The Business Management Services business unit is one of several business units within McKesson Technology Solutions. We refer to ourselves as “BPS” or “Business Performance Services” for internal communications and certain external communications, such as media releases. PST Services, Inc. is the legal entity BPS uses with contracts with its clients or third party vendors.)
Office of Inspector General (OIG) FY2015 Work Plan
Specialty: Radiology

FY 2016 Work Plan Introduction
This review of the Office of Inspector General (OIG) CY 2016 Work Plan will provide the various section(s) that were identified by the OIG that may affect the specialty of Radiology. 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 states that the purpose of the Work Plan is in part to provide brief descriptions of the activities the OIG intends to either initiate in FY 2016 or intends to continue from previous years as it exercises its oversight authority. The Work Plan is at its heart an allocation of resources to combat waste, fraud and abuse. How successful is the OIG in combating waste, fraud, and abuse? They reported for FY 2015 expected recoveries of more than $3 billion — $2.22 billion in investigative work and $1.13 billion in audit work. ¹ Also reported for FY 2015 were 4,112 individuals excluded from participating in Federal healthcare programs, along with 925 criminal cases and 682 civil cases related to criminal activities, false claims and unjust-enrichment lawsuits.²

This summary is presented in three sections:

1. Medicare Parts A and B
2. Medicaid
3. CMS Related Legal and Investigative Activities

Under each section we provide the projects, as written by the OIG, that we believe to be of interest. Text emphasis was added to bring attention to the reason why the project was added. Some projects included are the OIG’s oversight of CMS, Medicare Administrative Contractors (MACs) and Medicare Advantage. These are included because it is expected they may be a catalyst for additional physician oversight from these entities. We encourage a review of the entire Work Plan. To view the complete Work Plan, click here.

No status reports or progress notes will be provided, however periodic updates are made to the Work Plan and will be available at www.oig.hhs.gov.

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¹ Introductory Message from the Office of Inspector General, Work Plan Fiscal Year 2016. OIG, Department of Health and Human Services.
² Ibid.
Medicare Part A and Part B

We are all aware of the OIG’s efforts to ensure procedures are medically necessary. However, the OIG’s goal of reducing fraud, waste, and abuse goes further and also includes improving the quality of care and patient safety.

• **REVISED Medicare oversight of provider-based status**
  
  “We will determine the number of provider-based facilities that hospitals own and the extent to which CMS has methods to oversee provider-based billing. We 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 freestanding clinics**
  
  “We will review and compare Medicare payments for physician offices 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)”

• **Intensity-modulated radiation therapy**
  
  “We will review Medicare outpatient payments for intensity-modulated radiation therapy (IMRT) to determine whether the payments were made in accordance with Federal rules and regulations. IMRT is an advanced mode of high-precision radiotherapy that uses computer-controlled linear accelerators to deliver precise radiation doses to a malignant tumor or specific areas within the tumor. Prior OIG reviews have identified hospitals that have incorrectly billed for IMRT services. To be processed correctly and promptly, a bill must be completed accurately. (CMS’s Medicare Claims Processing Manual, Pub. No. 100-04, Ch. 1 § 80.3.2.2.) In addition, certain services should not be billed when they are performed as part of developing an IMRT plan. (CMS’s Medicare Claims Processing Manual, Pub. No. 100-04, Ch. 4 § 200.3.2) (OAS; W-00-15-35740; various reviews; expected issue date: FY 2016)”

• **Hospitals' electronic health record system contingency plans**
  
  “We will determine the extent to which hospitals comply with contingency planning requirements of the Health Insurance Portability and Accountability Act (HIPAA). We will also compare hospitals’ contingency plans with government- and industry-recommended practices. The HIPAA Security Rule requires covered entities to have a contingency plan that establishes policies and procedures for responding to an emergency or other occurrence that damages systems that contain protected health information (45 CFR, Par 164 § 308(7)(i)). (OEI; 01-14-00570; expected issue date: FY 2016)”

• **Ambulatory surgical centers – payment systems**
  
  “We will review the appropriateness of Medicare’s methodology for setting ambulatory surgical center (ASC) payment rates under the revised payment system. We 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

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4 Ibid at page 7.
5 Ibid at page 9.
6 Ibid at page 10.
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

- **Imaging services – payments for practice expenses**
  “We will review Medicare Part B payments for imaging services to determine whether they reflect the expenses incurred and whether the utilization rates reflect industry practices. For selected imaging services, we will focus on the practice expense components, including the equipment utilization rate. Practice expenses may include office rent, wages, and equipment. Physicians are paid for services pursuant to the Medicare physician fee schedule, which covers the major categories of costs, including the physician professional cost component, malpractice insurance costs, and practice expense. (Social Security Act, § 1848(c)(1)(B).) (OAS; W-00-13-35219; W-00-14-35219; W-00-15-35219; various reviews; expected issue date: FY 2016)”8

- **Portable x-ray equipment – supplier compliance with transportation and setup fee requirements**
  “We will review Medicare payments for portable x-ray equipment services to determine whether payments were correct and were supported by documentation. We will also assess the qualifications of the technologist who performed the services. Prior OIG work found that Medicare may have improperly paid portable x-ray suppliers for return trips to nursing facilities (i.e., multiple trips to a facility in 1 day). Medicare generally reimburses for portable x-ray services if the conditions for coverage are met. (42 CFR §§ 486.100-486.110.) (OAS; W-00-15-35464; various reviews; expected issue date: FY 2016)”9

- **NEW Physicians-referring/ordering Medicare services and supplies**
  “We 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 non-physician 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: FY2016, ACA)”10

- **Comparison of average sales prices to average manufacturer prices**
  “We will review Medicare Part B drug prices by comparing average sales prices (ASP) to average manufacturer prices (AMP) and identify drug prices that exceed a designated threshold. In 2005, Medicare began paying for most Part B drugs using a new methodology based on the ASP. The enabling law required that OIG compare ASPs with AMPs. (Social Security Act, § 1847A(d)(2)(B).) Pursuant to the requirement, OIG conducts such reviews and issues quarterly and annual reports of its findings. When OIG finds that the ASP for a drug exceeds the AMP by a certain percentage (5 percent), OIG notifies the Secretary, who may disregard the ASP for the drug when setting reimbursement amounts (e.g., apply a price substitution policy). (OEI; various studies; expected issue date: FY 2016)”11

- **Enhances enrollment screening process for Medicare providers**
  “We 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. We 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

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7 Ibid at page 16.
8 Ibid at page 18.
9 Ibid at page 19.
10 Ibid at page 20.
11 Ibid at page 21.
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)\(^{12}\)

- **NEW Accountable Care Organizations: strategies and promising practices**
  “We will review ACOs that participate in the Medicare Shared Savings Program (established by section 3022 of the Affordable Care Act). We 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, we will identify ACO’s 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)\(^{13}\)

- **NEW CMS Management of the ICD-10 implementation**
  “We will review aspects of CMS’s early management of the implementation of the 10\(^{th}\) 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 resubmission, appeals, and medical reviews. We 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).\(^{14}\)

- **REVISED National Correct Coding Initiative edits and CMS oversight**
  “We 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)\(^{15}\)

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**CMS-Related Legal and Investigative Activities**

\(^{12}\) Ibid at page 25.
\(^{13}\) Ibid at page 25.
\(^{14}\) Ibid at page 27.
\(^{15}\) Ibid at page 41.
OIG healthcare fraud cases can result in program exclusions and civil monetary penalties. They also monitor Corporate Integrity Agreements (CIA) and issue fraud alerts, advisory bulletins and advisory opinions.

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 FY2014, 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: http://exclusions.oig.hhs.gov/”

Civil Monetary Penalties (CMP)
“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 HHS OIG Work Plan FY2016 CMS-Related Legal and Investigative Activities recognized standards of health care; and other conduct actionable under the Social Security Act, §1128A, or other CMP authorities delegated to OIG.”

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 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

16 Ibid at page 45.
17 Ibid.
18 Ibid at page 46.
19 Ibid.
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](http://oig.hhs.gov/fraud/advisoryopinions.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](http://oig.hhs.gov/fraud/selfdisclosure.asp)

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


Investigative Activities

The majority of the work/investigations are related to fraud, waste, and abuse . . . related to Medicare and Medicaid program. The allegations include, but are not limited to, billing for services not rendered and services not being medically necessary. Their work also includes solicitation and receipt of kickbacks, also including patients in fraud schemes in which illegal payments are made to patients. There are several specific case types, but for this audience, the one of importance is diagnostic radiology testing.

Part of the OIG’s investigations focus around those scheming solely for the purpose of stealing Medicare dollars. There is a rise of health care providers and patients involved in these fraud schemes.

The OIG is tasked each year with the review, investigation and resolution of thousands of complaints related not only to Medicare and Medicaid fraud, but [fraud, waste and abuse] in other Health and Human Services (HHS) divisions. Depending on the investigation and overlap of other federal, state or local agencies, the OIG will partner with other investigative agencies to complete an investigation. If need be they will also work with local, city, and county officials. Some of the most significant cases can be viewed at: [http://oig.hhs.gov/publications.asp](http://oig.hhs.gov/publications.asp).

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20 Ibid.
21 Ibid at page 47.
22 Ibid.
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