Office of Inspector General (OIG)
Work Plan, FY 2016

PATHOLOGY/LABORATORY

Presented by: Rick Oliver, CPCO, CPC, MT(ASCP)
Compliance Program Director-Pathology/Laboratory
Office of Inspector General (OIG) FY2016 Work Plan
Specialty: Pathology/Laboratory

This review of the OIG FY2016 Work Plan will provide the various section(s) that were identified by the OIG that may affect the Pathology/Laboratory specialty. It does not include a comprehensive review of all components of the Work Plan. This document is for “informational use only” and it is not intended to provide legal advice or counseling on the various topic(s). If the reader has concerns or questions they should consult with their legal counsel for advice.

The OIG released its Fiscal Year 2016 (FY2016) Work Plan on Oct. 30, 2015. The work plan is published annually, with a mid-year update, when applicable and provides the OIG’s current ongoing audit and enforcement initiatives as well as identifying any new priorities for the upcoming year. The work plan is a very useful tool in indentifying compliance risk areas and focus for ongoing efforts relating to compliance program activities, audits and policy development.

The OIG identified several new areas of focus for the FY2016 plan as well as revised items from previously year’s plans. The OIG rolled over last year’s item for independent laboratory billing activities into this year’s plan to analyze potential overpayments. They also discussed the Centers for Medicare and Medicaid’s (CMS) new Clinical Lab Fee Schedule project that will base the fee schedule on private payer rates. OIG indicates they will conduct an annual analysis and monitor Medicare expenditures and the new payment system for laboratory tests. OIG added a new review for CMS’s early management of the implementation of the ICD-10 and may review the effectiveness of that implementation as well as how the new system may affect claim submissions and denials.

The OIG Work Plan outlines the current focus areas and states the primary objectives of each project. The word “New” in the project title indicates the project did not appear in the previous Work Plan. At the end of each project description, the OIG provides the internal identification code for the review (if a number has been assigned), the year in which they expect one or more reports to be issued as a result of the review, and whether the work was in progress at the start of the fiscal year or is planned as a new start.

The OIG states “[[i]n fiscal year (FY) 2016 and beyond, OIG will expand its focus on delivery system reform and the effectiveness of alternate payment models, coordinated care programs, and value-based purchasing. Areas under consideration for new work include, for example, a holistic examination of HHS’ efforts to reduce opioid abuse, adherence to safety standards in Administration for Children and Families’ Unaccompanied Children Program, and evaluation of CMS’s Fraud Prevention System. OIG will periodically update its online Work Plan, available at http://www.oig.hhs.gov.”

A companion document, FY 16 Justifications of Estimates for Appropriations Committees, provides what the OIG oversight is for Medicare/Medicaid. They state “OIG’s oversight work in FY 2016 will target wasteful spending, including improper payments, unreasonable payment methodologies, and unsafe or low quality health care. Oversight of specific programmatic areas includes Medicaid expansion—including beneficiary enrollment, managed care, and the sufficiency of data used for oversight; prescription drug fraud and abuse; home- and community-based services (HCBS) fraud; promoting industry compliance; contracting and contractor oversight; Medicare Advantage payment accuracy; home health agency compliance and payments; and new payment and delivery models in Medicare and Medicaid.” The full document provides the OIG accomplishments, return on investment and other budgetary request for FY16 as well as past return on investments and enforcement actions (i.e. sanctions, civil and criminal actions) can be accessed by clicking here.

---

2 OIG FY2016 Justification of Estimates for Appropriations Committees, Page 27.
The items selected in this document contain only those that may pertain to the Pathology/Laboratory Specialty (directly or indirectly). Providers are encouraged to read the full work plan to better assess their own individual business activities against the work plan. To view a complete version of the OIG 2016 Work Plan, Click Here.

**Medicare Part A and Part B**

Medicare Part A covers certain inpatient services in hospitals and skilled nursing facilities (SNF) and some home health services. Medicare Part B covers designated practitioners’ services; outpatient care; and certain other medical services, equipment, supplies, and drugs that Part A does not cover. The Centers for Medicare & Medicaid Services (CMS) uses Medicare Administrative Contractors (MAC) to administer Medicare Part A and Medicare Part B and to process claims for both parts.

OIG stated that they have focused its efforts on identifying and offering recommendations to reduce improper payments, prevent and deter fraud, and foster economical payment policies. Future planning efforts for FY 2016 and beyond will include: additional oversight of hospice care, including oversight of certification surveys and hospice-worker licensure requirements; oversight of Skilled Nursing Facilities’ (SNF) compliance with patient admission requirements; and evaluation of CMS’s Fraud Prevention System.

**Hospitals**

**Hospital-Related Policies and Practices**

- **Hospitals’ use of outpatient and inpatient stays under Medicare’s two-midnight rule**
  [OIG] “will determine how hospitals’ use of outpatient and inpatient stays changed under Medicare’s two-midnight rule, as well as how Medicare and beneficiary payments for these stays changed, by comparing claims for hospital stays in the year prior to the effective date of the two-midnight rule to stays in the year following the effective date of that rule. They will also determine the extent to which the use of outpatient and inpatient stays varied among hospitals. CMS implemented the two-midnight rule on October 1, 2013. This rule represents a substantial change to the criteria that hospital physicians are expected to use when deciding whether to admit beneficiaries as inpatients or treat them as outpatients. (OEI; 02-15-00020; expected issue date: FY 2016).”

- **REVISED- Medicare oversight of provider-based status**
  [OIG] “will determine the number of provider-based facilities that hospitals own and the extent to which CMS has methods to oversee provider-based billing. [It] will also determine the extent to which provider-based facilities meet requirements described in 42 CFR Sec. 413.65 and CMS Transmittal A-03-030, and whether there were any challenges associated with the provider-based attestation review process. Provider-based status allows facilities owned and operated by hospitals to bill as hospital outpatient departments. Provider-based status can result in higher Medicare payments for services furnished at provider-based facilities and may increase beneficiaries’ coinsurance liabilities. The Medicare Payment Advisory Commission (MedPAC) has expressed concerns about the financial incentives presented by provider-based status and stated that Medicare should seek to pay similar amounts for similar services. (OEI; 04-12-00380; expected issue date: FY 2016).”

- **Comparison of Provider-Based and Free-Standing Clinics**
  [OIG] “will review and compare Medicare payments for physician office visits in provider-based clinics and freestanding clinics to determine the difference in payments made to the clinics for similar procedures and assess the potential impact on Medicare of hospitals’ claiming provider-based status for such facilities. Provider-based facilities often receive higher payments for some services than do freestanding clinics. The requirements to be met for a facility to be treated as provider based are at 42 CFR § 413.65(d). (OAS; W-00-14-35724; W-00-15-35724; expected issue date: FY 2016)”

---

4 Ibid
5 Ibid at page 7.
review the requirements for provider-based clinics, CMS provided a program memorandum which can accessed by clicking here.

**Hospitals—Billing and Payments**

- **Bone marrow or stem cell transplants**
  [OIG] “will review Medicare payments to hospitals for bone marrow or stem cell transplants to determine whether the payments were made in accordance with Federal rules and regulations. Bone marrow or peripheral blood stem cell transplantation includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high-dose chemotherapy or radiotherapy before the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. (CMS’s Medicare Claims Processing Manual, Pub. No. 100-04, ch. 3, §90.3.) Bone marrow or stem cell transplants are covered under Medicare only for specific diagnoses. Procedure codes must be accompanied by the diagnosis codes that meet specified coverage criteria. Prior OIG reviews have identified hospitals that have incorrectly billed for bone marrow or stem cell transplants. (OAS; W-00-14-35723; expected issue date: FY 2016)”6

**Other Providers and Suppliers**

**Other Providers – Policies and Practices**

- **Ambulatory surgical centers—Payment system**
  [OIG] “will review the appropriateness of Medicare’s methodology for setting ambulatory surgical center (ASC) payment rates under the revised payment system. They will also determine whether a payment disparity exists between the ASC and hospital outpatient department payment rates for similar surgical procedures provided in both settings. A change in Federal law required the Secretary to implement a revised payment system for surgical services furnished in ASCs beginning January 1, 2008. Accordingly, CMS implemented a revised ASC payment system modeled on the Outpatient Prospective Payment System. (MMA, § 626.) (See also 42 CFR § 416.171.) (OAS; W-00-13-35423; W-00-14-35423; W-00-15-35423; various reviews; expected issue date: FY 2016)”7

**Other Providers - Billing and Payment**

- **Selected independent clinical laboratory billing requirements**
  [OIG] “will review Medicare payments to independent clinical laboratories to determine laboratories’ compliance with selected billing requirements. They will use the results of these reviews to identify clinical laboratories that routinely submit improper claims, and they will recommend recovery of overpayments. Prior OIG audits, investigations, and inspections have identified independent clinical laboratory areas at risk for noncompliance with Medicare billing requirements. Payments to service providers are precluded unless the provider has and furnishes upon request the information necessary to determine the amounts due. (Social Security Act, § 1833(e).) They will focus on independent clinical laboratories with claims that may be at risk for overpayments. (OAS; W-00-14-35726; W-00-15-35726; various reviews; expected issue date: FY 2016)”8

- **Annual analysis of Medicare clinical laboratory payments**
  [OIG] “will analyze Medicare payments for clinical diagnostic laboratory tests, including the top 25 clinical diagnostic laboratory tests by Medicare expenditures in 2014. Previous OIG work has found that Medicare pays more than other insurers for certain high-volume and high-expenditure laboratory tests. Section 216 of the Protecting Access to Medicare Act of 2014 requires new Medicare payment rates for laboratory tests beginning in 2017 that are based on private payer rates and establishes processes for determining initial payments for new laboratory tests. Pursuant to a requirement of the Protecting Access to Medicare Act, OIG will conduct an annual analysis and monitor Medicare expenditures for these tests.”

---

6 Ibid at page 9.
7 Ibid at page 16.
8 Ibid at page 18.
expenditures and the new payment system for laboratory tests. (OEI; 00-00-00000; expected issue date: FY 2016)\(^9\)

- **NEW- Physicians–referring/ordering Medicare services and supplies**
  [OIG] “will review select Medicare services, supplies and durable medical equipment (DME) referred/ordered by physicians and non-physician practitioners to determine whether the payments were made in accordance with Medicare requirements. Pursuant to ACA Sec. 6405, CMS requires that physicians and non-physician practitioners who order certain services, supplies and/or DME are required to be Medicare-enrolled physicians or nonphysician practitioners and legally eligible to refer/order services, supplies and DME. If the referring/ordering physician or non-physician practitioner is not eligible to order or refer, then Medicare claims should not be paid. (OAS; W-00-15-35748; expected issue date: FY 2016, ACA)\(^10\)

- **NEW- Histocompatibility laboratories–supplier compliance with payment requirements**
  [OIG] “will determine whether payments to histocompatibility laboratories were made in accordance with Medicare requirements. From March 31, 2013, through September 30, 2014, histocompatibility laboratories reported $131 million in reimbursable costs on their most recent cost reports. Histocompatibility laboratories are reimbursed on the basis of reasonable costs. Costs claimed in the cost report must be related to the care of beneficiaries; reasonable, necessary, and proper; (42 CFR §413.9(a), (b), and (c)(3)) and cost information must be accurate and in sufficient detail to support payments made for services provided (42 CFR § 413.24(a) and (c)). (OAS; W-00-15-35742; expected issue date: FY 2016)\(^11\)

**Part A and Part B Contractors**

**Contractor Functions and Performance**

- **REVISED- Medicare benefit integrity contractors’ activities in 2012 and 2013: a data compendium**
  [OIG] “will review the level of benefit integrity activity performed by Medicare benefit integrity contractors in CYs 2012 and 2013. This review will highlight trends in integrity activities and allow for a quick comparison of program results across years, across contractors, and across the parts of the Medicare program. CMS contracts with entities to carry out benefit integrity activities to safeguard Medicare against fraud, waste, and abuse. Activities that these contractors perform include analyzing data to identify aberrant billing patterns, conducting fraud investigations, responding to requests for information from law enforcement, and referring suspected cases of fraud to law enforcement for prosecution. Program Safeguard Contractors (PSCs) and Zone Program Integrity Contractors (ZPICs) carry out benefit integrity activities for Medicare Parts A and B, and a Medicare Drug Integrity Contractor (MEDIC) carries out benefit integrity activities for Medicare Parts C and D. (OEI; 03-13-00620; expected issue date: FY 2016)\(^12\)

- **Collection status of ZPIC and PSC—identified Medicare overpayments**
  [OIG] “will determine the total amount of overpayments that ZPICs and PSCs identified and referred to claims processors in 2014 and the amount of these overpayments that claims processors collected. They will also review the procedures for tracking collections of overpayments identified by ZPICs and PSCs. OIG has issued several reports regarding the tracking and collection of the overpayments that Medicare’s contractors have made to providers. In response, CMS stated that it has added reporting requirements that would improve overpayment tracking among the claims processors and ZPICs and PSCs. ZPICs and PSCs are required to detect and deter fraud and abuse in Medicare Part A and/or Part B in their jurisdictions. They conduct investigations; refer cases to law

---

\(^9\) Ibid.
\(^10\) Ibid at page 20.
\(^11\) Ibid at page 21.
\(^12\) Ibid at page 24.
Other Part A and Part B Program Management Issues

Provider Eligibility

- **Enhanced enrollment screening process for Medicare providers**
  [OIG] "will determine the extent to which and the way in which CMS and its contractors have implemented enhanced screening procedures for Medicare providers pursuant to the ACA, §6401. They will also collect data on and report the number of initial enrollments and enrollment revalidations approved and denied by CMS before and after the implementation of the enhanced screening procedures. As part of an effort to prevent fraud, waste, and abuse resulting from vulnerabilities in the Medicare enrollment process, CMS is implementing new authorities that include site visits, fingerprinting, and background checks, as well as an automated provider screening process. (OEI; 03-13-00050; expected issue date: FY 2016; ACA.)"14

Delivery System Reform

- **Use of electronic health records to support care coordination through ACOs**
  [OIG] "will review the extent to which providers participating in ACOs in the Medicare Shared Savings Program use electronic health records (EHRs) to exchange health information to achieve their care coordination goals. They will also assess providers’ use of EHRs to identify best practices and possible challenges to the exchange and use of health data, such as degree of interoperability, financial barriers, or information blocking. The Medicare Shared Savings Program promotes accountability of hospitals, physicians, and other providers for a patient population, coordinates items and services, and encourages investment in infrastructure and redesigned care processes for high-quality and efficient service delivery. (ACA, § 3022.) OEI; 00-00-00000; expected issue date: FY 2017; ACA)"15

- **NEW- Accountable Care Organizations: Strategies and Promising Practices**
  [OIG] "will review ACOs that participate in the Medicare Shared Savings Program (established by section 3022 of the Affordable Care Act). They will describe their performance on the quality measures and cost savings over the first three years of the program and describe the characteristics of those ACOs that performed well on measures and achieved savings. In addition, they will identify ACOs’ strategies for and challenges to achieving quality and cost savings. The Medicare Shared Savings Program is a key component of the Medicare delivery system reform initiatives and is a vehicle through which providers who work in ACOs can share in Medicare cost-savings while providing high-quality care to patients. (OEI; 02-15-00450; expected issue date: FY 2017; ACA)"16

Billing and Payments

- **NEW- Medicare payments for unlawfully present beneficiaries in the United States – mandated review**
  [OIG] "will review the procedures established by CMS to prevent and recoup Medicare payments for items and services furnished to unlawfully present beneficiaries in the United States. Pursuant to section 401 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, CMS’s Medicare Claims Processing Manual, Ch. 1, §10.1.4.8 states that Medicare payment may not be made for items and services furnished to alien beneficiaries who are not lawfully present in the United States. Section 502 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), enacted in April 2015, requires the Secretary of Health and Human Services to establish and maintain procedures to ensure that payment is not made for Medicare services rendered to individuals not lawfully present in the United States. Prior OIG review identified $91.6 million of improper payments"17

---

13 Ibid.
14 Ibid at page 25.
15 Ibid.
16 Ibid.
made to providers for services rendered to unlawfully present beneficiaries for CYs 2009 through 2011. OIG is required to submit to Congress a report on such activities established by CMS no later than 18 months after the date of the enactment (MACRA, §502(b).) (OAS; W-00-15-35625; various reviews; expected issue date: FY 2016; work in progress)"17

- **NEW- Medicare payments for incarcerated beneficiaries—mandated review**

  [OIG] “will review the procedures established by CMS to prevent and recoup Medicare payments for items and services furnished to incarcerated beneficiaries. Medicare, in general, does not pay for services rendered to incarcerated beneficiaries because they do not have a legal obligation to pay (Social Security Act, § 1862); however, the regulation does permit Medicare payment where an incarcerated beneficiary has an obligation for the cost of care. (42 CFR § 411.4.) Section 502 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), enacted in April 2015, requires the Secretary of Health and Human Services to establish and maintain procedures to ensure that Medicare does not pay for services rendered to incarcerated beneficiaries. Prior OIG review identified $33.6 million of improper payments made to providers for services rendered to incarcerated beneficiaries for CYs 2009 through 2011. OIG is required to submit to Congress a report on such activities established by CMS no later than 18 months after the date of the enactment (MACRA§502(b).) (OAS; W-00-15-35624; W-00-16-35624; various reviews; expected issue date: FY 2016; work in progress)"18

- **NEW- CMS management of the ICD-10 implementation**

  [OIG] “will review aspects of CMS’s early management of the implementation of the 10th version of the International Classification of Diseases (ICD-10) codes in Medicare Parts A and B. This may include reviewing CMS’s and its contractors’ (e.g., MACs) assistance and guidance to hospitals and physicians and assessing how the transition to ICD-10 is affecting claims processing, including claims resubmissions, appeals, and medical reviews. They may also determine how ICD-10 diagnosis codes are being applied to selected CMS payment rules and safeguards (e.g., national or local coverage decisions related to coverable conditions). Starting on October 1, 2015, Medicare claims with a date of service on or after October 1, 2015, are required to contain a valid ICD-10 code. The ICD-10 system includes about 70,000 diagnosis codes and replaces the use of ICD-9 in Medicare, which included only about 15,000 codes. CMS has advised providers that it will allow for some flexibility during the first 12 months of implementation; e.g., Medicare review contractors will not deny claims billed under the Part B physician fee schedule based solely on the specificity of the ICD-10 diagnosis code as long as the physician/practitioner used a code from the correct “family” of codes. (OEI; 00-00-00000; expected issue date: FY 2017).”19

**Medicaid Reviews**

OIG states that “[p]rotecting an expanding Medicaid program from fraud, waste, and abuse takes on a heightened urgency as the program continues to grow in spending and in the number of people it serves. Additional Medicaid work for FY 2016 and beyond may examine: new health care payment and delivery models; Medicaid managed care focusing on county operated MCOs; State financing mechanisms focusing on compliance with upper payment limits; drug diversion and abuse; and States’ lock-in programs that restrict beneficiaries to a limited number of pharmacies or prescribers to reduce prescription drug abuse. Going forward, OIG also expects to examine beneficiary access to, and program integrity of, mental and behavioral health services.”20

**Other Medicaid Services, Equipment and Supplies**

**State Program Integrity Activities and Compliance with Federal Requirements**

- **REVISED - State and CMS oversight of provider ownership information**

---

17 Ibid at page 26.
18 Ibid.
19 Ibid.
20 Ibid at page 31.
[OIG] “will determine the extent to which States collect required ownership information for provider entities enrolled in Medicare and Medicaid, and we will describe the extent to which they verify the collected information. They will also determine whether States and CMS checked exclusions databases for enrolling and enrolled providers, as required. Finally, they will compare the ownership information that selected providers gave to States to enroll in Medicaid, and that providers gave to CMS to enroll in Medicare, to the ownership information that the same providers gave to OIG for the purposes of this study. Federal regulations require Medicaid and Medicare providers to disclose ownership information, such as the name and address of each person and corporation with an ownership or controlling interest in the provider entity. (See e.g., 42 CFR § 455.104 and 42 CFR §420.206.) (OEI; 04-11-00590, 04-11-00591; expected issue date: FY 2016)²¹

• **REVISED-** States’ experiences with enhanced provider screening

[OIG] “will review whether States are conducting enhanced screenings that assess risk for fraud, waste, and abuse for moderate- and high-risk enrolling and revalidating Medicaid providers and suppliers. They will also determine extent to which States have screened moderate- and high-risk providers and suppliers using these risk-based screenings. The ACA, §6402, requires enhanced screening for providers and suppliers seeking initial enrollment, reenrollment, or revalidation in Medicare, Medicaid, and CHIP. States are responsible for employing screening and revalidation procedures for their Medicaid and CHIP providers. (OEI; 05-13-00520; expected issue date: FY 2016; ACA)”²²

• **REVISED-** Provider payment suspensions during pending investigations of credible fraud allegations

[OIG] “will review payments to providers with allegations of fraud deemed credible by States. They will also review States’ use of payment suspensions. FFP (Federal financial participation) in Medicaid is not available for items or services furnished by an individual or entity when the State has failed to suspend payments during a period when there is a credible allegation of fraud. (Social Security Act, §1903(i)(2), as amended by the ACA, §6402(h)(2).) Upon determinations that allegations of fraud are credible, States must suspend all Medicaid payments to the providers, unless the States have good cause to not suspend payments or to suspend payment only in part. (42 CFR §455.23(a).) States are required to make fraud referrals to Medicaid Fraud Control Units (MFCUs) or to appropriate law enforcement agencies in States with no certified MFCUs. (42 CFR § 455.23(d).) The OIG will determine whether select Medicaid State agencies are in compliance with these provisions. (OAS; W-00-14-31473; various reviews; expected issue date: FY 2016; and OEI; 09-14-00020; expected issue date: FY 2016; ACA)”²³

**Medicaid Information System Controls and Security Controls to Prevent Improper Medicaid Payments**

• **REVISED- National Correct Coding Initiative Edits and CMS Oversight**

[OIG] “will review selected States’ implementation of National Correct Coding initiative (NCCI) edits for Medicaid claims and describe CMS’s oversight of NCCI edits. The NCCI consists of coding policies and automatic computer edits. The NCCI’s original purpose was to promote correct coding of health care services provided to Medicare beneficiaries and to prevent payment for improperly coded services. Federal law required States to incorporate methodologies compatible with NCCI for Medicaid claims filed on or after October 1, 2010. (Social Security Act, § 1903(r), as amended by the ACA, §6507.) States were permitted to deactivate some or all NCCI edits because of conflicts with State laws, regulations, administrative rules, payment policies, and/or the States’ levels of operational readiness. (State Medicaid Director Letter #10-017.) As of April 1, 2011, lack of operational readiness was no longer a permissible basis for deactivation of the edits. (State Medicaid Director Letter #11-003.) After April 1, 2011, the only basis for deactivation is conflicts with State laws, regulations,
administrative rules, and/or payments policies. (OEI; 09-14-00440; expected issue date: FY 2016, ACA)\textsuperscript{24}

\section*{Medicaid Managed Care}

\subsection*{Program Integrity in Managed Care}

- **Medicaid managed care entities’ identification of fraud and abuse**
  
  [OIG] will determine whether Medicaid MCOs identified and addressed incidents of potential fraud and abuse. They will also describe how States oversee MCOs’ efforts to identify and address fraud and abuse. A prior OIG report revealed that over a quarter of the MCOs surveyed did not report a single case of suspected fraud and abuse to their State Medicaid agencies in 2009. The report also found that MCOs and States are taking steps to address fraud and abuse in managed care and they remain concerned about their prevalence. All MCOs are required to have processes to detect, correct, and prevent fraud, waste, and abuse. However, the Federal requirements surrounding these activities are general in nature (42 CFR §438.608), and MCOs vary widely in how they deter fraud, waste, and abuse. (OEI; 02-15-00260; expected issue date: FY 2017)\textsuperscript{25}

\section*{Legal and Investigative Activities Related to Medicare and Medicaid}

\subsection*{Legal Activities}

\textbf{Exclusions from Program Participation}

“OIG may exclude individuals and entities from participation in Medicare, Medicaid, and all other Federal health care programs for many reasons, some of which include program-related convictions, patient abuse or neglect convictions, licensing board disciplinary actions, or other actions that pose a risk to beneficiaries or programs. (Social Security Act, § 1128, § 1156, and other statutes.) Exclusions are generally based on referrals from Federal and State agencies. We work with these agencies to ensure the timely referral of convictions and licensing board and administrative actions. In FY 2014, OIG excluded 4,017 individuals and entities from participation in Federal health care programs. Searchable exclusion lists are available on OIG’s Web site at: \url{http://exclusions.oig.hhs.gov/} \textsuperscript{26}

\subsection*{Civil Monetary Penalties}

“OIG pursues CMP cases, when supported by appropriate evidence, on the basis of the submission of false or fraudulent claims; the offer, payment, solicitation, or receipt of remuneration (kickbacks) in violation of the Social Security Act, §1128B(b); violations of the Emergency Medical Treatment and Labor Act of 1986; items and services furnished to patients of a quality that fails to meet professionally recognized standards of health care; and other conduct actionable under the Social Security Act, §1128A, or other CMP authorities delegated to OIG.”\textsuperscript{27}

\subsection*{False Claims Act Cases and Corporate Integrity Agreements}

“When adequate evidence of violations exists, OIG staff work closely with prosecutors from the Department of Justice (DOJ) to develop and pursue Federal false claims cases against individuals and entities that defraud the Government. Authorities relevant to this work come from the False Claims Amendments Act of 1986 and the Fraud Enforcement and Recovery Act of 2009. We assist DOJ prosecutors in litigation and settlement negotiations arising from these cases. We also consider whether to invoke our exclusion authority on the basis of the defendants’ conduct. When appropriate and

\textsuperscript{24} Ibid at page 41.  
\textsuperscript{25} Ibid at page 43.  
\textsuperscript{26} Ibid at page 45.  
\textsuperscript{27} Ibid at page 46.
necessary, we require defendants to implement CIAs aimed at ensuring compliance with Federal health care program requirements.”

Providers’ Compliance with Corporate Integrity Agreements
“OIG often negotiates compliance obligations with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. Subsequently, OIG assesses providers’ compliance with the terms of the CIAs. For example, we conduct site visits to entities that are subject to CIAs to verify compliance, to confirm information submitted to us by the entities, and to assess the providers’ compliance programs. We review a variety of types of information submitted by providers to determine whether their compliance mechanisms are appropriate and identify problems and establish a basis for corrective action. When warranted, we impose sanctions, in the form of stipulated penalties or exclusions, on providers that breach CIA obligations. Current CIAs and other integrity agreements are listed on OIG’s Web site at: http://oig.hhs.gov/fraud/cia/cia_list.asp

Advisory Opinions and Other Industry Guidance
“To foster compliance by providers and industry groups, OIG responds to requests for formal advisory opinions on applying the anti-kickback statute and other fraud and abuse statutes to specific business arrangements or practices. Advisory opinions provide meaningful guidance on statutes in specific factual situations. We also issue special fraud alerts and advisory bulletins about practices that we determine are suspect and compliance program guidance for specific areas. Examples are available on OIG’s Web site at:

- Advisory Opinions: http://oig.hhs.gov/fraud/advisoryopinions.asp
- Fraud Alerts: http://oig.hhs.gov/compliance/alerts/index.asp
- Compliance Guidance: http://oig.hhs.gov/fraud/complianceguidance.asp
- Open Letters: http://oig.hhs.gov/fraud/openletters.asp
- Other Guidance: http://oig.hhs.gov/compliance/alerts/guidance/index.asp

Provider Self-Disclosure
“OIG is committed to assisting health care providers and suppliers in detecting and preventing fraud and abuse. Since 1998, we have made available comprehensive guidelines describing the process for providers to voluntarily submit self-disclosures to OIG of fraud, waste, or abuse. The Provider Self-Disclosure Protocol gives providers an opportunity to minimize the potential costs and disruption that a full-scale OIG audit or investigation might entail if fraud is uncovered. The self-disclosure also enables the provider to negotiate a fair monetary settlement and potentially avoid being excluded from participation in Federal health care programs.

The protocol guides providers and suppliers through the process of structuring a disclosure to OIG about matters that constitute potential violations of Federal laws (as opposed to honest mistakes that may have resulted in being overpaid by a Federal program). The provider or supplier is expected to thoroughly investigate the nature and cause of the matters uncovered and make a reliable assessment of their economic impact (e.g., an estimate of the losses to Federal health care programs). OIG evaluates the reported results of each internal investigation to determine the appropriate course of action. The self-disclosure guidelines are available on the OIG Web site at:

- http://oig.hhs.gov/fraud/selfdisclosure.asp

On April 17, 2013, OIG updated its Provider Self-Disclosure Protocol, which is available at:


---

28 Ibid.
29 Ibid.
30 Ibid.
31 Ibid at page 47.
Investigative Activities

"OIG investigates allegations of fraud, waste, and abuse in all of the Department’s programs. Our largest body of work involves investigating matters related to Medicare and Medicaid. This can include billing for services not rendered, medically unnecessary and misrepresented services, and patient harm. OIG’s work also includes the illegal billing, sale, diversion, and off-label marketing of prescription drugs; and solicitation and receipt of kickbacks, including illegal payments to patients for involvement in the fraud scheme and illegal referral arrangements between physicians and medical companies.

Specific case types include health care fraud schemes related to:
- controlled and noncontrolled prescription drugs;
- home health agencies, personal care, and home and community based services;
- ambulance transportation;
- durable medical equipment; and
- diagnostic radiology and laboratory testing.

OIG also conducts investigations involving organized criminal activity, including medical identity theft and fraudulent medical schemes established for the sole purpose of stealing Medicare dollars. Investigators are seeing an increase in individuals, including both health care providers and patients, engaging in these health care fraud schemes. Those who participate in these schemes may face heavy fines, jail time, and exclusion from participating in Federal health care programs.

In addition to investigating Medicare and Medicaid fraud, OIG investigates fraud, waste, and abuse in other HHS operating divisions, including the Administration for Children and Families, the Administration for Community Living, Health Resources and Services Administration, and Indian Health Service. OIG also investigates potential misuse of grants and contracts funds awarded by the Centers for Disease Control and Prevention, National Institutes of Health, the Substance Abuse and Mental Health Services Administration, and other HHS agencies (HHS is the largest grant-making organization and one of the largest contracting agencies in the Federal Government). Under certain circumstances, OIG investigates noncustodial parents who fail to pay court-ordered child support. Additionally, OIG investigates allegations of employee misconduct, whistleblower reprisals, and wrongdoing by HHS agency officials.

OIG conducts joint investigations with other investigative agencies when investigative authorities overlap Federal, State, or local statutes. OIG works with the FBI, U.S. Attorneys’ Offices, State agencies, such as MFCUs, and the State police. OIG may also work with local investigative agencies, such as a county sheriff’s office or a municipal police department and program integrity partners, including the CMS Center for Program Integrity and associated Medicare contractors.

In addition to collaboration with law enforcement and program integrity partners, OIG engages with external stakeholders to enhance the relevance and impact of our work to combat health care fraud, as demonstrated by our leadership in the Healthcare Fraud Prevention Partnership (HFPP) and our association with the National Health Care Anti-Fraud Association (NHCAA).

The HFPP is a groundbreaking partnership between the Federal and private sectors to share data and information for the purposes of detecting and combating fraud, waste, and abuse in health care. The HFPP was created as a voluntary public-private partnership, between the Federal Government, State officials, private health insurance organizations, and health care antifraud associations. The NHCAA is the leading national nonprofit organization focused exclusively on combating health care fraud and abuse. The NHCAA mission is to protect and serve the public interest by increasing awareness and improving the detection, investigation, civil and criminal prosecution, and prevention of health care fraud and abuse. Both organizations are engaged in efforts to combat the problem of health care fraud.

Each year, thousands of complaints from various sources are brought to OIG’s attention for review, investigation, and resolution. The nature and volume of complaints and priority of issues vary from year to year. We describe some of the more significant investigative outcomes in OIG’s Semiannual Report(s) to Congress, which are available on our Web site at:
Medicare Fraud Strike Force Teams

“In 2009, HHS and DOJ partnered to establish the Health Care Fraud Prevention and Enforcement Action Team (HEAT). This initiative was created to strengthen programs and invest in new resources and technologies to prevent and combat health care fraud, waste, and abuse.

Using a collaborative model, Medicare Fraud Strike Force teams coordinate law enforcement operations among Federal, State, and local law enforcement entities. Medicare Fraud Strike Force Teams harness data analytics and the combined resources of Federal, State, and local law enforcement entities to prevent and combat health care fraud, waste, and abuse. First established in March 2007, Strike Force teams operate in nine areas: Miami, Florida; Los Angeles, California; Detroit, Michigan; southern Texas; Brooklyn, New York; southern Louisiana; Tampa, Florida; Chicago, Illinois; and Dallas, Texas.

These teams have a proven record of success in analyzing data and investigative intelligence to quickly identify fraud and bring prosecutions. The interagency collaboration also enhances the effectiveness of the Strike Force model. For example, OIG refers credible allegations of fraud to the Centers for Medicare & Medicaid Services (CMS) so that it can suspend payments to the suspected perpetrators, thereby immediately preventing losses from claims submitted by Strike Force targets.

Strike Force teams have shut down health care fraud schemes around the country, arrested more than a thousand criminals, and recovered millions of taxpayer dollars.

Highlights of recent enforcement actions to which OIG has contributed are posted to OIG’s Web site at http://oig.hhs.gov/fraud/enforcement/index.asp.”

The information contained herein is deemed accurate, but its accuracy is not guaranteed or warranted by McKesson Business Performance Services (BPS). The materials contained herein have been abridged from the statutory sources and should not be construed or relied upon for legal advice. Readers are urged to consult legal counsel concerning particular situations and specific legal questions.

To ensure compliance with requirements imposed by the IRS, we inform you that this message is not intended to be used, and cannot be used, by the addressee or any other person for the purpose of avoiding penalties that may be imposed under the Internal Revenue Code.

32 Ibid at page 48.
33 Ibid at page 49.