncompliance with health and safety requirements. The remaining 37 instances related to administrative requirements, some of which could significantly affect health and safety.

Kentucky did not fully comply with Federal waiver and State requirements because its annual inspections of facilities were insufficient to ensure a continuously safe and nonhazardous environment. Officials stated, however, that Kentucky improved monitoring in April 2018 by modifying its provider recertification process to include annually reviewing all providers and completing a certification tool during an announced site visit to each provider.

Kentucky did not indicate concurrence or nonconcurrence with our recommendation that it ensure that providers correct the 63 instances of provider noncompliance identified in this report. Kentucky concurred with our recommendations that it improve its oversight and monitoring of providers by considering unannounced site visits and by enhancing its certification tool as it pertains to reviewing participant records and that it work with providers to improve their facilities, staffing, and training.

Oversight of Opioid Prescribing and Monitoring of Opioid Use: States Have Taken Action To Address the Opioid Epidemic (A-09-18-01005), July 2019

We identified actions that selected States took related to their oversight of opioid prescribing and their monitoring of opioid use. The selected States were Nebraska, Nevada, New Hampshire, Tennessee, Texas, Utah, Washington, and West Virginia. This report summarizes and compares information provided by the eight States.

The States have created policies and procedures and passed laws and regulations related to opioids. The States are using opioid-related data to perform data analytics, as well as performing outreach to providers and patients. The States have implemented a number of opioid-related

prevention, detection, and treatment programs. Finally, the States have taken many other actions to address the opioid epidemic.

This report contains no recommendations.

Many Medicaid-Enrolled Children Who Were Treated for ADHD Did Not Receive Recommended Followup Care (OEI-07-17-00170), August 2019

OIG reviewed Medicaid claims data from all States and the District of Columbia and found over 500,000 Medicaid-enrolled children newly prescribed an ADHD medication did not receive followup care within the timeframes outlined in the national quality measures. Followup care is an important part of treatment for ADHD as the disorder can affect all aspects of a child's academic and health outcomes.

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

- collaborate with partners to develop strategies for improving rates of followup care for children treated for ADHD,
- provide technical assistance to States to implement strategies for improving rates of followup care for children treated for ADHD, and
- analyze the effectiveness of strategies for improving rates of followup care for children treated for ADHD.

National Review of Opioid Prescribing in Medicaid Is Not Yet Possible (OEI-05-18-00480), August 2019

We found that 32 States were missing data for variables needed to review opioid prescribing in Medicaid and that limitations of data from the national Medicaid claims database—the Transformed Medicaid Statistical Information System (T-MSIS)—impede identification of individual beneficiaries for national opioid analysis. Until T-MSIS data are complete in all States and limitations across States are addressed, it will not be possible to conduct a national evaluation of Medicaid beneficiaries at risk of opioid misuse or overdose.

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

- work to ensure that individual beneficiaries can be uniquely identified at a national level using T-MSIS,
- ensure the correct submission of National Provider Identifiers for prescribers, and
- clarify requirements for diagnosis codes.

National Background Check Program: Assessment of Concluded State Grant Programs in 2017 and 2018 (OEI-07-18-00290), August 2019

OIG reviewed the National Background Check Program for Long-Term-Care Providers (Program) and found that 9 of the 11 States that concluded their participation in 2017 and 2018 did not implement all of the selected Program requirements, primarily because of a lack of State legislative authority. The findings of this report are consistent with our previous assessments of the Program and provide further support for one open OIG recommendation. We strongly encourage CMS to implement the open recommendation to take appropriate actions to encourage States to obtain the necessary legislative authority to fully implement Program requirements.

Provider Shortages and Limited Availability of Behavioral Health Services in New Mexico's Medicaid Managed Care (OEI-02-17-00490), September 2019

New Mexico's Medicaid managed care program has limited availability of behavioral health services for its enrollees, including few behavioral health providers and difficulty arranging services. The challenges faced by New Mexico—including provider shortages and limited availability of behavioral health services—are likely shared by other States and will require both State and national attention.

Both CMS and the New Mexico Human Services Department concurred with our recommendations. The first recommendation was made to CMS and the following 10 recommendations were made to the State:

- Identify States that have limited availability of behavioral health services and develop strategies and share information to ensure that Medicaid managed care enrollees have timely access to these services.
- Take steps to expand New Mexico's overall behavioral health workforce.
- Increase behavioral health providers' participation in Medicaid managed care.
- Review New Mexico's standards governing access to care and determine whether additional standards are needed for behavioral health providers.
- Improve access to transportation for Medicaid managed care enrollees needing behavioral health services.
- Work with State partners to strengthen access to broadband in rural and frontier counties.
- Expand the use of telehealth to increase the availability of behavioral health services.
- Take steps to increase adoption of electronic health records and participation in the State Health Information Exchange by behavioral health providers.
- Identify and share information about strategies to improve care coordination.
- Expand initiatives to integrate behavioral and primary healthcare.
- Share information about open-access scheduling and the Treat First Clinical Model and promote expansion.

Program Integrity

Problems Remain for Ensuring All High Risk Medicaid Providers Undergo Criminal Background Checks (OEI-05-18-00070), July 2019

We found that 13 States had not implemented fingerprint-based criminal background checks for their high-risk Medicaid providers as of January 1, 2019. We also found that unscrupulous providers could exploit loopholes in the provider enrollment process to enroll in Medicaid without undergoing these checks. If not all high-risk providers undergo criminal background checks, the Federal and State Governments are vulnerable to unscrupulous providers intent on defrauding the Medicaid program.

CMS concurred with our recommendation to:

- ensure that all States fully implement fingerprint-based criminal background checks for high-risk Medicaid providers.

CMS did not concur with our recommendations to:

- amend CMS guidance so that States cannot forgo conducting criminal background checks on high-risk providers applying for Medicaid that have already enrolled in Medicare unless Medicare has conducted the checks, and
- compare high-risk Medicaid providers' self-reported ownership information to Medicare's provider ownership information to help States identify discrepancies.

California Needs To Improve Oversight of Community-Based Adult Services Providers' Compliance With Health and Safety and Administrative Requirements (A-09-18-02002), September 2019

California's oversight did not ensure that providers serving vulnerable adults who received services through the Community-Based Adult Services Program complied with Federal waiver and State requirements. All 24 providers we reviewed did not comply with 1 or more health and safety or administrative requirements. The 24 providers reviewed each had from 1 to 21 instances of noncompliance. In total, we found 290 instances of noncompliance with health and safety and administrative requirements.

According to State officials from the administering departments, relicensing surveys were not always conducted within the required 2-year timeframe because of competing priorities and staffing issues. In addition, because recertification focuses on quality-of-care issues, some instances of noncompliance related to the centers' physical environment were not always identified during inspections.

California agreed with our recommendations that it (1) ensure that the 24 providers we reviewed correct the 290 instances of noncompliance identified in this report and (2) work with the other administering departments to improve the oversight of providers to ensure that relicensing surveys are conducted within the required 2-year timeframe and recertification inspections evaluate all applicable compliance areas.

Drug Pricing and Reimbursement

Medicaid Could Save Hundreds of Millions by Excluding Authorized Generic Drug Transactions to Secondary Manufacturers from Brand Name Drugs' Average Manufacturer Price Calculations ([A-06-18-04002](#)), April 2019

By including authorized generic drug transactions to secondary manufacturers in the brand name drugs' AMP calculations, Medicaid received 46 percent less in rebates than it otherwise would have for the nine brand-name drugs we reviewed, amounting to \$595 million for CY 2017.

CMS concurred with our recommendation that it seek legislative change to exclude authorized generic drug transactions to secondary manufacturers from the AMP calculation of the brand-name drug, which may increase manufacturer Medicaid rebate obligations by hundreds of millions each year.

Indiana Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs ([A-05-17-00038](#)), April 2019

New Jersey Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs ([A-02-16-01012](#)), May 2019

Illinois Claimed Unallowable Federal Reimbursement for Some Medicaid Physician-Administered Drugs ([A-05-18-00030](#)), June 2019

Connecticut Claimed Unallowable Federal Reimbursement for Medicaid Physician-Administered Drugs That Were Not Invoiced to Manufacturers for Rebates ([A-07-18-06078](#)), August 2019

For a covered outpatient drug to be eligible for Federal reimbursement under the Medicaid program's drug rebate requirements, manufacturers must pay rebates to the States for the drugs. We reviewed four States' compliance with Federal Medicaid requirements for invoicing manufacturers for rebates for physician-administered drugs. These States' internal controls did not always ensure that they invoiced manufacturers to secure rebates.

Indiana did not invoice manufacturers for rebates associated with \$710,420 (Federal share) in single-source and top-20 multiple-source physician-administered drugs. Further, Indiana did not submit the drug utilization data necessary to secure rebates for other physician-administered drugs totaling \$142,339 (Federal share).

New Jersey did not invoice manufacturers for rebates associated with \$8.1 million (Federal share) in single-source and top-20 multiple-source physician-administered drugs. Further, New Jersey did not submit the drug utilization data necessary to secure rebates for other physician-administered

drugs. These drugs were included in claims totaling \$7,889 (Federal share) that did not have drug codes and in claims totaling \$1.1 million (Federal share) that contained drug codes.

Illinois did not invoice manufacturers for rebates associated with \$4.1 million (Federal share) in physician-administered drugs. Further, Illinois did not submit the drug utilization data necessary to secure rebates for other physician-administered drugs, totaling \$258,640 (Federal share).

Connecticut did not invoice manufacturers for rebates associated with \$1.1 million (Federal share) in physician-administered drugs. Further, Connecticut did not submit the utilization data necessary to secure rebates for all other physician-administered drug claims totaling \$2.8 million (Federal share).

Indiana generally agreed with our recommendations that it refund \$710,420 and work with CMS to determine the proper resolution of the \$142,339 for the other drug claims in question.

New Jersey concurred with our procedural recommendations and partially concurred with our recommendations that it refund to the Federal Government \$8.1 million for single-source and top-20 multiple-source physician-administered drugs and work with CMS to determine the unallowable portion of the \$1.1 million for other drug claims in question.

Illinois concurred with our recommendations that it refund \$4.1 million and work with CMS to determine the proper resolution of the \$258,640 for the other drug claims in question.

Connecticut generally concurred with our recommendations that it refund to the Federal Government \$1.07 million (Federal share) for claims for single-source physician-administered drugs, and \$46,210 for claims for top-20 multiple-source physician-administered drugs, and work with CMS to determine the unallowable portion of the \$2.8 million (Federal share) for other claims for outpatient physician-administered drugs that were at issue.

One Percent of Drugs With Medicaid Reimbursement Were Not FDA-Approved (OEI-03-17-00120), May 2019

We found that nearly all drugs with Medicaid reimbursement in 2016 were approved by FDA. However, 1 percent of drugs with Medicaid reimbursement were not FDA-approved, and we were unable to determine the FDA approval status for another 3 percent of drugs. CMS concurred with all of our recommendations, which were to:

- work with States to recoup any potentially inappropriate Federal reimbursement for drugs that it determines were not FDA approved and did not meet the criteria for an exception,
- continue to improve its reporting system to prevent inappropriate reimbursement for drugs that are not FDA approved, and
- work with States to ensure that they prevent inappropriate reimbursement for drugs that are not FDA approved and do not meet the criteria for an exception.

New Jersey Did Not Bill Manufacturers for Tens of Millions of Dollars in Rebates for Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-02-16-01011), August 2019

Texas Did Not Bill Manufacturers for Some Rebates for Physician-Administered Drugs Dispensed to Enrollees of Medicaid Managed-Care Organizations (A-06-17-04001), August 2019

New Jersey did not bill for and collect from manufacturers estimated rebates of \$75.5 million (Federal share) for pharmacy and physician-administered drugs that were eligible or may have been eligible for rebates for our audit period. Additionally, using data for our audit period, we estimated that the State did not bill for and collect \$119.6 million (Federal share) in drug rebates from manufacturers for the nearly 4-year period before our audit period.

Texas did not bill for and collect from manufacturers rebates of \$4.4 million (\$2.6 million Federal share) for physician-administered drugs. In addition, Texas did not bill for rebates for 160,579 claim lines for other physician-administered drugs that may have been eligible for rebates.

New Jersey agreed with our recommendations that it (1) bill for and collect from manufacturers rebates for single-source and top-20 multiple-source pharmacy and physician-administered drugs and refund the estimated \$28.1 million (Federal share) and (2) work with CMS to determine whether the other pharmacy and physician-administered drugs were eligible for rebates and, if so, upon receipt of the rebates, refund up to an estimated \$47.4 million (Federal share) for our audit period and \$119.6 million (Federal share) for the nearly 4-year period before our audit period. We also made procedural recommendations.

Texas did not indicate concurrence or nonconcurrence with our recommendations that it (1) bill manufacturers for the \$2.2 million (Federal share) in rebates for single-source and top-20 multiple-source physician-administered drugs, and refund the Federal share of rebates collected; (2) work with CMS to determine whether the non-top-20 multiple-source physician-administered drugs were eligible for rebates and, if so, bill manufacturers for the rebates and refund the Federal share of rebates collected; (3) work with CMS to determine whether the other physician-administered drugs were eligible for rebates and, if so, determine the rebates due and refund the Federal share of the rebates collected; and (4) strengthen internal controls to ensure that all eligible physician-administered drugs are billed for rebate.

Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices (OEI-12-17-00130), September 2019

We found that under current practices, CMS never assesses the majority of the “reasonable assumptions” that it allows manufacturers to make when calculating average manufacturer price (AMP) and best price (BP). Historically, CMS has provided little formalized oversight of the reasonable assumptions process, specifically instructing manufacturers not to submit their reasonable assumptions to CMS. Ensuring the accuracy of manufacturer-reported AMPs and BPs is

vital given that these prices are the primary benchmarks that the Federal Government uses to calculate the rebates and discounts available to Medicaid and certain safety-net providers.

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

- issue guidance related to the areas identified in the report—specifically, value-based purchasing arrangements;
- assess the costs and benefits of implementing a targeted process to review certain assumptions; and
- implement a system to share responses to manufacturer inquiries for technical assistance.

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 healthcare providers who engage in these healthcare 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 FCA. 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 353 criminal and 357 civil actions against individuals or entities that engaged in offenses related to healthcare. We also reported over \$1.47 billion in investigative receivables due to HHS and more than \$1.13 billion in non-HHS investigative receivables, including civil and administrative settlements or civil judgments related to Medicare, Medicaid, and other Federal, State, and private healthcare 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.

Pharmaceutical Companies

The following case examples involve pharmaceutical companies:

Virginia—Reckitt Benckiser Group PLC and Reckitt Benckiser LLC (collectively "RB Group") entered into a \$700 million civil FCA settlement with the United States in connection with the marketing and promotion of the opioid addiction treatment drug Suboxone. The civil settlement agreement is part of a global criminal, civil, and administrative settlement under which RB Group agreed to pay a total of \$1.4 billion. The civil settlement agreement resolved FCA allegations that RB Group (directly and through its subsidiaries) caused false claims for Suboxone to be submitted to Federal health care programs. More specifically, the civil settlement resolved allegations that RB Group knowingly (1) promoted the sale and use of Suboxone to physicians who were writing prescriptions for the drug without any counseling or psychosocial support and for uses that were unsafe, ineffective and medically unnecessary and that were often diverted for uses that lacked a legitimate medical purpose; (2) promoted the sale or use of Suboxone film to physicians and State Medicaid agencies using false and misleading claims; and (3) submitted a Citizen's Petition containing fraudulent claims about Suboxone tablet to the FDA in 2012 and took other steps to delay the entry of generic competition for Suboxone tablets.

Massachusetts—Three pharmaceutical companies—Jazz Pharmaceuticals (Jazz), Lundbeck LLC (Lundbeck), and Alexion Pharmaceuticals Inc. (Alexion)—agreed to pay a total of \$122.6 million to resolve allegations that they each violated the FCA by illegally paying the Medicare or Civilian Health and Medical Program (ChampVA) copayments for their own products, through purportedly independent 501(c)3 foundations that the companies used as mere conduits for unlawful payments to patients. The foundations operated funds that pay the copayments of certain patients, including Medicare patients. The Federal anti-kickback statute prohibits pharmaceutical companies from paying remuneration (either directly or indirectly) to induce Federal health care program beneficiaries to purchase the companies' drugs. Jazz and Lundbeck each entered into a CIA in connection with its respective settlement.

Pharmacies

The following case example involves a pharmacy:

Florida—Eliseo Dejesus Espaillat, owner and operator of AC National Pharmacy, Inc., was convicted of charges resulting from his involvement in a scheme to defraud Medicare Part D. According to court documents, Espaillat and his co-conspirators submitted and caused the submission of fraudulent claims to healthcare benefit programs, concealed the submission of the fraudulent claims to healthcare benefit programs, concealed the receipt and transfer of fraud proceeds, and diverted the fraud proceeds for their personal use.

Specifically, Espaillat billed Medicare for drugs that it neither purchased nor dispensed, and opened multiple shell companies to launder the proceeds. Espaillat was indicted in February 2017 and in April 2018 was apprehended by the United States Marshals Service deputies while attempting to enter a courthouse in the Dominican Republic. Espaillat was extradited to Miami where he pleaded guilty and was sentenced to 4 years and 3 months in prison and ordered to pay \$1.13 million in restitution, joint and several. One defendant involved in the scheme was previously sentenced to 3 years and 10 months and ordered to pay \$1.1 million in restitution, joint and several.

Ambulance Transportation Companies

The following case example involves an ambulance transportation company:

Texas—Keeble Lovall, owner of Your Health EMS (Your Health), was involved in a scheme to defraud Medicare out of more than \$2.8 million. Lovall knowingly and falsely billed Medicare and Medicaid for non-eligible transports. Specifically, Lovall submitted claims for individual ambulance transports, when in fact, multiple patients were being transported via one ambulance. Moreover, Your Health submitted claims for transporting Medicare patients via an ambulance to Partial Hospitalization Programs at various facilities, which is an unauthorized transport. Additionally, Lovall billed Medicare through Your Health for ambulance transportation services when there was no medical necessity for the transport. As a result of Lovall's actions, Your Health falsely billed Medicare for approximately \$2.8 million in ambulance transports which were never provided or were not medically necessary, and Your Health was reimbursed approximately \$1.0 million by Medicare. Lovall pleaded guilty to conspiracy to commit healthcare fraud and was sentenced to 5 years and 3 months in prison and was ordered to pay \$1.3 million in restitution.

Laboratories

The following case example involves a laboratory:

District of Columbia—Boston Heart Diagnostics Corp (BHD) entered into a settlement agreement with the United States to resolve allegations that BHD submitted false claims to the Medicare, Medicaid, and TRICARE programs. BHD agreed to pay \$1,728,818 to resolve allegations that BHD engaged in a scheme to encourage physicians to order medically unnecessary clinical laboratory testing services for 26 tests.

Home Health Agencies

The following case examples involve home health agencies:

California—Two Los Angeles-area home health agency owners and operators, Angela Avetisyan and Ashot Minasyan, were sentenced to a total of 16 years and 6 months in prison for their roles in a scheme to bill Medicare for various items and services, including home health services, diagnostic testing, medical procedures and DME that were not medically necessary and/or were not provided. The two were ordered to pay \$4.2 million in restitution, jointly and severally. In addition to Avetisyan and Minasyan, Robert Glazer and Marina Merino were also charged based on their involvement in the scheme and are awaiting sentencing. Avetisyan and Minasyan each pleaded guilty to conspiracy to commit healthcare fraud. As part of their guilty pleas, the two admitted that as co-owners and operators of Fifth Avenue Home Health (Fifth Avenue), they engaged in a conspiracy with Glazer, Merino, and others to recruit Medicare patients to Glazer’s clinic so that Glazer could use those patients’ information to bill for medically unnecessary outpatient clinic services and refer those patients for medically unnecessary home health services from Fifth Avenue and other home health agencies. Avetisyan and Minasyan further admitted that they paid Merino and other patient recruiters illegal kickbacks to bring Medicare patients to the Glazer clinic. A court found that Avetisyan and Minasyan, along with their co-conspirators, submitted and caused the submission of false and fraudulent claims for home health services that were medically unnecessary, for services that were not provided, and for claims obtained by the payment of illegal kickbacks.

Texas—Egondu “Kate” Koko, a patient recruiter in Houston, was sentenced for her role in a \$20 million scheme to pay illegal healthcare kickbacks to physicians and Medicare beneficiaries to fraudulently bill for medically unnecessary home health services, and to launder the proceeds. Koko pleaded guilty to conspiracy to pay and receive healthcare kickbacks and conspiracy to launder monetary instruments. As part of her guilty plea, Koko admitted to being a patient recruiter for Criseven Health Management, Beechwood Home Health, JMM Home Health and Trinity Healthcare Service, home health agencies that operated in the Houston area. Koko was also the owner and operator of Circuit Wide Home Health Services, a home health company. Koko admitted that she paid illegal kickbacks and bribes to physicians and patients for paperwork necessary for Criseven, Beechwood, JMM, Trinity, and Circuit Wide (collectively, “the HHAs”) to bill Medicare. Koko admitted that she and her co-conspirators submitted and were paid more than \$9.5 million in claims to Medicare for home health services purportedly provided by the HHAs. Koko further admitted to committing money laundering by opening a bank account under the identity of Person A, a Nigerian national. Koko transferred proceeds from her fraud on the United States from accounts controlled by Koko into the bank account of the Nigerian national. To further the scheme, Koko purchased a home using the funds from the Nigerian national’s account, which were proceeds from the fraud. Koko was sentenced to 15 years and 8 months in prison and ordered to pay \$12.9 million in restitution.

Physicians and Physician Practices

The following case examples involve physicians and physician practices:

Michigan—Dr. Zongli Chang and his co-conspirators engaged in an \$18 million healthcare fraud scheme involving the illegal distribution of prescription drugs. According to court documents, Chang wrote medically unnecessary and highly addictive controlled substance prescriptions, including prescriptions for hydrocodone-acetaminophen, oxycodone HCl, alprazolam, carisoprodol, and promethazine/codeine syrup, in return for cash payments. According to the indictment, Chang prescribed more than 2,700,000 dosage units of Schedule II, III, and IV controlled substances during the course of the conspiracy. Chang used patient recruiters to bring fake patients to his office. These recruiters paid cash to acquaintances to act as patients of Dr. Chang, and also paid Chang cash at each office visit for the prescriptions provided. After a cursory examination or no examination at all, Chang always prescribed the requested controlled substances. The patient recruiters ultimately took control of the controlled substances prescribed by Chang for illegal distribution in Michigan and elsewhere. Dr. Chang pleaded guilty to conspiracy to distribute and possess with intent to distribute controlled substances and was sentenced to 11 years and 3 months in prison. Six defendants involved in the scheme were previously sentenced to a combined 8 years and 4 months in prison.

Kansas—Dr. Joseph P. Galichia and Galichia Medical Group, P.A. (GMED) entered into a settlement agreement with the United States and Relator Aly Gadalla, M.D., to resolve allegations that Dr. Galichia and GMED submitted, or caused to be submitted, false claims to Medicare, TRICARE, and the Federal Employees Health Benefits Program for cardiac stent procedures that were not medically necessary. Galichia and GMED agreed to pay \$5.8 million to resolve the allegations. As a part of the settlement, Dr. Galichia also agreed to be excluded for 3 years.

DME Companies

The following case examples involve DME companies:

Maryland—ACell, Inc., a small medical device manufacturer based in Maryland, entered into a \$12 million civil settlement with the United States to resolve FCA liability associated with a wound dressing powder called MicroMatrix. Through the civil settlement, ACell resolved allegations that it (1) promoted MicroMatrix in ways that were false and misleading, (2) provided inaccurate coding recommendations about MicroMatrix to hospitals, and (3) provided improper inducements to encourage healthcare providers to order ACell products. The civil settlement was one component of a global resolution with ACell relating to MicroMatrix. ACell also entered into a 5-year CIA with OIG as part of the resolution. Finally, in June 2019, ACell pled guilty to criminal charges relating to its failure

to notify the FDA about the removal of MicroMatrix product from hospitals and other healthcare centers in 2012. In connection with the criminal plea, ACell agreed to pay a fine of \$3 million.

Georgia—Roderic Bain, the CEO of a string of Savannah-based durable medical equipment companies was sentenced to 3 years and 4 months in prison for his role in a scheme that defrauded Medicare out of millions of dollars. Bain, who had previously pled guilty to false statements relating to healthcare matters, was also ordered to pay more than \$1.9 million in restitution. Bain oversaw a multiyear scheme resulting in nearly \$10 million in claims billed to Medicare. Working with a number of others, Bain operated a network that paid kickbacks to obtain patient information, specifically that of Medicare patients. Using a third-party biller, Bain would then bill Medicare Part B and Part C plans for medically unnecessary medical equipment and orthotics, including a variety of back and knee braces that were not ordered as medically necessary by a physician. Bain also billed for equipment not provided and utilized sales representatives to promote equipment to Medicare patient utilizing the cold-calling method. During the course of the investigation, agents determined Bain and his affiliates were linked to a larger nation-wide scheme, recently announced as “Operation Brace Yourself.” Bain is the first defendant sentenced under the ongoing investigation.

Inpatient Rehabilitation Facilities

The following case example involves inpatient rehabilitation facilities:

Florida—Encompass Health Corporation (formerly known as HealthSouth Corporation) (Encompass) entered into an FCA settlement agreement wherein Encompass agreed to pay \$48 million to resolve allegations related to Encompass’s submission of claims for care provided at inpatient rehabilitation facilities (IRFs) to Medicare and Medicaid. Encompass owned and operated IRFs throughout the United States and provided care to beneficiaries covered by Medicare and Medicaid. The United States alleged that: (1) Encompass provided inaccurate information on Patient Assessment Instrument forms (IRF-PAIs) for a class of patients Encompass improperly assigned to Impairment Group Code (IGC) 3.8, indicating the patients in that class required rehabilitation for neuromuscular disorders. Specifically, the United States alleged that certain patients were diagnosed with a myopathy, including disuse myopathy and proximal myopathy, and represented in IRF-PAIs by IGC 3.8 and etiologic diagnosis codes of 359.89 and G72.89, when not all such patients, in fact, had a myopathy. The information contained on the IRF-PAI is used by CMS to determine whether or not IRFs are entitled to obtain or maintain classification as an IRF for reimbursement purposes. As a result, the United States alleged that Encompass submitted false claims to Medicare and Medicaid by representing that some of the IRFs owned and/or operated by Encompass were appropriately classified as an IRF for Federal program reimbursement purposes when they were not; (2) Encompass, through its subsidiary IRFs,

knowingly submitted false claims to Medicare and Medicaid by improperly causing the assignment of the class of patients described above to a Case Mix Group that provided reimbursement at a higher rate from Medicare than it was otherwise entitled to; and (3) Encompass knowingly submitted false claims to Medicare and Medicaid by admitting patients to its facilities for whom IRF services were not medically necessary pursuant to 42 U.S.C. § 1395y(a)(1)(A) and/or did not meet the IRF coverage criteria set forth in 42 C.F.R. § 412.622(a)(3); in particular, the United States alleged that Encompass IRFs admitted patients (1) who were too sick or disabled to be able to participate in and benefit from therapy; (2) for whom an intensive inpatient rehabilitation program was not medically necessary; (3) who did not require supervision by a rehabilitation physician at least three times a week; or (4) who did not need therapeutic intervention from multiple therapy disciplines.

Skilled Nursing Facilities

The following case examples involve skilled nursing facilities:

California—Five Star Quality Care-CA, LLC, doing business as Van Nuys Healthcare Center (Van Nuys), entered into a settlement agreement with the Office of Inspector General (OIG) to resolve Van Nuys' alleged liability under the Civil Monetary Penalties Law (CMPL) for its improper submission of claims to the Medicare and California Medicaid programs when its Director of Nursing and Minimum Data Set (MDS) Coordinator entered false Assessment Reference Dates on MDS reports required under 42 C.F.R. § 413.343. Van Nuys self-disclosed this conduct pursuant to OIG's Provider Self-Disclosure Protocol, and agreed to pay \$1,138,807.29 to resolve its CMPL liability.

Tennessee—Vanguard Healthcare, LLC, and related facilities (collectively, "Vanguard") entered into an FCA settlement to resolve allegations that from January 1, 2010, through December 31, 2015, Vanguard knowingly provided non-existent, grossly substandard, and/or worthless nursing home items and services to skilled nursing facility residents, and submitted claims for such items and services to Medicare and TennCare for reimbursement. The settlement agreement also resolves allegations that the settling parties submitted pre-admission forms and resident reviews that contained forged physician and nurse signatures and certifications. Vanguard agreed to pay over \$18.8 million to resolve its potential liability and entered into a 5-year quality-of-care CIA.

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 healthcare 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 successfully analyze healthcare 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 163 individuals or entities, 79 criminal actions, and more than \$130.2 million in investigative receivables.

In April 2019, OIG and our law enforcement partners announced an investigation (known as Operation Brace Yourself) that dismantled a healthcare fraud scheme involving over \$1.2 billion in losses. In the alleged scheme, medical professionals working with fraudulent telemedicine companies received illegal kickbacks and bribes from medical equipment companies. In exchange, the medical equipment companies obtained prescriptions for medically unnecessary orthotic braces and used them to fraudulently bill Medicare. The operation led to charges against 24 defendants across 17 Federal districts.

In April 2019, OIG and our law enforcement partners also led the first Appalachian Regional Opioid Strike Force Takedown. The takedown resulted in enforcement actions involving 60 charged defendants across 11 Federal districts, including 31 doctors, 7 pharmacists, 8 nurse practitioners, and 7 other licensed medical professionals, for their alleged participation in the illegal prescribing and distributing of opioids and other dangerous narcotics and for healthcare fraud schemes. To ensure that patients impacted by law enforcement operations maintain continuity of care, this takedown coordinated an unprecedented public health response in partnership with the Drug Enforcement Administration, the Substance Abuse and Mental Health Services Administration (SAMHSA), CDC, and all impacted State Departments of Health.

In September 2019, OIG and our Federal and State law enforcement partners announced Strike Force efforts in dismantling one of the largest healthcare fraud schemes ever charged. The takedown has resulted in charges in 5 Federal districts against 35 defendants associated with dozens of telemedicine companies and cancer genetic testing (CGx) laboratories for their alleged participation. According to the charges, these defendants fraudulently billed Medicare more than \$2.1 billion for CGx tests. Among those charged are 10 medical professionals, including 9 doctors. The alleged scheme involved the payment of illegal kickbacks and bribes by CGx laboratories in exchange for the referral of Medicare beneficiaries by medical professionals working with fraudulent telemedicine companies for expensive cancer genetic tests that were medically unnecessary.

During this semiannual reporting period, Strike Force efforts led to the following 11 regional takedowns:

Operation	Date	Subject	Statistics
Telemedicine Takedown ("Operation Brace Yourself")	4/11/2019	Orthotic Braces	24 criminal defendants \$1.2 billion in losses
Appalachian Regional Opioid Takedown	4/17/2019	Opioids	60 criminal defendants Over 32 million pills involved
Houston Opioid Takedown	8/28/2019	Opioids and Medical Professionals	41 criminal defendants

West Coast (L.A.) Takedown	9/18/2019	Healthcare Fraud	34 criminal defendants \$258 million in losses
Texas Strike Force/Rocky Mountain Takedown	9/18/2019	Opioids and Medical Professionals	58 criminal defendants \$66 million in losses 6.2 million pills involved
Appalachian Regional Opioid Takedown	9/24/2019	Opioids	13 criminal defendants Over 17 million pills involved
Gulf Coast Takedown	9/25/2019	Compounding Pharmacies	33 criminal defendants Over \$515 million in losses
Florida/Georgia Takedown	9/25/2019	Medical Professionals	83 criminal defendants Over \$161 million in losses
Northeast Regional Takedown	9/26/2019	Opioids and Medical Professionals	48 criminal defendants \$800 million in losses 3.25 million pills involved
Midwest Takedown	9/27/2019	Medical Professionals	53 criminal defendants \$250 million in losses
Genetic Testing Takedown	9/27/2019	Genetic Testing and Telemedicine Professionals	35 criminal defendants \$2.1 billion in losses

The following case examples involve Strike Force cases:

Florida—Philip Esformes and Arnaldo Carmouze were convicted for their role in the largest healthcare fraud scheme ever charged by DOJ, involving \$1.3 billion in fraudulent claims. According to the investigation, Esformes led an extensive healthcare fraud conspiracy involving a network of assisted living facilities and SNFs that he owned. Esformes bribed physicians to admit patients into his facilities, and then cycled the patients through his facilities, where they often failed to receive appropriate medical services, or received medically unnecessary services, which were then billed to Medicare and Medicaid. Several witnesses testified to the poor conditions in the facilities and the inadequate care patients received, which Esformes was able to conceal from authorities by bribing an employee of a Florida state regulator for advance notice of surprise inspections scheduled to take place at his facilities. Carmouze worked as a physician’s assistant and facilitated the fraud scheme by prescribing medically unnecessary prescriptions for treatment at SNFs. Carmouze pleaded guilty to conspiracy to commit healthcare fraud and wire fraud. He was sentenced to 6 years and 8 months in prison, and was ordered to pay \$12.5 million in restitution. Six defendants involved in the scheme were previously sentenced to a combined 2 years and 3 months in prison and ordered to pay \$425,470.29. Esformes was convicted by jury and was sentenced to 20 years in prison. The amount of restitution due has not been determined yet.

New York—Svetlana Mazina and her co-conspirators engaged in a scheme to defraud Medicare. Mazina was an employee at Neponsit Medical PC, a medical clinic in New York City. Mazina and others billed Medicare for medically unnecessary services and services not rendered. Medicare

beneficiaries were given cash payment, a kickback, to induce them to undergo medically unnecessary procedures, services, and tests. Mazina pleaded guilty to conspiracy to defraud the United States and pay healthcare kickbacks, and was sentenced to time served. Mazina was ordered to pay \$3.6 million in restitution, joint and several. Four defendants involved in the scheme were previously sentenced and ordered to pay \$5.3 million, joint and several.

Compliance Trainings

Healthcare Provider Compliance Training

OIG provides free training on our website for healthcare providers, compliance professionals, and attorneys. OIG's Provider Compliance Training was an initiative developed in 2011 that continues to reach the healthcare community with OIG's message of compliance and prevention via free downloadable comprehensive training materials and podcasts. OIG's provider compliance training resources can be accessed 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 healthcare 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 can be accessed 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 can be accessed at <https://oig.hhs.gov/fraud/fugitives/>. During this semiannual reporting period, six fugitives were captured.

The following is a case example involving a captured fugitive:

One of OIG's Most Wanted Fugitives, Juan Carlos Jaime, was captured during this reporting period. Jaime was involved in a scheme to fraudulently bill Medicare for services that were not medically necessary and were never provided. Jaime has been a fugitive since 2016 and was believed to have absconded to his native Cuba—he was recently picked up at Miami International Airport. He is currently in U.S. custody and will face charges stemming from his indictment.

According to court documents, on or around April 2015 Juan Carlos Jaime became the Registered Agent, Secretary, and sole Director of A-Superior Home Health Agency (A-Superior) located in Miami, Florida. Jaime obtained the names and Medicare numbers of Medicare beneficiaries so that he could submit fraudulent claims for home health services that were not medically necessary and were never provided. Jaime also obtained the names and provider numbers of physicians to submit false claims to Medicare purportedly prescribed by a licensed physician. As a result of these fraudulent claims, Medicare paid approximately \$1.4 million to A-Superior. In June 2016, Jaime was indicted on charges of healthcare fraud, and later pled guilty.

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 “Report Fraud” link on the HHS-OIG website. During this semiannual reporting period, the OIG Hotline reported expected recoveries of \$8 million as a direct result of cases originating from hotline complaints.

OIG Hotline Activity (4/1/2019–9/30/2019)

Contacts to 1-800-HHS-TIPS phone line, including callers seeking information	81,762
Total tips evaluated	21,146
Tips referred for action	15,419
Closed; no basis provided for further action	5,850
Closed; no HHS violation	716

Sources of tips referred for action

Phone	5,431
OIG website	7,695
Letters or faxes	1,112
Other	1,181

State Medicaid Fraud Control Units

OIG Oversight of State Medicaid Fraud Control Units

State 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 the State of 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 and patient abuse and neglect in healthcare facilities or board and care facilities.

OIG Onsite Reviews of MFCUs

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

Nevada State Medicaid Fraud Control Unit: 2018 Onsite Review (OEI-06-18-00190), June 2019

Kansas State Medicaid Fraud Control Unit: 2018 Onsite Review (OEI-12-18-00210), July 2019

Idaho Medicaid Fraud Control Unit: 2018 Onsite Inspection (OEI-12-18-00320), August 2019

Utah Medicaid Fraud Control Unit: 2018 Onsite Inspection (OEI-09-18-00170), August 2019

OIG Joint Casework with MFCUs

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

West Virginia—CRC Health, LLC (CRC) and its parent corporation, Acadia Healthcare Corporation, (Acadia) agreed to pay \$17 million to resolve allegations of a billing scheme that defrauded Medicaid of \$8.5 million. Specifically, the United States alleged that specified CRC outpatient drug treatment centers submitted claims to West Virginia Medicaid for moderate- to high-complexity urine drug tests as if they were performed by the CRC outpatient drug treatment centers when those centers did not have the proper laboratory certifications to perform that testing. OIG partnered with the West Virginia MFCU in both the investigation and analysis of this matter. Leveraging the cooperation and combined knowledge and expertise of OIG and West Virginia's MFCU allowed the case to progress quickly and achieved an optimal outcome. The settlement represents the

largest healthcare fraud settlement in the history of West Virginia. CRC and Acadia agreed to enter into a Corporate Integrity Agreement with OIG as an element of the settlement.

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 healthcare fraud and abuse sanctions. During FY 2019, OIG received 45 requests for advisory opinions and issued 9 advisory opinions.

Sanction Authorities and Other Administrative Actions

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

During this semiannual reporting period, OIG imposed 1,452 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 D and on our website at <http://oig.hhs.gov/fraud/enforcement/cmp/index.asp>.

Program Exclusions

During this semiannual reporting period, OIG excluded 1,347 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 exclusion. 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:

Pennsylvania—Pediatrician Johnnie Barto was excluded for a minimum period of 75 years based on his conviction for indecent assault, corruption of minors, endangering the welfare of children, unlawful contact with minors and aggravated indecent assault. Dr. Barto sexually assaulted 31 minor victims, most of them patients. The court sentenced Dr. Barto to serve 79 to 158 years in prison. In addition, the Pennsylvania State Board of Medicine suspended his license to practice as a medical doctor.

Texas—Daniela Gozes-Wagner, an employee of several testing facilities, was excluded for a minimum period of 50 years based on her conviction for conspiracy to commit healthcare fraud and conspiracy to commit money laundering. Gozes-Wagner conspired with others to defraud Medicare and Medicaid by submitting claims for services that had not been performed or were not medically necessary. As part of the scheme, Gozes-Wagner rented offices for testing facilities but kept the actual spaces empty. No patients were seen, and no testing was performed at the offices. To further deceive Medicare and Medicaid, Gozes-Wagner hired people to pose as patients to sit in the empty offices and answer the phones as though the facility was open and operational. The court sentenced Ms. Gozes-Wagner to 20 years in prison and ordered her to pay approximately \$15.2 million in restitution.

Suspensions and Debarments

Suspensions and debarments are administrative tools used by HHS and other Federal agencies to protect the Government from individuals and entities that have engaged in contract fraud, have misused grant funds, or are otherwise not presently responsible. Because these are 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 examples involve debarment:

Minnesota—Fozia Shiek Ali was the controlling agent and program director of Salama Child Care Center (Salama). Investigators found that Ali overbilled the State of Minnesota through the Child Care Assistance Program (CCAP), which receives funding from HHS. It was found that Ali, through Salama, overbilled CCAP for more children than were actually receiving services or for more hours of services than were actually being provided. Ali pled guilty to aiding and abetting theft of public funds and was sentenced to 2 years in prison

and ordered to pay \$1.4 million in restitution. Ali was debarred for a 3-year period based on an OIG referral to the Department.

Missouri—James Shields II was the owner of Endless Possibilities and was licensed to provide childcare for 47 children. OI’s review of the single month’s attendance records obtained by OAS showed an overpayment of 38 percent. The investigative review revealed that the center billed for (1) authorized children who were not in attendance on the dates claimed, (2) non-authorized children who were signed in at the center (and likely substituted for authorized children who were absent), and (3) weekend attendance on days the center was not open for business. Shields also violated a number of program requirements for contractors approved by the State of Missouri to provide services to eligible families. Shields pled guilty to false statements related to healthcare matters and was ordered to pay restitution of \$52,265. Shields was also barred from engaging in any employment involving accounting or financial responsibilities without prior approval from the Probation Office. Shields was debarred for a 3-year period based on an OIG referral to the Department.

Civil Monetary Penalties Law

The 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 \$30 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:

Kentucky—On June 28, 2019, Ethos Laboratory (Ethos) entered into a \$1,345,959.74 CMPL settlement agreement with OIG. The settlement agreement resolves allegations that Ethos 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 if it is consistent with normal human urine and to ensure that the sample has not been substituted, adulterated, or diluted.

Florida—Midland Medical, Inc., and its subsidiary, Midland Medical-Broward, Inc. (collectively, "Midland") entered into a \$102,204 CMPL settlement agreement with OIG. The settlement agreement resolves allegations that Midland received remuneration from laboratory companies Health Diagnostic Laboratory, Inc. (HDL) and Singulex, Inc. (Singulex), in the form of "process and handling" payments related to the collection of blood. OIG alleged that Midland received the remuneration from HDL and Singulex in exchange for Midland and Midland employees referring patients for laboratory testing services to HDL and Singulex, for which the Medicare program paid.

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:

Florida—On May 6, 2019, Park Royal Hospital (Park Royal) entered into a \$52,414 settlement agreement with OIG. The settlement agreement resolves allegations that, based on OIG's investigation, Park Royal violated EMTALA when it failed to accept a transfer of a patient with an unstabilized emergency medical condition, from the emergency department of another hospital. The patient presented to that hospital's emergency department following a suicide attempt and was diagnosed with lacerations to the wrist and an emergency psychiatric condition. Park Royal is a hospital with specialized psychiatric capabilities. OIG alleged that Park Royal refused to accept a transfer of the patient, despite having the specialized capabilities to stabilize the patient and the capacity at the time of transfer, because the patient's insurance was out of network.

North Carolina—On June 26, 2019, Transylvania Regional Hospital (TRH), MH Transylvania Regional Hospital, LLLP, and Transylvania Community Hospital, Inc., entered into a \$25,000 settlement agreement with OIG. The settlement agreement resolves allegations that, based on OIG's investigation, TRH violated the EMTALA when it failed to provide an adequate medical screening examination and stabilizing treatment for a patient. The patient presented to TRH's emergency department complaining of abdominal pain and pain radiating bilaterally to his lower extremities. In addition, the patient had an elevated blood pressure and respiratory rate. Despite this presentment, TRH discharged the patient without providing an adequate medical screening examination or stabilizing treatment. The patient returned to TRH's emergency department later the same day via ambulance, complaining of paralysis of the lower extremities, leg pain, and leg swelling. TRH ultimately transferred the patient to another hospital. Under EMTALA, the maximum penalty for hospitals with fewer than 100 beds at time of this alleged violation was \$25,000.

Self-Disclosure Programs

Healthcare 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 FCA or other Federal criminal laws prohibiting fraud, conflict of interest, bribery, or gratuity. This self-disclosure process is available only to those with a 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 \$28.6 million in HHS receivables.

The following case example pertains to provider self-disclosure settlements:

Iowa—After they self-disclosed conduct to OIG, Great River Health System, Inc. (GRHS), Great River Foundation (GRF), Riverview System, Inc. (RSI), Great River Medical Center (GRMC), and Great River Physicians and Clinics, Inc. (GRPC) agreed to pay \$3,008,326.50 for allegedly violating the CMPL, including provisions applicable to kickbacks. OIG alleged that GRHS, GRF, RSI, and GRPC paid remuneration to a physician in the form of excessive compensation in exchange for referrals. OIG also alleged that GRHS, GRMC, and GRPC submitted or caused to be submitted false claims to Medicare, Medicaid, and Tricare for medically unnecessary and improperly coded hyperbaric oxygen therapy and wound care services provided by the physician.

Corporate Integrity Agreements

Many healthcare 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:

Indiana—The OIG excluded Tri-County Ambulance (Tri-County), for a period of 5 years based on a material breach of its CIA. On November 9, 2018, OIG issued a letter demanding stipulated penalties of \$25,000 based on Tri-County's failure to submit its Annual Report. After Tri-County failed to pay the stipulated penalties and cure the breach or request a hearing by an HHS Administrative Law Judge, OIG issued a notice of material breach and intent to exclude in January 2019. Under the terms of the CIA, Tri-County had 25 days to request a hearing with an Administrative Law Judge. Tri-County did not request a hearing. OIG excluded Tri-County effective April 3, 2019.

Florida—Effective August 31, 2015, North Broward Hospital District d/b/a Broward Health (Broward Health) entered into a CIA with HHS-OIG to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs. On June 28, 2019, Broward Health paid a stipulated penalty of \$690,000 for failing to comply with certain CIA requirements. Specifically, Broward Health failed to (1) develop and implement written policies designed to promote compliance with the anti-kickback statute and the Stark Law, (2) provide all employees with general compliance training, (3) implement and comply with all of the arrangements procedures and arrangements requirements of the CIA, and (4) comply with certain disclosure program requirements.

Public Health and Human Service Agency Reports and Reviews

Public Health Agency Reports and Reviews

Agency for Healthcare Research and Quality

Patient Safety Organizations: Hospital Participation, Value, and Challenges ([OEI-01-17-00420](#)), September 2019

Nearly all hospitals that participate in the Patient Safety Organization (PSO) program find it valuable, but challenges with the program have slowed progress toward a national system of learning to improve patient safety. Our findings can help the Agency for Healthcare Research and Quality (AHRQ) identify ways to strengthen its support and promotion of the PSO program.

AHRQ concurred with our first and third recommendations and partially concurred with our second recommendation, which were to:

- develop and execute a communications strategy to increase hospitals' awareness of the program and its value to participants;
- take steps to encourage PSOs to participate in the Network of Patient Safety Databases (NPSD), including accepting data into the NPSD in other formats in addition to the Common Formats; and
- update guidance for PSOs on the processes for being approved by AHRQ for initial listing as a PSO and continued listing.

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention's South Africa Office Generally Implemented Our Prior Audit Recommendation ([A-04-18-01009](#)), April 2019

CDC-South Africa (CDC-SA) generally implemented corrective actions for the recommendation from our prior audit report. CDC-SA provided documentation supporting that it had monitored most of its recipient cooperative agreements (CoAg). However, CDC-SA was still missing some documentation supporting its remaining monitoring activities. In our current audit, three of the six CoAg that CDC-SA monitors contained five monitoring activities that were not supported by documentation.

The documentation deficiencies we identified occurred primarily because CDC-SA did not always use a CoAg tracking process, such as a grant file checklist, that staff members could fill out at the end of a CoAg budget period to ensure that CDC-SA had completed and filed in a timely manner

all required documentation of reviews. Additionally, CDC-SA did not periodically review and update its standard operating procedures to include changes and specific procedures for monitoring the recipient CoAgs.

CDC-SA concurred with our recommendations that it continue to strengthen its CoAg tracking process by consistently completing a grant file checklist at the end of the CoAg's budget period and update and review its SOPs annually to include specific and clear procedures when changes in control activities occur for monitoring recipient CoAgs.

Food and Drug Administration

The Food and Drug Administration Generally Complied With Federal Requirements for the Preparation and Receipt of Select Agent Shipments (A-03-16-00354), June 2019

Generally, FDA has designed and put in place controls to ensure that select agent shipments are prepared and received in accordance with Federal regulations and related supporting laboratory guidance and instruction. However, 8 of FDA's 11 registered entities' security plans did not include certain procedures for notifying the Federal Select Agent Program (FSAP) if a select agent shipment is not received on time or receives damage, and none of FDA's registered entities' security plans included certain procedures for notifying FSAP if an authorization for a select agent transfer expires or becomes void before the shipment is completed. In addition, we found that FDA's registered entities did not always maintain required select agent training documentation and did not ensure compliance with all new requirements for shipping select agents that have undergone inactivation.

FDA concurred with our recommendations that it update its registered entities' security plans to include procedures for notifying FSAP if a select agent (1) shipment is not received within 48 hours after the expected time of delivery, (2) package is received damaged to the extent that a release of the select agent may have occurred, (3) shipment will not be completed within 30 calendar days after transfer authorization issuance, or (4) transfer authorization becomes void because the facts supporting the authorization changed. We also made recommendations regarding FDA's select agent training documentation and policies for shipping inactivated select agents.

Most Hospitals Obtain Compounded Drugs From Outsourcing Facilities, Which Must Meet FDA Quality Standards (OEI-01-17-00090), June 2019

Most hospitals that obtained non-patient-specific compounded drugs from outside compounders obtained them from compounders registered with the FDA, known as outsourcing facilities. Factors associated with quality, including registration with FDA as an outsourcing facility, are among the most important factors considered when hospitals decide where to obtain their non-patient-specific compounded drugs. Few hospitals consider registering their own pharmacies as outsourcing facilities. Patient safety is advanced when hospitals obtain compounded drugs from

outsourcing facilities that are registered with FDA because those facilities are subject to regular FDA oversight and must adhere to current good manufacturing practices.

FDA concurred with all of our recommendations, which were to:

- further communicate with hospitals about the importance of obtaining their NPS compounded drugs from outsourcing facilities, and
- take appropriate followup actions with unregistered compounding facilities on a list that we provided based on our survey of hospitals.

The Food and Drug Administration Did Not Submit Clearance Documents for Any Audit Recommendations During Fiscal Years 2015 and 2016 but Has Since Made Significant Progress (A-07-18-03231), August 2019

FDA's audit resolution guidelines did not address the submission of clearance documents to OIG. As a result, FDA did not submit any clearance documents within the required 6-month resolution period. Also, FDA did not perform periodic, formal reconciliations between OIG's stewardship reports and its own audit resolution records.

Without resolving all audit recommendations in a timely manner, FDA runs the risk of noncompliance with Federal requirements and mismanagement of Federal funds. The prompt resolution of audit recommendations helps ensure that Federal funds are effectively and efficiently used to carry out the activities for which they were authorized.

FDA concurred with all of our recommendations that it finalize and implement formal policies and procedures for the resolution of audit recommendations, promptly resolve the 32 remaining recommendations that were past due as of September 30, 2016, and reconcile each month OIG's audit resolution information with FDA's audit resolution records and follow up on any differences noted. Since our audit period, FDA has made significant progress in resolving audit recommendations.

Indian Health Service

IHS Needs To Improve Oversight of Its Hospitals' Opioid Prescribing and Dispensing Practices and Consider Centralizing Its Information Technology Functions (A-18-17-11400), July 2019

The IHS hospitals we reviewed did not always follow the *Indian Health Manual* when prescribing and dispensing opioids. Through our patient record review, we found that hospitals did not always review the course of patient treatment and causes of pain within required timeframes, perform the required urine drug screenings within recommended time intervals, review patient health records before filling a prescription from a non-IHS provider, or maintain pain management documents to support that provider responsibilities had been performed. We also found that these IHS hospitals

did not fully use the States' prescription drug monitoring programs when prescribing or dispensing opioids.

IHS's decentralized IT management structure led to vulnerabilities and weaknesses in implementing security controls at all five hospitals. IHS's controls were not effective at preventing or detecting our penetration test cyberattacks. In addition, the hospitals implemented IT security controls to protect health information and patient safety differently. As a result, IHS hospital operations and delivery of patient care could have been significantly affected.

IHS concurred with our procedural recommendations and our recommendations that it work with hospitals to ensure that they follow the *Indian Health Manual* when prescribing and dispensing opioids and that it consider centralizing its IT systems, services, and functions by conducting a cost-benefit analysis of adopting a cloud computing policy, including centralization of IT systems, services, and functions.

Case Study: Indian Health Service Management of Rosebud Hospital Emergency Department Closure and Reopening (OEI-06-17-00270), July 2019

We found that IHS closed the Rosebud Hospital emergency department in December 2015, due to immediate jeopardy (IJ) deficiencies and staffing shortages. IHS diverted Rosebud patients to the nearest hospitals but did not provide the hospitals or the emergency medical services (EMS) adequate time to prepare. IHS reopened the emergency department in July 2016, but Rosebud Hospital was again cited with an IJ-related deficiency in the emergency department in July 2018. Longstanding problems at Rosebud Hospital remain a concern, including difficulty recruiting and retaining staff and frequent changes in leadership.

IHS concurred with all of our recommendations, which were to:

- develop and implement, as a management priority, a staffing program for recruiting, retaining, and transitioning staff and leadership to remote hospitals;
- enhance training and orientation for new hospital leaders to ensure that they follow IHS directives and continue improvement efforts;
- continue to take steps to ensure early and effective intervention when IHS identifies problems at hospitals; and
- develop procedures for temporary emergency department closures and communicate those procedures with receiving hospitals and EMS.

Organizational Challenges to Improving Quality of Care in Indian Health Service Hospitals (OEI-06-16-00390), August 2019

We found three core organizational challenges that, if not addressed, could continue to limit the IHS's ability to improve hospital operations and quality of care. First, IHS lacks formal structure, policies, and roles. IHS officials reported that they were often uncertain about their roles and those

of other officials, including the authority to act in correcting problems. The absence of clear roles was especially problematic with regard to the roles of IHS headquarters and Area Offices. Second, IHS lacks awareness and insight about Area Office and hospital performance, and IHS's organizational culture does not always encourage candid discussion of problems. Third, IHS officials lack confidence in the agency's ability to succeed. IHS officials consistently expressed a deep commitment to and passion for the agency's mission and beneficiaries, but also expressed doubt in the agency's ability to make sustained improvements.

To address these underlying organizational challenges, IHS should incorporate the strategies we outline as it implements its new plans to improve hospital quality and agency operations. Specifically, IHS officials need to support an agency structure that outlines policies and roles; cultivate a culture of continuous learning to support sustained improvements; and inspire greater confidence in the agency's capacity to overcome longstanding challenges. Additionally, in other evaluations OIG has recommended specific actions for improving quality in IHS hospitals, such as establishing a comprehensive compliance program focused on quality of care. We continue to urge IHS to implement those recommendations.

National Institutes of Health

The National Institutes of Health Could Improve Its Monitoring To Ensure That an Awardee of the All of Us Research Program Had Adequate Cybersecurity Controls To Protect Participants' Sensitive Data (A-18-17-09304), June 2019

The Participant Technology Systems Center (PTSC) did not have adequate controls to protect the sensitive data of participants in the *All of Us* Research Program (*All of Us*). NIH did not adequately monitor the PTSC to ensure that the PTSC had implemented adequate cybersecurity controls to protect the participants' sensitive data. On the basis of the results of our penetration testing at the PTSC, we identified vulnerabilities that could expose personally identifiable information, including personal health information of the *All of Us* participants, and allow access to their data. These vulnerabilities could have allowed an attacker with limited technical knowledge to exploit and compromise the PTSC's systems, as most of the vulnerabilities did not require significant technical knowledge to exploit. In addition, the PTSC failed to encrypt its cloud storage. The PTSC did not have policies and procedures to address remediating source code vulnerabilities and timely disabling of network access. Finally, the PTSC did not adequately scan its network. We did not identify any general control vulnerabilities at the Data and Research Center.

During the audit, NIH and the PTSC addressed and remediated all of the vulnerabilities we identified.

NIH generally concurred with our recommendations that it revise its *All of Us* cooperative agreements and cooperative agreements with security and privacy requirements to include a

detailed description of how NIH will monitor cybersecurity and ensure that future awardees adequately implement security controls to protect sensitive data.

The National Institutes of Health Administered Superfund Appropriations During Fiscal Year 2016 in Accordance With Federal Requirements (A-04-18-04065), June 2019

During FY 2016, NIH administered Superfund appropriations in accordance with applicable Federal requirements. NIH obligated and disbursed Superfund appropriations in accordance with Federal requirements and in similar proportions to prior years. In addition, the Institute's monitoring of Superfund grants generally ensured that grantees met requirements for financial, performance, and audit reporting. This report contains no recommendations.

The National Institutes of Health Has Limited Policies, Procedures, and Controls in Place for Helping To Ensure That Institutions Report All Sources of Research Support, Financial Interests, and Affiliations (A-03-19-03003), September 2019

NIH has limited policies, procedures, and controls in place for helping to ensure that institutions report all sources of research support, financial interests, and affiliations. Although no Federal regulation requires NIH to proactively ensure that each investigator has disclosed all sources of research support, financial interests, and affiliations, NIH is responsible for overseeing institutional compliance with the regulations.

Not all NIH-funded investigators may be aware that they are required to disclose FCOIs with regards to research support, financial interests, and affiliations. Although NIH has conducted outreach and provided technical assistance regarding FCOI policy requirements, some institutions stated that they were not aware of their responsibility to create and maintain FCOI policies.

NIH stated the report conflated reporting requirements for research support and affiliations with reporting requirements for FCOIs but concurred with our recommendations that it (1) ensure that the 1,013 institutions identified by this review as not having FCOI policies on their website post those FCOI policies as required, (2) enhance its FCOI monitoring program to ensure that institutions resolve identified deficiencies and to review all grantee websites to ensure that FCOI policies are publicly accessible, and (3) implement procedures to ensure that all institutions that are required to have FCOI policies have FCOI policies.

NIH Has Made Strides in Reviewing Financial Conflicts of Interest in Extramural Research, but Could Do More (OEI-03-19-00150), September 2019

Over the past decade, NIH has strengthened its reporting requirements and developed an online system for collecting, reviewing, and storing the FCOIs that extramural grantee institutions report for their research investigators. Overall, 3 percent of NIH grants in FY 2018 had investigators with financial conflicts. These grants received \$1 billion in funding during FY 2018, and institutions

reported a total of 2,755 financial conflicts. Although NIH has made substantial strides in reviewing the financial conflicts that institutions report, we found inconsistencies in the depth of its oversight reviews. Across the three NIH Institutes and Centers that we reviewed, staff differed in the level of scrutiny they applied to their review of financial conflicts. Furthermore, NIH lacks quality assurance procedures in its review process. Lastly, NIH cannot identify—and does not plan to identify—whether investigators’ financial conflicts involve foreign interests; instead, it is identifying foreign affiliations through a clarification of its requirements for pre-award reporting.

NIH concurred with both of our recommendations, which were to:

- perform periodic quality assurance reviews of the financial-conflict information in its online system to ensure the adequacy of its oversight, and
- use information regarding foreign affiliations and support that it collects during the pre-award reporting process to decide whether to revise its financial-conflict review process to address concerns regarding foreign threats.

Vetting Peer Reviewers at NIH’s Center for Scientific Review: Strengths and Limitations (OEI-01-19-00160), September 2019

NIH’s Center for Scientific Review (CSR) has strengths in its approach to vetting peer reviewer nominees’ ability to be effective peer reviewers. However, beyond requiring a justification for reviewers who are not based in North America, CSR gives little attention to foreign affiliation in its vetting of peer reviewer nominees. In August 2018, the Director of NIH raised concerns that peer reviewers were, in some cases, inappropriately sharing confidential information with foreign entities. NIH concurred with our recommendations, which were to:

- update its guidance on vetting peer reviewer nominees to identify potential foreign threats to research integrity, in consultation with national security experts, as needed; and
- work with the HHS Office of National Security to develop a risk-based approach for identifying those peer reviewer nominees who warrant additional vetting.

Substance Abuse and Mental Health Services Administration

The Substance Abuse and Mental Health Services Administration Resolved Approximately One-Third of Its Audit Recommendations, None in Accordance With Federal Timeframe Requirements (A-07-19-03233), July 2019

SAMHSA did not resolve audit recommendations in a timely manner during FYs 2015 and 2016. SAMHSA resolved 104 of the 292 audit recommendations that were outstanding during FYs 2015 and 2016. However, it did not resolve any of the 104 recommendations within the required 6-month resolution period. In addition, as of September 30, 2016, SAMHSA had not resolved 188 audit recommendations that were past due for resolution. These 188 past-due recommendations were procedural; none of them involved dollar amounts such as recommended disallowances.

As of July 1, 2015, SAMHSA had draft policies and procedures in place (which were orally conveyed to its staff before that date) to ensure that audit recommendations were resolved in compliance with Federal requirements but did not generally follow them. As a result, SAMHSA did not issue any management decisions (and submit the related clearance documents to OIG) within the required 6-month resolution period. In addition, SAMHSA's policies and procedures had not been finalized at the time of our audit work, and SAMHSA did not perform periodic reconciliations with OIG's stewardship reports.

SAMHSA concurred with our recommendations that it finalize and follow its policies and procedures related to the audit resolution process, promptly resolve the 188 outstanding audit recommendations that were past due as of September 30, 2016, and reconcile each month the appropriate OIG or HHS records with SAMHSA's audit resolution records and follow up on any differences noted.

Human Services Agency Reports and Reviews

Administration for Children and Families

The Children's Village, Inc., an Administration for Children and Families Grantee, Did Not Always Comply with Applicable Federal and State Policies and Requirements (A-02-16-02013), April 2019

The Children's Village, Inc. (Children's Village), a UAC Program grantee responsible for caring for children in ORR custody, failed to meet or properly document that it had met certain requirements for the care and release of children in its custody in 46 of the 50 case files reviewed. Additionally, the files for 2 of 20 employees did not contain evidence that Children's Village had performed all required background checks.

In addition, Children's Village claimed unallowable expenditures totaling at least \$2.6 million related to transactions that were not properly approved, allocated, or supported. Finally, Children's Village did not disburse drawdowns of Federal funds in a timely manner, drew down funds from one UAC Program grant to cover expenditures related to its other UAC Program grant, and did not separately track expenditures for its two UAC grants.

Children's Village generally concurred with our procedural recommendations, including that it ensure that its facility is free from potentially harmful conditions and implement improvements to its financial management system. Children's Village did not concur with our recommendation that it refund to the Federal Government \$2.6 million in unallowable grant expenditures.

Southwest Key Did Not Have Adequate Controls in Place To Secure Personally Identifiable Information Under the Unaccompanied Alien Children Program (A-18-18-06001), August 2019

Southwest Key had not implemented an adequate information systems security program to protect the personally identifiable information (PII) of UAC. Southwest Key officials explained that they were unaware of information systems security requirements from ORR or other Federal requirements. Based on the control areas we reviewed, we determined that Southwest Key's security program lacked several fundamental security controls needed to protect the confidentiality, integrity, and availability of UAC Program PII. Without fundamental information systems security controls (e.g., having an information systems security officer, a risk assessment, and an information systems security awareness training program), Southwest Key management cannot ensure that it has established a control environment that meets minimal information security requirements as required by Federal regulations to safeguard the UAC Program PII from both internal and external threats.

Southwest Key, while disputing the corresponding findings, generally concurred with the spirit of our recommendations that it develop and implement an information systems security program in accordance with Federal requirements and that it communicate with ORR, ACF, and HHS to obtain Federal security requirements and guidance to improve its security posture and protect UAC PII.

Southwest Key Programs Did Not Always Comply With Health and Safety Requirements for the Unaccompanied Alien Children Program (A-06-17-07005), August 2019

Southwest Key did not meet or properly document that it met certain safety standards for the care or release of some children in its custody. Additionally, we found that Southwest Key was unable to support the number of reunifications reported to ORR for FFY 2016.

Based on our UAC case file sample review results, we estimated that Southwest Key did not properly document the care or release of 38 percent of all children released to sponsors in FY 2016. Without adequate documentation in the UAC case files, ORR could not be assured that for 8,323 children, Southwest Key had followed ORR policies regarding sponsor background checks and prompt care or that DHS was notified about a child's release to a sponsor. Finally, we determined that some Southwest Key employee and volunteer files we reviewed were missing evidence of required background checks.

Southwest Key generally concurred with our recommendations that it comply with ORR regulations pertaining to (1) video monitoring in common areas, (2) sponsor and other household members background checks, (3) admission/intake assessments and medical exams, (4) discharge notifications to DHS and other stakeholders, and (5) safety and well-being followup calls. We also recommended that Southwest Key ensure that information reported to ORR is accurate. The report also contains other procedural recommendations for Southwest Key to operate its UAC Program in accordance with Federal and State requirements.

States' Payment Rates Under the Child Care and Development Fund Program Could Limit Access to Child Care Providers (OEI-03-15-00170), August 2019

We found that the majority of child care providers charge more for infant care than States' payment rates, which could limit access to care for Child Care and Development Fund (CCDF) families. Operating with finite resources, States must balance competing priorities and perform tradeoffs between raising payment rates to providers, serving eligible families, and ensuring compliance with program requirements. ACF does not evaluate States' payment rates, nor does it determine whether States have ensured equal access to child care services for eligible families. Only seven States set payment rates at the level that ACF recommends for ensuring equal access. The majority of States have implemented provider-friendly payment practices, such as paying providers timely, to incentivize providers to participate in the CCDF program and ensure access for eligible families. However, some providers still report concerns about payment amounts, payment frequencies, and other administrative burdens associated with CCDF program participation.

ACF concurred with all of our recommendations, which were to:

- evaluate whether States are ensuring equal access for CCDF families, as required;
- ensure that States comply with the new requirement to use the results of the most recent market-rate survey, or alternative methodology, to set CCDF payment rates;
- establish a forum for States to share strategies regarding how they set payment rates to ensure equal access for eligible families while balancing competing program priorities; and
- encourage States to minimize administrative burdens for CCDF providers, with a goal of expanding access for eligible families.

Unaccompanied Alien Children Care Provider Facilities Generally Conducted Required Background Checks but Faced Challenges in Hiring, Screening, and Retaining Employees (A-12-19-20001), September 2019

ORR, a Program Office of ACF, manages the UAC Program. In general, facilities serving UAC met a range of background checks and qualification requirements designed to keep individuals who may pose a risk to the safety and well-being of children from having direct access to children. However, some facilities did not have evidence of the required the FBI fingerprint or Child Protective Services (CPS) check results and did not always ensure that the out-of-State CPS checks were conducted. In addition, we found that over half of the facilities we reviewed allowed employees to begin employment before receiving the results of the FBI fingerprint check, the CPS check, or both. (ORR issued guidance to address this in March 2019.) In addition to the compliance-related issues, ORR granted six facilities a waiver from conducting the CPS check for employees with direct access to children.

From our review of employee qualifications, we found that most facilities hired mental health clinicians who met ORR education requirements; however, many facilities hired case managers who did not. In addition, facilities had difficulty maintaining required staffing ratios because of challenges experienced in screening, hiring, and retaining qualified employees.

We made several recommendations to ORR to improve UAC Program operations related to background checks, education requirements, staffing ratios, and waivers of CPS checks. ACF concurred with our recommendations and outlined corrective actions it had taken or plans to take to address the findings identified in the report.

Care Provider Facilities Described Challenges Addressing Mental Health Needs of Children in HHS Custody (OEI-09-18-00431), September 2019

OIG found that facilities struggled to address the mental health needs of children who had experienced intense trauma and had difficulty accessing specialized treatment for children who needed it. Facilities reported that challenges employing mental health clinicians resulted in high caseloads and limited their effectiveness in addressing children's needs. Facilities also reported challenges accessing external mental health care providers and transferring children to facilities within ORR's network that provide specialized treatment. Policy changes in 2018 exacerbated these concerns, as they resulted in longer stays in ORR custody and a rapid increase in the number of younger children—many of whom had been separated from their parents after entering the United States.

ACF concurred with our six recommendations for practical steps that ORR can take to assist facilities. ORR should provide facilities with evidence-based guidance on addressing trauma in short-term therapy. ORR should also develop strategies for overcoming obstacles to hiring and retaining qualified mental health clinicians and consider maximum caseloads for individual clinicians. Finally, ORR should address gaps in options for children who require more specialized treatment and take all reasonable steps to minimize the amount of time that children remain in ORR custody.

The Next Door Foundation Claimed Unallowable Indirect Costs and Did Not Document the Funding Source of Program Expenditures in Accordance With Federal Requirements (A-05-18-00008), September 2019

The Next Door Foundation (NDF) did not always claim and account for HHS grant funds in accordance with Federal requirements. We identified unallowable claims for indirect costs totaling \$142,104. We also identified other costs totaling \$15,618 that did not fully meet Federal requirements but were related to the purpose of the grant. These costs included \$9,968 for contractual services and \$5,650 for cost transfers. In addition, NDF's financial management system was not in compliance with Federal regulations. NDF claimed unallowable costs because it did not always follow its policies and procedures for claiming and accounting for HHS grant funds.

NDF partly agreed and partly disagreed with our recommendations that it (1) refund \$142,104 in unallowable indirect costs and work with its HHS funding agencies to ensure proper claiming of indirect costs, (2) ensure that contractual agreements are signed and in place before services are provided, (3) ensure that cost transfers meet applicable criteria and are fully documented, and (4)

ensure that the financial management system accurately matches expenditures with the source of funds.

Safety of Children in Foster Care

All Six States Reviewed Had Partially Implemented New Criminal Background Check Requirements for Childcare Providers, and Five of the States Anticipate Full Implementation by Fiscal Year 2020 (A-05-19-00015), August 2019

All six States reviewed (Colorado, Georgia, Illinois, Nevada, New Hampshire, and New York) had implemented some of the new criminal background check requirements established under the Child Care and Development Block Grant Act of 2014 as of March and October 2018. Five of the six States anticipate full implementation by FY 2020. However, certain criminal background check requirements for childcare providers remained unimplemented, and significant challenges may delay full implementation. These challenges included data system limitations, insufficient funds and staff to process the criminal background checks, and delays associated with making required changes to State laws or policies and procedures.

ACF concurred with our recommendations that it (1) continue to monitor the States' actions and progress toward implementation of the new background check requirements and (2) continue to work with States and Federal partners to ensure that all remaining background check requirements are implemented.

Low-Income Home Energy Assistance Program

The Administration for Children and Families Should Improve the Oversight of Tribal Grantees' Low-Income Home Energy Assistance Programs (A-07-17-04105), August 2019

ACF's oversight of the Low-Income Home Energy Assistance Program (LIHEAP) did not ensure that grant funds were (1) used to provide the maximum available LIHEAP benefits to eligible households and (2) consistently administered in accordance with Federal laws, regulations, and guidance. ACF's oversight of Tribal grantees focused on the reporting of obligated funds and not on whether the grantees had adequate policies and procedures to ensure that they used obligated funds to provide the maximum available LIHEAP benefits to eligible households. Furthermore, ACF selected only a limited number of Tribal grantees for onsite compliance reviews each year. These reviews did not ensure that grantees complied with Federal regulations. ACF did not have adequate policies and procedures to effectively oversee the Tribal grantees' LIHEAP grants.

We made a series of procedural recommendations to ACF, including that it enhance its policies and procedures for the Tribal grantees' use of obligated funds, review the grantees' reports and their policies and procedures, and expand its program monitoring activities.

ACF concurred with most of our recommendations. It did not concur with part of one recommendation that dealt with the timing of the return of grant funds from home energy suppliers to the Tribal grantees and with our recommendation to continue to expand its program monitoring activities.

Administration for Community Living

Although the Administration for Community Living Resolved Nearly All Audit Recommendations, It Did Not Always Do So in Accordance With Federal Timeframe Requirements (A-07-18-03232), April 2019

ACL did not always resolve audit recommendations in a timely manner during FYs 2015 and 2016. Specifically, it did not resolve 34 of the 65 recommendations (52.3 percent) within the required 6-month resolution period. In addition, as of September 30, 2016, ACL had not resolved six audit recommendations that were past due for resolution. These recommendations were procedural in nature; none of them involved dollar amounts such as recommended disallowances.

ACL did not always follow policies and procedures in place to ensure that audit recommendations were resolved in compliance with Federal requirements. Although ACL did not always issue management decisions and submit the related clearance documents to OIG within the required 6-month resolution period, ACL has made progress in this respect by increasing the percentage of audit recommendations that were resolved in a timely manner.

ACL concurred with our recommendation that it follow its policies and procedures related to the audit resolution process. ACL did not directly concur with our recommendation that it promptly resolve the six outstanding audit recommendations that were past due as of September 30, 2016, but it described corrective actions that it had taken related to both recommendations.

The Administration for Community Living Failed To Conduct Any of the Required Onsite Compliance Reviews of Independent Living Programs (A-05-18-00034), August 2019

ACL did not appropriately oversee the activities of two independent living programs. Specifically, as of the audit date, ACL had not conducted any onsite compliance reviews of either the Centers for Independent Living program or the Independent Living Services program since beginning its oversight of the programs in July 2014.

Although ACL conducted some monitoring activities, ACL's comprehensive and targeted desk reviews did not include any onsite compliance reviews of the programs as of December 31, 2018. ACL was appropriated \$156.6 million for independent living program services during the audit period. Of this amount, ACL awarded \$151.4 million to grantees for independent living program services. However, ACL did not allocate sufficient funds to support onsite compliance reviews.

ACL officials said that they were unable to conduct onsite compliance reviews because of limited travel funding. Without the required onsite compliance reviews, there is no assurance that independent living programs are effectively working to maximize the independence, well-being, and health of older adults, people with disabilities, and the families and caregivers of both.

ACL generally did not state whether it concurred with our recommendations that it determine whether it can allocate its funds differently to enable onsite compliance reviews, seek additional department funding or resources to conduct the onsite compliance reviews, and perform required onsite compliance reviews of independent living programs.

Health Resources and Services Administration

The Health Resources and Services Administration Resolved All of Its Audit Recommendations, With Over 99 Percent Resolved in Accordance With Federal Timeliness Requirements (A-07-19-03235), August 2019

HRSA resolved all of its audit recommendations during FYs 2015 and 2016, nearly all of them in a timely manner. Of the 1,434 audit recommendations that HRSA resolved during FYs 2015 and 2016, 1,427 (99.5 percent) were resolved within the required 6-month period. All of the other seven recommendations (0.5 percent) that were not resolved within the 6-month resolution period were resolved within 21 days or less of the end of that resolution period.

HRSA had policies and procedures in place to ensure that audit recommendations were resolved in compliance with Federal requirements, which require resolution of audit recommendations within 6 months of the audit report's issuance date. HRSA consistently followed these policies and procedures, and as a result, it issued nearly all management decisions and submitted nearly all of the related clearance documents to OIG within the required 6-month resolution period. In addition, HRSA performed reconciliations between its records and the OIG stewardship reports and followed up with OIG on differences when they were noted. According to HRSA officials, timely audit resolution is a very high priority.

Because HRSA was substantially in compliance with Federal audit resolution requirements, this report contains no recommendations.

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, 16 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. Of that amount, one individual was excluded as a result of a default on a settlement agreement.

After being excluded for nonpayment of their HEAL debts, 2,802 individuals chose to enter into settlement agreements or completely repay their debts. That figure includes 23 individuals who entered into such settlement agreements or completely repaid their debts. More than \$224.7 million is being repaid through settlement agreements or through complete repayment. Of that amount, more than \$3.2 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:

New York—Renee Wasserman, Podiatrist—\$886,827

Alabama—Russell Douglas Alexander, Medical Doctor—\$86,432

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 nation-wide resulted in 6 criminal actions and court-ordered restitution and settlements of \$648,240.

The following case examples involve child support enforcement:

New Jersey—In August 2002, Robert Whitley was ordered to pay child support payments of \$229.50 per week for support of two children. Whitley only sporadically made payments to the custodial parent of his children, and last made a payment in 2011. Whitley pleaded guilty to failure to pay legal child support obligations and was ordered to pay \$191,673.83 in restitution.

South Dakota—In October 2003, Joseph Mesteth was ordered to pay child support payments of \$455 per month for support of three children. Mesteth only sporadically made payments to the custodial parent of his children. Mesteth pleaded guilty to failure to pay legal child support and was ordered to pay \$104,160.81 in restitution.

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

HHS Did Not Always Efficiently Plan and Coordinate Its International Ebola Response Efforts (A-04-16-03567), August 2019

HHS made significant contributions to controlling the Ebola crisis during 2014 and 2015 and was ultimately effective in helping to stop the spread of Ebola. However, HHS had no strategic framework in place to coordinate global health security at the international or departmental levels before the Ebola outbreak, was not prepared to deploy the resources needed for a large-scale international response, and did not have in place internal or external communication channels for responding to an international public health emergency.

HHS's response efforts were further complicated by external factors: the World Health Organization did not declare the epidemic an emergency until well after the epidemic had significantly expanded in West Africa, and Congress did not provide supplemental funding until HHS's response was well underway.

Without effective internal controls that include a department-wide strategic framework for responding to an international health crisis, HHS may continue to inefficiently plan and coordinate its international response efforts in future health crises.

HHS concurred with our recommendations that it (1) develop department-wide objectives and a strategic framework for responding to international public health emergencies, (2) develop policies and procedures that clearly define HHS components' roles and responsibilities for responding to international public health emergencies, (3) develop large-scale international response plans, (4) develop various means of obtaining and using quality data for decision making, and (5) work with other U.S. Government agencies to develop a flexible multiagency international response framework.

Department of Health and Human Services Had Email Requirements for Political Appointees, but Office of the Secretary Lacked Effective Monitoring and Enforcement (A-18-18-11050), September 2019

HHS had some controls in place to restrict and monitor the use of personal email accounts to conduct government business, in accordance with Federal laws and regulations, as well as policies and procedures to preserve all government emails on official email systems. However, three of the five HHS agencies or offices we audited did not have automated controls in place to block

employees from accessing personal email accounts while logged into HHS, Office of the Secretary (OS), or OpDiv networks. In addition, we found that OS did not ensure that all political appointees received security awareness training due to improper listing and classification of the political appointees.

HHS concurred with our recommendations that (1) HHS implement a policy requiring all HHS agencies and offices to implement automated controls to block employees from accessing personal email accounts from HHS networks; (2) OS implement a process to ensure that all OS political appointees, employees, and contractors complete the required security awareness trainings in a timely manner; and (3) OS implement procedures to ensure that its staff are properly listed and classified as political appointees, employees, contractors, and supervisors.

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 example relates to misuse of grant funds:

New Mexico—Pecos Valley Medical Center, Inc. (PVMC) entered into a settlement agreement with OIG to resolve its liability under the CMPL, 42 U.S.C. § 1320a-7a(o), stemming from allegations that PVMC knowingly presented to HHS a specified claim under an HHS grant that PVMC knew or should have known was false or fraudulent. Specifically, PVMC made seven drawdowns from a HRSA Health Infrastructure Investment Grant between October and December 2017 and used the funds for unallowable operating costs not related to the grant.

Contract Fraud Investigations

The following case example relates to misuse of contract funds:

Maryland—Cúram Software Ltd. and Cúram Software, Inc. (collectively, "Cúram"), and International Business Machines Corporation (IBM) (Cúram and IBM are collectively referred to as "Cúram-IBM") entered into a settlement agreement with the United States. In December 2011, in response to a request for proposals (RFP) from the State of Maryland,

acting through the Maryland Health Benefit Exchange (MHBE), Noridian Administrative Services, LLC (Noridian) submitted a proposal to support the Maryland Health Insurance Exchange (HIX) eligibility and enrollment system. The proposal was drafted in part by Cúram and included Cúram as a subcontractor providing software and services. IBM acquired Cúram on December 19, 2011, after Noridian made its proposal but before the subcontract was awarded. The proposal (and information provided in subsequent meetings) included statements regarding the commercial off-the-shelf (COTS) status of Cúram software and its existing and intended functionality to meet specific requirements listed in the RFP. The State of Maryland, through the MHBE, awarded the contract to Noridian on February 22, 2012, and Cúram-IBM served as Noridian's subcontractor. After repeated problems following the launch of the HIX website in October 2013, the State of Maryland terminated the Noridian contract and replaced the HIX website and IT platform, including the Cúram software. The United States alleges that Cúram-IBM has FCA liability for fraudulently inducing an award of the contract by misrepresenting the functionality of the software. It is alleged that Cúram-IBM represented that they had a COTS product that could be implemented in a timely manner with minimal modification. Instead, the product did not have the functionality that was promised and required a lot more work, time, and money to implement.

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 2018 report delivered to the three congressional oversight committees, we reported that OIG spent approximately \$392,837 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 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 158 reports covering \$2.1 trillion in audited costs. Federal dollars covered by these audits totaled \$674 billion, of which about \$377 billion were HHS funds.

Office of Management and Budget (OMB) Circular A-133 and the more recent 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 circular and 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, April 1, 2019, Through September 30, 2019

Not requiring changes or having minor changes	156
Requiring major changes	1
Having significant technical inadequacies	1
Total Number of Non-Federal Audits	158

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.

- Our [Semiannual Report 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 IG 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.

Table 1: Audit Reports With Questioned Costs

Description	Number of Reports	Dollar Value Questioned	Dollar Value Unsupported
Section 1			
Reports for which no management decisions had been made by the beginning of the reporting period ¹	124	\$1,895,594,000	\$512,492,000
Issued during the reporting period	32	\$666,549,000	\$51,163,000
Total Section 1	156	\$2,562,143,000	\$563,655,000
Section 2			
Reports for which management decisions were made during the reporting period ^{2,3}			
Disallowed costs	95	*\$322,724,000	\$495,000
Costs not disallowed	6	\$33,449,000	\$0
Total Section 2	101	\$356,173,000	\$495,000
*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)	55	\$2,205,970,000	\$563,160,000
Section 4			
Reports for which no management decisions were made within 6 months of issuance ⁴	27	\$1,608,663,000	\$511,997,000

Table 1 End Notes

¹ The opening balance was adjusted upward by \$127.7 million because of a reevaluation of previously issued recommendations.

² Revisions to previously reported management decisions:

- A-01-14-00001, *Review of Medicaid Payments for Targeted Case Management Services in Connecticut*. Subsequent review by CMS determined that the original finding amount was mitigated through rate adjustments resulting in a decreased previously sustained amount by \$20,049,886.
- A-07-14-06050, *Physician Administered Drug Rebate Review—Colorado*. Subsequent review by CMS determined that the original sustained cost should have been \$317,343. The disallowed cost was reduced by \$6,420,952 due to a CMS miscalculation.
- A-10-14-25191, *State of Oregon*. ACF increased the sustained amount by \$3,393,350 due to the receipt of additional documentation.
- A-05-16-00064, *Medicare Compliance Review of the University of Michigan Health System for 2014 and 2015*. OIG and CMS agreed to re-calculate the overpayment estimates based on already known settlement results. As a result, the sustained amount was reduced by \$2,800,850.
- **Not detailed are reductions to previously disallowed management decisions totaling \$3.7 million.**

³ Included are management decisions to disallow \$119 million in questioned costs that were identified by non-Federal auditors in audits of State and local governments, colleges and universities, and nonprofit organizations receiving Federal awards conducted in accordance with Office of Management and Budget Circular A-133. OIG is currently ensuring that work performed by these non-Federal auditors complies with Federal audit standards; accordingly, OIG tracks, resolves, and reports on recommendations in these audits.

⁴ Because of administrative delays, some of which were beyond management control, resolution of the following 27 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-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-02-16-02012	<i>CDC Reimbursed Contractors For Some Unallowable World Trade Center Health Program Administrative Costs, February 2019, \$8,066,551</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-07-11-06013	<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-07-16-04230	<i>The Three Affiliated Tribes Improperly Administered Low-Income Home Energy Assistance Program Funds for FYs 2010 through 2014, July 2017, \$1,221,425</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-07-16-04233	<i>The Turtle Mountain Band of Chippewa Indians Improperly Administered Some Low-Income Home Energy Assistance Program Funds for Fiscal Years 2010 Through 2013, September 2017, \$587,248</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-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</i> , June 2014, \$352,843
A-09-17-01002	<i>Florence Crittenton Services of Orange County, Inc., Did Not Always Claim Expenditures in Accordance With Federal Requirements</i> , October 2018, \$342,263
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</i> , July 2018, \$341,616
A-06-11-00058	<i>Crowley's Ridge Development Council, Inc., Claimed Unallowable Costs Under a Recovery Act Grant</i> , August 2012, \$115,420
TOTAL CINS: 27	
TOTAL AMOUNT: \$1,608,663,000	

Audit Reports With Funds Recommended To Be Put to Better Use

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

Table 2: Audit Reports With Funds Put to Better Use

Description	Number of Reports	Dollar Value
Section 1		
Reports for which no management decisions had been made by the beginning of the reporting period ¹	6	\$15,275,825,000
Reports issued during the reporting period	6	\$573,037,000
Total Section 1	12	\$15,848,862,000
Section 2		
Reports for which management decisions were made during the reporting period		
Value of recommendations agreed to by management		
Based on proposed management action	2	\$223,749,000
Based on proposed legislative action	0	\$0
Value of recommendations not agreed to by management		\$0
Total Section 2	2	\$223,749,000
Section 3		
Reports for which no management decisions had been made by the end of the reporting period ² (<i>Sec. 1 minus Sec. 2</i>)	10	\$15,625,113,000

Table 2 End Notes

¹The opening balance was adjusted down by \$37 million because of a reevaluation of previously issued recommendations.

²Because of administrative delays, some of which were beyond management control, 4 of the 10 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-03-13-03002	<i>HHS Did Not Identify and Report Antideficiency Act Violations, May 2017, \$49,445,025</i>
A-05-13-00015	<i>The Minnesota Medicaid Program Could Significantly Lower Payment Rates For Select Durable Equipment and Medical Supplies, January 2014, \$2,268,928</i>
A-02-16-02012	<i>CDC Reimbursed Contractors for Some Unallowable World Trade Center Health Program Administrative Costs, February 2019, \$362,324</i>
TOTAL CINS: 4	
TOTAL AMOUNT: \$15,052,076,000	

Appendix B: Savings Decisions Supported by OIG Recommendations

The table below lists policy decisions reflected in legislation, regulations, or other directives from prior years that are supported by OIG recommendations and for which cost savings were estimated, usually by third parties, such as the Congressional Budget Office (CBO) or HHS actuaries. Of the \$150.5 billion in savings estimated for the decisions below, \$27.5 billion was attributed to FY 2019. This figure reflects the most recent available savings estimates issued by the third-party appraiser; actual savings may be higher or lower.

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

To quantify the value of administrative decisions, we use estimates developed by, or in consultation with, HHS operating or staff divisions. To quantify the value of legislative decisions, we generally use estimates developed by CBO. CBO projects the annual increases or reductions in Federal spending that it expects would result from enacting the legislation. The policy decisions shown on the table beginning on the next page mirror not only OIG’s recommendations but also the contributions of others, such as HHS staff and OpDivs, congressional committees, and the GAO.

Centers for Medicare & Medicaid Services Programs		
OIG Recommendations	Policy Decisions	Estimated Savings (millions)
<p>Hospital Transfer Policy for Early Discharges to Hospice Care Change regulations or pursue a legislative change, if necessary, to establish a hospital transfer payment policy for early discharges to hospice care. The recommendation reflected findings in OIG report A-01-12-00507.</p>	<p>Section 53109 of the Bipartisan Budget Act of 2018 modified existing law to require that, beginning in FY 2019, discharges to hospice care would also qualify as a postacute care transfer and be subject to payment adjustments.</p>	<p>\$485</p>
<p>Medicare Part C Prepayments Modify monthly capitated payments to a level fully supported by empirical</p>	<p>Section 3201 of the ACA changed the Medicare Advantage benchmark percentages that are applied to Medicare fee-for-service and imposed a cap on the benchmarks, resulting in cost savings for</p>	<p>\$25,000</p>

<p>data. The recommendation reflected findings in OIG report A-14-00-00212.</p>	<p>Medicare Part C as compared to prior law. CBO estimated Part C savings through FY 2019, including \$23.2 billion for FY 2018. CBO produced its estimate in 2010, prior to two significant implementation decisions by HHS that affect the actual savings; however, neither CBO nor HHS has calculated a revised estimate.</p>	
<p>Reductions in Medicare Bad Debt Reimbursement Seek legislative authority to eliminate (or reduce) Medicare payments to hospitals for bad debt associated with beneficiaries' failure to pay their deductibles and coinsurance. The recommendations reflected findings in OIG report A-14-90-00339 and subsequent reviews.</p>	<p>Section 3201 of the Middle Class Tax Extension and Job Creation Act of 2012 applied percentage reductions in bad debt reimbursement to all providers eligible to receive bad debt reimbursement. CMS estimated savings to Medicare of \$10.92 billion over 10 years with \$1.21 billion attributed to FY 2018. (77 Fed. Reg. 67450, 67523 (November 9, 2012))</p>	<p>\$1,300</p>
<p>Payments for Prescription Drugs Provided to Incarcerated Beneficiaries Work with prescription drug plan sponsors to identify and resolve improper Medicare Part D payments made for prescription drugs provided to incarcerated beneficiaries. The recommendation reflected findings in OIG report A-07-12-06035.</p>	<p>CMS issued a final rule about the Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug programs. The eligibility requirements to enroll in Medicare Advantage and Part D are outlined in Sections 1851(a)(3)(B) and 1860D-1(a)(3)(A) of the Act. To enroll in Medicare Advantage, a beneficiary must be entitled to Part A and enrolled in Part B. To enroll in Part D, a beneficiary must be entitled to Part A and/or enrolled in Part B. An incarcerated beneficiary is not precluded from meeting the eligibility requirements for Part A and Part B, but in general, no Medicare Payment is made for these individuals. CMS promulgated regulations to require Part D plans to disenroll incarcerated beneficiaries. CMS estimated savings of \$1.6 billion over 10 years with \$129 million attributed to FY 2018. (79 Fed. Reg. 29844, 29953 (May 23, 2014))</p>	<p>\$152</p>
<p>Medicare Payments for Vacuum Erection Systems Seek legislative authority to include vacuum erection systems (VES) in the Competitive Bidding program and then implement a National Mail-Order Competitive Bidding Program for VES. The recommendation reflected findings in OIG report A-07-12-05024.</p>	<p>Section 203 of the Achieving a Better Life Experience Act of 2014 implements changes to treat VES prosthetic devices and related accessories as statutorily noncovered in the same manner that erectile dysfunction drugs are treated in Medicare Part D. CBO estimated savings of \$444 million over 10 years.</p>	<p>\$44.4</p>
<p>Additional Rebates for Brand-Name Drugs with Multiple Versions</p>	<p>Section 2501(d) of the ACA, as amended by section 1206(a) of the Health Care and Education</p>	<p>\$300</p>

<p>OIG recommended that CMS continue to seek legislative authority to modify the rebate formula calculation to ensure that manufacturers cannot circumvent additional rebates by bringing new versions of existing brand-name drugs to market. The recommendation reflected findings in OIG report A-06-09-00033.</p>	<p>Reconciliation Act of 2010, addresses this issue. CBO estimated savings of \$300 million for FY 2018.</p>	
<p>Medicaid Provider Reimbursement for Durable Medical Equipment OIG recommended that CMS seek legislative authority to limit State Medicaid DME reimbursement rates to Medicare program rates and encourage further reduction of Medicaid reimbursement rates through competitive bidding or manufacturer rebates. OIG also recommended that that CMS work with State Medicaid agencies to determine whether the use of manufacturer rebates and lower provider reimbursement rates could achieve net savings for the purchase of test strips. The recommendations reflected findings in OIG reports A-05-15-00025 and A-05-13-00033.</p>	<p>In December 2015, the Consolidated Appropriations Act, 2016 section 503, Congress added section 1903(i)(27) to the Social Security Act (the Act) which prohibits federal Medicaid reimbursement to States for certain DME expenditures that are, in the aggregate, in excess of what Medicare would have paid for such items. The requirement was scheduled to effect January 1, 2019. The 21st Century Cures Act Section 5002 moved up the effective date to January 1, 2018, when it was passed in December 2016. CBO estimated savings of \$275 million for FY 2018.</p>	<p>\$95</p>
<p>Excessive Medicaid Payments to New York State Ensure that expenditures related to developmental centers and other intermediate care facilities and any revised payment methodology be consistent with efficiency and economy. The recommendation reflected findings in OIG reports A-02-11-01029, A-02-13-01008, and other reviews.</p>	<p>Agreement between CMS and the State of New York, dated March 20, 2015, to repay \$1.95 billion over 12 years with \$100 million attributed to FY 2018.</p>	<p>\$100</p>

Appendix C: Peer-Review Results

The Inspector General Act of 1978, as amended, requires OIGs to report the results of peer reviews of their operations conducted by other OIGs, the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by an OIG of other OIGs in the semiannual period. Peer reviews are conducted by member organizations of the Council of the Inspectors General on Integrity and Efficiency (CIGIE). Recently, CIGIE has approved a new peer-review process for Inspection and Evaluation units within OIGs across the Federal Government, including at HHS-OIG, the implementation of which will begin in 2018.

Office of Audit Services

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

OEI	Date	Reviewing Office	Office Reviewed
	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 through November 17, 2017.

Appendix D: Summary of Sanction Authorities

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

Program Exclusions

The Social Security Act, § 1128 (42 U.S.C. § 1320a-7), provides several grounds for excluding individuals and entities from participation in Medicare, Medicaid, and other Federal health care programs. Exclusions are required (mandatory exclusion) for individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud; (2) patient abuse or neglect; (3) felonies for other healthcare 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 healthcare fraud (other than Medicare or Medicaid); suspension or revocation of a license to provide healthcare for reasons bearing on professional competence, professional performance or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a Federal health care program; or engaging in unlawful kickback arrangements.

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

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

Civil Monetary Penalties Law

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

For the purposes of the CMPL, "should know" is defined to mean that the person acted in reckless disregard or deliberate ignorance of the truth or falsity of the claim. The law and its implementing regulations also authorize actions for a variety of other violations, including submission of claims for items

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

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

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

Patient Dumping

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

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

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

Anti-Kickback Statute and Civil False Claims Act Enforcement Authorities

The Anti-Kickback Statute

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

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

The False Claims Act

Under the FCA, 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 FCA 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 FCA 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 FCA, no specific intent to defraud is required. Further, the FCA 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 FCA 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 FCA to false claims submitted to contractors or grantees of the Federal Government.

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

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

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

Section	Requirement	Location
	within 60 days, and in which there are any outstanding unimplemented recommendations	
(a)(11)	Description and explanation of revised management decisions	Appendix A
(a)(12)	Management decisions with which the Inspector General disagrees	None for this reporting period
(a)(13)	Information required by the Federal Information Security Management Act.	Reported annually in the spring Semiannual Report, "Other HHS-Related Reviews and Investigations" section
(a)(14)-(16)	Results of peer reviews of HHS-OIG conducted by other OIGs or the date of the last peer review, outstanding recommendations from peer reviews, and peer reviews conducted by HHS-OIG of other OIGs	Appendix 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.	Reported annually in the fall Semiannual Report, Appendix G

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

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

The Inspector General Empowerment Act of 2016 (IGEA) 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 2019, OIG had 92 reports with overdue final management decisions.¹

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.

¹ 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 with overdue management decisions from FY 1990 through FY 2010.

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

OIG is actively tracking 1,235 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 (2011–2019)	Number of Reports with Unimplemented Recommendations	Number of Unimplemented Recommendations	Dollar Value of Aggregate Potential Cost Savings
2011	14	22	\$434,404,003
2012	25	31	\$397,437,195
2013	36	62	\$238,018,798
2014	34	58	\$15,140,127,422
2015	37	66	\$333,957,018
2016	37	85	\$195,448,338
2017	49	164	\$1,119,790,864
2018	71	236	\$2,235,268,673
2019	131	511	\$1,418,992,826
Totals	434	1,235	\$21,513,445,137

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 Department of Justice 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 informations 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	0
Total number of persons referred ² to Federal prosecuting authorities for criminal prosecution during the reporting period ³	1,346
Total number of persons referred to State and local prosecuting authorities for criminal prosecutions during the reporting period	150
Total number of Federal indictments and criminal informations during the reporting period that resulted from any prior referral to prosecuting authorities	537
Total number of State and local indictments and criminal informations during the reporting period that resulted from any prior referral to prosecuting authorities	41

(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 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.

² A referral includes OIG presentations to DOJ and/or State/local prosecutorial authorities.

³ OIG counts "persons" as both individuals and entities.

Regarding (17)(D), the table above provides the number of indictments/criminal informations during the semiannual reporting period, including sealed indictments/criminal informations. 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 one senior Government employees for misconduct, and OIG determined the allegations to be substantiated, but no prosecution resulted. A description of the investigation is below.

Description of Investigation	Status	Disposition	DOJ Referral	DOJ Referral Date	DOJ Declination	DOJ Declination Date
OI was advised of a suspected computer misuse case involving the employee. It had been alleged that the employee may have accessed databases and systems for purposes that were not authorized. OI examined the matter and found no criminal activity.	Closed	Closed	No	None	None	None

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

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

During the time period from April 1, 2019, through September 30, 2019, OIG did not issue any reports that included findings of retaliation.

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

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

- (A) with budget constraints designed to limit the capabilities of the Office; and*
- (B) incidents where the establishment has resisted or objected to oversight activities of the Office or restricted or significantly delayed access to information, including the justification of the establishment for such action; and*

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

- (22) Detailed descriptions of the particular circumstances of each—
 (A) inspection, evaluation, and audit conducted by the Office that is closed and was not disclosed to the public; and

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

Nonpublic Reports by Category, April 1, 2019, to September 30, 2019

Category/Description	Number of Reports
IT security reviews (involve IT systems, e.g., penetration test audits)	0
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 ⁴	0
Finance-related attestation reviews	2
Total	2

⁴ 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.

(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 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 one 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
Allegations of conflict of interest and post-employment violations were received regarding a senior government employee.	Closed	No evidence to support allegations.	No	N/A	N/A	N/A

Appendix G: Anti-Kickback Statute—Safe Harbors

Pursuant to the Health Insurance Portability and Accountability Act (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, the Office of Inspector General (OIG) did not publish its typical December annual solicitation in the *Federal Register*.⁵

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, 2018.⁶ 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 proposals 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

⁵ 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>.

⁶ OIG, Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, 83 Fed. Reg. 43,607 (Aug. 27, 2018), available at https://oig.hhs.gov/authorities/docs/2018/RFI_Regarding_AKS_Beneficiary_Inducements_CMP.pdf.

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

- new safe harbors protecting financial arrangements among parties participating in alternative payment models (APMs), value-based arrangements, and care coordination activities;
- safe harbor protection for financial arrangements with entities not participating in Innovation Center models, including commercial and self-pay APM arrangements;
- additional protection for patient tools and supports, such as in-kind items and services to support patient compliance with discharge and care plans, services and supports to address unmet social needs affecting health, and expanded protections under the local transportation safe harbor;
- enhanced safe harbor protection for transfers of 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” (the OIG NPRM).⁷ 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 the proposed 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;

⁷ 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(jjj)) for donations of cybersecurity technology and services;
- proposed modifications to the existing safe harbor for electronic health records items and services (1001.952(y)) to add protections for certain cybersecurity technology included as part of an electronic health records 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 are due December 31, 2019, and will be considered at that time. 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.