Key Highlights of the Fiscal Year 2016 OIG Work Plan

INTRODUCTION

On November 2, 2015, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) released its annual Work Plan for Fiscal Year (FY) 2016. The 2016 Work Plan sets forth planned audits and evaluations with indicators for whether the work was in progress at the start of FY 2016, revised for FY 2016, or represents a new project to be implemented in FY 2016 and beyond.

Review of the FY 2016 Work Plan reveals a significant overlap in the OIG's audits and evaluations for FY 2016 and FY 2015. However, the FY 2016 Work Plan also sets forth a number of new focus areas including: medical device credits; physician referrals and orders of Medicare services and supplies; the Centers for Medicare & Medicaid Services (CMS) management of the ICD-10 implementation; and Medicaid specialty drug pricing and reimbursement. The Work Plan also identifies several areas that have been revised since FY 2015 including: hospice general inpatient care; covered uses for Medicare Part B drugs; review of financial interests reported under the Open Payments Program; and CMS oversight of States' Medicaid information systems security controls.

The OIG directs a vast majority of its resources toward safeguarding the integrity of the Medicare and Medicaid programs. This brief highlights select new and revised OIG reviews that impact Medicare and Medicaid providers and suppliers. This brief also identifies reviews with expected issue dates beyond FY 2016. Strategic Management selected reviews based on current client practice areas, high risk areas, and new initiatives. The OIG Office of Audit Services (OAS) or the OIG Office of Evaluation and Inspection (OEI) perform the reviews noted below. Health care providers and organizations may use the FY 2016 OIG Work Plan to identify corporate compliance risks, prioritize audit focus areas, and facilitate compliance program activities.

MEDICARE PART A AND PART B

Hospitals

Medicare Oversight of Provider-Based Status (Revised) – Provider-based status allows hospital-owned and operated facilities to bill as hospital outpatient departments. The higher Medicare payments for services furnished at provider-based facilities may increase beneficiaries' coinsurance liabilities. The Medicare Payment Advisory Commission has expressed concerns regarding the financial incentives related to provider-based status and stated that Medicare should seek to pay similar amounts for similar services. The OEI will determine the number of provider-based facilities that hospitals own and evaluate CMS's provider-based billing oversight methods. The OEI will further determine whether provider-based

facilities meet regulatory requirements[1] and whether any challenges surround the provider-based attestation review process.

Medical Device Credits for Replaced Medical Devices (New) – Medical devices implanted during inpatient or outpatient procedures may require replacement due to defects, recalls, or other complications. Federal regulations[2] require reducing Medicare payments for the replacement of implanted devices. Prior OIG reviews have determined that Medicare Administrative Contractors (MACs) have made improper payments to hospitals for inpatient and outpatient claims for replaced medical devices. The OAS will determine whether Medicare payments for replaced medical devices followed Medicare requirements.

Medicare Payments during MS-DRG Payment Window (New) – The OIG has determined that Medicare payments to acute care hospitals are at risk for noncompliance with Medicare billing requirements. Certain items, supplies, and services furnished to inpatients are erroneously billed to Part B rather than Part A. The OAS will review such payments to determine whether the claims billed to Part B for services provided during inpatient stays were allowable according to the inpatient prospective payment system.

CMS Validation of Hospital-Submitted Quality Reporting Data (New) – CMS relies on validated hospital inpatient quality reporting data to maintain completeness and accuracy in the hospital value-based purchasing program and the hospital acquired condition reduction program. The OEI will determine the extent to which CMS validated inpatient quality reporting data and describe the actions that CMS has taken as a result of its validation.

Nursing Homes

Skilled Nursing Facility Prospective Payment System Requirements (New) – Skilled Nursing Facility (SNF) documentation must include: (1) a physician order at the time of admission for the resident's immediate care; (2) a comprehensive assessment; and (3) a comprehensive plan of care prepared by an interdisciplinary team that includes the attending physician, a registered nurse, and other appropriate staff.[3] Prior OIG reviews have found that Medicare payments for therapy greatly exceeded SNFs' costs for therapy, and that SNFs have increasingly billed for the highest level of therapy despite a lack of change in beneficiary characteristics. Further, the OIG has previously identified areas at risk for noncompliance with SNF Medicare billing requirements. The OAS will review compliance with various aspects of the SNF prospective payment system, including the documentation requirements, to determine whether SNF claims were paid in accordance with federal laws and regulations.

[1] 42 C.F.R. § 413.65 (2011); The Centers for Medicare & Medicaid Services. "Provider-based Status On or After October 1, 2002." Transmittal A-03-030. 18 Apr. 2003.
[2] 42 C.F.R. § 412.89 (2010); 42 C.F.R. § 419.45 (2007).
[3] 42 C.F.R. § 483.20 (2011).

Hospices

Hospice General Inpatient Care (Revised) – When a beneficiary elects hospice care, the hospice agency is responsible for medical care associated with a beneficiary's terminal illness and related conditions. Beneficiaries may revoke their election of hospice care and return to standard Medicare coverage at any time.[4] The OEI will evaluate the appropriateness of hospice general inpatient care claims and the content of election statements for hospice beneficiaries who receive general inpatient care. Additionally, the OEI will review beneficiaries' plans of care to determine whether they meet key requirements.

Medical Equipment and Supplies

Orthotic Braces—Reasonableness of Medicare Payments Compared to Amounts Paid by Other Payers (New) – The OAS will compare Medicare payments and non-Medicare amounts paid for orthotic braces to determine whether the Medicare fee schedule amounts are reasonable and to identify potentially wasteful spending. Additionally, the OAS will calculate the financial impact on Medicare and on beneficiaries of aligning the fee schedule for orthotic braces with those of non-Medicare payers.

Orthotic Braces—Supplier Compliance with Payment Requirements (New) – Prior OIG findings indicate that some durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers billed Medicare for medically unnecessary or improperly documented services. In some instances, a beneficiary received multiple braces even when the physician did not see the beneficiary. Medicare requires that such items be "reasonable and necessary." In addition, Medicare contractors issue local coverage determinations that include utilization guidelines and documentation requirements for orthotic braces. The OAS will review Medicare Part B payments to determine whether DMEPOS suppliers' claims were medically necessary and adhered to Medicare documentation requirements.

Increased Billing for Ventilators (New) – CMS and its contractors have expressed concerns regarding the increase in billing for ventilators, specifically HCPCS code E0464. Suppliers may be inappropriately billing for ventilators for beneficiaries with non-life threatening conditions, which should instead be billed to codes for Respiratory Assist Devices (RAD) or Continuous Positive Airway Pressure (CPAP) devices. Ventilators are covered for severe conditions associated with neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.[5] They are not reasonable and necessary to treat any of the conditions described in the LCDs for either CPAPs or RADs. The OEI will describe billing trends for ventilators, RAD, and CPAPs and examine factors associated with the increase in ventilator claims. The OEI will also examine the impact of the Competitive Bidding Program on ventilator billing trends.

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[4] 42 C.F.R. § 418.28 (2014).

[5] The Centers for Medicare & Medicaid Services, *National Coverage Determinations Manual*, Pub. 100-03, ch. 1, § 280.1.

Other Providers and Suppliers

Ambulatory Surgical Centers—Quality Oversight (New) – CMS requires that ambulatory surgical centers (ASCs) become Medicare-certified or privately accredited to ensure that they meet Medicare's conditions of coverage, which establish minimum health and safety requirements. The OIG has identified problems with Medicare oversight of ASC certification surveys, State survey agencies, and ASC accreditors. Further, minimal information regarding the quality of ASCs is available to the public. The OEI will review Medicare's quality oversight of ASCs. The OEI expects to issue a report on this initiative in FY 2017.

Physicians—Referring/Ordering Medicare Services and Supplies (New) – Physicians and non-physician practitioners who order certain services, supplies, and durable medical equipment (DME) must be enrolled in Medicare and legally eligible to refer/order services, supplies and DME.[6] Medicare should not pay claims for services, supplies, and DME ordered by ineligible referring/ordering physicians and non-physician practitioners. The OAS will review select Medicare services, supplies, and DME to determine whether the payments complied with Medicare requirements.

Anesthesia Services—Non-Covered Services (New) – Medicare will only cover anesthesia services that are "reasonable and necessary." The OAS will review Medicare Part B claims for anesthesia services to determine whether they were supported in accordance with Medicare requirements. Specifically, the OAS will assess whether beneficiaries receiving anesthesia services had a related Medicare service.

Physician Home Visits—Reasonableness of Services (New) – Since January 2013, Medicare has paid $559 million for physician home visits. Physicians must document the medical necessity of a home visit in lieu of an office or outpatient visit. The OAS will determine whether Medicare payments to physicians for evaluation and management home visits were reasonable and adhered to Medicare requirements.

Prolonged Services—Reasonableness of Services (New) – Prolonged services are for additional care provided to a beneficiary after an evaluation and management (E/M) service has been performed. Physicians must submit claims for prolonged services when they spend additional time for a standard companion E/M service. Prolonged services are rarely necessary, and therefore must meet certain billing requirements.[7] The OAS will determine whether Medicare payments to physicians for prolonged E/M services were reasonable and made in accordance with Medicare requirements.

Histocompatibility Laboratories—Supplier Compliance with Payment Requirements (New) – From March 2013 to September 2014, histocompatibility laboratories reported $131 million in reimbursable costs. Because histocompatibility laboratories are reimbursed on the basis of reasonable costs, cost reports must claim costs that are (1) related to the care of beneficiaries; (2) reasonable, necessary, and proper; and (3) accurate and in sufficient detail to support payments made for services provided. The

[6] The Patient Protection and Affordable Care Act, Pub. Law No. 111-148, § 6405 (2010).
[7] The Centers for Medicare & Medicaid Services, *Medicare Claims Processing Manual*, Pub. 100-04, ch. 12, § 30.6.15.1.

OAS will determine whether payments to histocompatibility laboratories were made in accordance with Medicare requirements.

Part B Payments for Drugs Purchased under the 340B Program (Revised) – The 340B Drug Discount Program allows eligible providers (typically those serving a disproportionate share of needy patients) to purchase prescription drugs at discounted prices while charging paying patients and insurers full price. Under the Program and Part B payment rules, the eligible provider fully retains the difference between the amount Medicare pays and the cost to acquire the drugs. The OIG previously discovered that some Medicare payments to eligible providers substantially exceeded the providers' costs. Additionally, policymakers have questioned whether a portion of these savings should instead be distributed to Medicare and its beneficiaries. The OEI will determine the financial impact on 340B-covered entities, the Medicare program, and Medicaid beneficiaries of three different shared savings arrangements. The OEI will further calculate the amount by which the average sales price-payments exceed 340B prices.

Covered Uses for Medicare Part B Drugs (Revised) – Medicare Part B generally covers "on-label" uses of drugs that treat Food and Drug Administration (FDA)-approved conditions, but may also cover "off-label" uses when they are supported in major drug compendia or by clinical evidence in authoritative medical literature. However, if Part B MACs do not have effective oversight mechanisms, Medicare and its beneficiaries may pay for drug uses that are not medically accepted. The OEI will review CMS's and its claims processing contractors' oversight actions to ensure that payments for Part B drugs meet the appropriate coverage criteria. Additionally, the OEI will identify the challenges that contractors face when making coverage decisions for drugs.

Medicare Part A and Part B Contractors

Medicare Benefit Integrity Contractors' Activities in 2012 and 2013: A Data Compendium (Revised) – CMS contracts with entities to carry out benefit integrity activities, such as 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. Benefit integrity activity contractors include Program Safeguard Contractors (PSCs), Zone Program Integrity Contractors (ZPICs), and Medicare Drug Integrity Contractors (MEDICs). The OEI will review and report the level of benefit integrity activity that these contractors performed in calendar years 2012 and 2013, highlighting trends in integrity activities and allow for a quick comparison of program results across years, contractors, and parts of the Medicare program.

Medicare Contractor Information Systems Security Programs—Annual Report to Congress (Revised) – Federal law requires OIG to assess independent evaluations of MAC information systems security programs and report the results to Congress. The OAS will review the independent evaluations, report to Congress on its assessment of the scope and sufficiency of the evaluations, and summarize evaluation results.

Other Part A and Part B Management and Systems Issues

Accountable Care Organizations: Strategies and Promising Practices (New) – The Medicare Shared Savings Program is a key component of the Medicare delivery system reform initiatives and allows providers working in Accountable Care Organizations (ACOs) to share in Medicare cost-savings while providing high quality care. The OEI will review ACOs that participate in the Medicare Shared Savings Program.[8] The OEI will describe ACO performance on the quality measures and cost savings under the first three years of the program and describe the characteristics of the ACOs that performed well. Additionally, the OEI will identify ACOs' strategies for and challenges to achieving quality and cost savings. The OEI expects to issue a report on this initiative in FY 2017.

Medicare Payments for Unlawfully Present Beneficiaries in the United States—Mandated Review (New) – In previous years, the OIG has identified $91.6 million of improper payments made to providers for services rendered to unlawfully present beneficiaries for calendar years 2009 through 2011. Medicare payments may not be made for items and services furnished to alien beneficiaries who are not lawfully present in the United States.[9] The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires the HHS Secretary to establish and maintain procedures to ensure that Medicare does not pay for services rendered to individuals not lawfully present in the United States. MACRA also requires OIG to submit a report to Congress on CMS's activities to prevent and recoup these payments no later than 18 months after the date of enactment.[10] The OAS will review the procedures established by CMS to prevent such improper payments.

CMS Management of the ICD-10 Implementation (New) – As of October 1, 2015, Medicare claims with a date of service on or after October 1, 2015 must contain a valid ICD-10 code. CMS will permit some flexibility to providers during the first 12 months of implementation, such as allowing claims billed under the Part B physician fee schedule as long as the physician or practitioner used a code from the correct "family." The OEI will review CMS's early management of ICD-10 implementation in Medicare Parts A and B. The OEI may also review CMS and MAC assistance and guidance to hospitals and physicians in assessing how the ICD-10 transition affects claims processing, and determine how ICD-10 diagnosis codes are being applied to selected CMS payment rules and safeguards. The OEI expects to issue a report on this initiative in FY 2017.

MEDICARE PART C AND PART D

Part C (Medicare Advantage)

Medicare Advantage Encounter Data—CMS Oversight of Data Integrity (Revised) – Prior CMS and OIG audits reveal vulnerabilities in the accuracy of risk adjustment data reporting by Medicare Advantage organizations (MAOs). Realizing the potential benefits of MAO encounter data for payment and

[8] The Patient Protection and Affordable Care Act, Pub. Law No. 111-148, § 3022 (2010).
[9] The Personal Responsibility and Work Opportunity Reconciliation Act, Pub. Law No. 104-193, § 401 (1996); The Centers for Medicare & Medicaid Services, *Medicare Claims Processing Manual*, Pub. 100-04, ch. 1, § 10.1.4.8.
[10] Medicare Access and CHIP Reauthorization Act, Pub. Law No. 114-10, § 502(b) (2015).

program integrity is contingent upon the data's completeness, validity, and timeliness. The OEI will review the extent to which CMS's Integrated Data Repository contains complete, timely, and valid MAO encounter data. The OEI expects to issue a report on this initiative in FY 2017.

Medicare Advantage Organization Practices in Puerto Rico (New) – MAOs may select which providers offer benefits under the plan as long as: (1) the MAO makes such benefits available and accessible to each individual electing the plan within the plan service area; and (2) uses reasonable promptness and continuity in the provision of benefits. MAOs provide access to appropriate providers, including credentialed specialists for medically necessary treatment and services. MAOs must disclose the plan's service area and the number, mix, and distribution of plan providers to each plan enrollee at enrollment and at least annually thereafter in a clear, accurate, standardized form. The OAS will determine whether MAO provider networks in Puerto Rico were established in accordance with federal requirements, and whether MAO beneficiaries have access to appropriate medical care. The OAS will further determine whether providers in the network complied with Federal, State, and local credentialing requirements.

Part D (Prescription Drug Program)

Review of Financial Interests Reported under the Open Payments Program (Revised) – Under the Affordable Care Act (ACA), manufacturers must disclose payments made to physicians and teaching hospitals to CMS.[11] Further, manufacturers and group purchasing organizations (GPOs) must report ownership and investment interests held by physicians. The Open Payments Program provides public transparency regarding provider-industry relationships, which allows consumers to make educated decisions about their health care choices. The OEI will determine the number and nature of financial interests reported to CMS under the Open Payments Program. The OEI will also assess CMS oversight of manufacturer and GPO compliance with data reporting requirements and whether the required payment data are valid.

MEDICAID

State Management of Medicaid

State and CMS Oversight of Provider Ownership Information (Revised) – 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.[12] The OEI will evaluate how States collect required ownership information for Medicare and Medicaid-enrolled providers, and describe the extent to which they verify the information collected. The OEI will also determine whether States and CMS checked exclusions databases for enrolling and enrolled providers. Lastly, the OEI will compare the ownership information that providers sent to enroll in Medicare and Medicaid against the ownership information that providers gave to OIG.

[11] The Patient Protection and Affordable Care Act, Pub. Law No. 111-148, § 6002 (2010).
[12] 42 C.F.R. § 455.104 (2007); 42 C.F.R. § 420.206 (2012).

States' Experiences with Enhanced Provider Screening (Revised) – The ACA requires enhanced screening for providers and suppliers seeking initial enrollment, reenrollment, or revalidation in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).[13] The OEI will review States' use of enhanced screenings for moderate- and high-risk enrolling and revalidating Medicaid providers and suppliers, and determine the States' ability to screen moderate- and high-risk providers and suppliers using these screenings.

Provider Payment Suspensions during Pending Investigations of Credible Fraud Allegations (Revised) – Federal financial participation in Medicaid is not available when the State has failed to suspend payment for items or services furnished pursuant to a credible allegation of fraud.[14] States must suspend all Medicaid payments to providers upon discovering that allegations of fraud are credible, unless there is good cause not to suspend or to suspend only in part. States are also required to refer fraudulent activity to Medicaid Fraud Control Units (MFCUs) or law enforcement agencies in States without MFCUs.[15] The OAS will determine whether select Medicaid State agencies are complying with these provisions by reviewing payments to providers with credible fraud allegations against them. The OAS will also review States' use of payment suspensions to determine whether select Medicaid State agencies are in compliance with the requirements.

Medicaid Information System Controls and Security

CMS Oversight of States' Medicaid Information Systems Security Controls (Revised) – Prior OIG audits have shown that States lack sufficient security features, potentially exposing Medicaid beneficiary health information to unauthorized access. Despite federal requirements for information system security, States have not consistently applied, and CMS has not adequately monitored, system controls for Medicaid data and transactions. The OAS will evaluate CMS oversight of States' Medicaid system and information security controls including the policies, technical assistance, and security and operational guidance provided. The OAS will also assess the controls for information system networks, databases, Web-facing applications, and logical and wireless access for selected States, as well as general controls.

Medicaid Managed Care

Review of States' Methodologies for Assigning Managed Care Organization Payments to Different Medicaid FMAPs (New) – The federal government pays its share of a State's medical assistance expenditures under Medicaid based on the federal medical assistance percentage (FMAP), which varies based on the State's per capita income. Certain Medicaid services receive a higher FMAP than others. FMAPs are varied and the actual services provided are less transparent under a managed care model. Therefore, States must create accurate and reasonable methodologies to assign managed care payments to FMAPs. The OAS will review methodologies for assigning MCO payments to different Medicaid FMAPs. The OAS expects to issue a report on this initiative in FY 2017.

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[13] The Patient Protection and Affordable Care Act, Pub. Law No. 111-148, § 6402 (2010).
[14] The Patient Protection and Affordable Care Act, Pub. Law No. 111-148, § 6402(h)(2) (2010).
[15] 42 C.F.R. § 455.23(a), (d) (2011).

CONCLUSION

This brief highlights the FY 2016 reviews that are pertinent to Strategic Management's clients. Providers should review the full OIG Work Plan for further details on the OIG's audit and evaluation plans for FY 2016. Providers should consider the topics listed in the Work Plan in determining risk areas for their organization and prioritizing compliance goals.

The OIG Work Plan for FY 2016 is available at:
http://oig.hhs.gov/reports-and-publications/archives/workplan/2016/oig-work-plan-2016.pdf.