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New Initiatives for the New Year: Highlights of the OIG's 2017 Work Plan

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On November 10, 2016, the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) issued its 2017 *Work Plan*.[1] The 2017 *Work Plan* outlines the areas of special concern to the OIG and describes the enforcement and monitoring initiatives the OIG will pursue in Fiscal Year 2017 in connection with its oversight of the Centers for Medicare & Medicaid Services (CMS) and other agencies of HHS. The OIG's mission is to protect the integrity, quality and safety of HHS programs while also reducing fraud, waste and abuse of those programs through various enforcement and monitoring initiatives. Companies in the health care industry should be aware of the OIG's initiatives when planning their business strategies, risk assessments, internal audits and compliance efforts for the year.

Specifically, the 2017 *Work Plan* describes audits and evaluations that are underway or anticipated, as well as certain legal and investigative initiatives that are continuing. It also includes several new initiatives, as well as a number of completed, revised and removed items from the previous fiscal year. The 2017 *Work Plan* covers a broad array of projects related to CMS programs, organized by type of provider and federal reimbursement structure. While this advisory focuses on new initiatives, companies in the health care industry should also take special note of items that appear on the work plan for multiple years, as those items tend to signal an area of particular focus by OIG. Here are notable highlights of some of the new projects in the 2017 *Work Plan*:

New OIG Initiatives

CMS: Medicare Parts A & B

- **Hyperbaric Oxygen Therapy Services – Provider Reimbursement in Compliance with Federal Regulations.** The OIG will determine whether Medicare payments related to hyperbaric oxygen therapy – which involves administering high concentrations of oxygen within a pressurized chamber as an adjunctive treatment for select non-healing wounds – were reimbursed in accordance with federal requirements.

[1] https://oig.hhs.gov/reports-and-publications/archives/workplan/2017/hhs%20oig%20work%20plan%202017.pdf

- **Incorrect Medical Assistance Days Claimed by Hospitals.** The OIG will determine whether Medicare administrative contractors properly settled Medicare cost reports for Medicare disproportionate share hospital payments with respect to Medicaid patient days. The Medicare program includes provisions under which Medicare-participating hospitals that serve a disproportionate share of low-income patients may receive disproportionate share hospital payments, which are based upon Medicaid patient days that the hospitals furnish. Because those payments are the result of calculations involving a number of complex factors and variables, they are at risk of overpayment.

- **Inpatient Psychiatric Facility Outlier Payments.** The OIG will determine whether Inpatient Psychiatric Facilities – which provide active psychiatric treatment to meet the needs of those experiencing an acute mental health crisis – complied with Medicare documentation, coverage and coding requirements for stays that resulted in outlier payments. From FY2014 to FY2015, the number of claims with outlier payments increased by 28 percent, and total Medicare payments for stays that resulted in outlier payments increased by 19 percent.

- **Case Review of Inpatient Rehabilitation Hospital Patients Not Suited for Intensive Therapy.** The OIG will conduct a case review to assess a sample of rehabilitation hospital admissions to determine whether the patients participated in and benefited from intense therapy. For patients who were not suitable candidates, the OIG will identify reasons they were not able to participate and benefit from therapy.

- **Nursing Home Complaint Investigation Data Brief.** All nursing home complaints categorized as immediate jeopardy and actual harm must be investigated within two 10 days, respectively. A 2006 OIG report found that state agencies did not investigate some of the most serious complaints within these required timeframes. The OIG will determine the extent to which state agencies investigate the most serious nursing home complaints within the required timeframes.

- **Skilled Nursing Facilities – Unreported Incidents of Potential Abuse and Neglect.** The OIG will assess the frequency of abuse and neglect of Medicare beneficiaries receiving treatment in skilled nursing facilities (SNFs) and determine whether those incidents were properly reported and investigated. Additionally, the OIG will interview state officials to determine whether each sampled incident was reported (if required) and whether each reportable incident was investigated and subsequently prosecuted by the state (if appropriate).

- **Skilled Nursing Facility Reimbursement.** SNFs are required to assess their patients using a tool called the Minimum Data Set, which helps classify each patient into a "resource utilization group" for payment. Medicare payments increase as the care and therapy required for the patient increase, and previous OIG reviews have found that SNFs are billing for higher levels of therapy than were provided or were reasonable or necessary. Thus, the OIG will review documentation at selected SNFs to determine whether it meets the requirements for each particular resource utilization group.

- **Skilled Nursing Facility Adverse Event Screening Tool.** As part of its study "Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries," the OIG developed the SNF adverse event trigger tool with assistance from the Institute for Healthcare Improvement (IHI), which also published the tool for industry use. This product will describe the purpose, use and benefits of the SNF adverse event trigger tool and the guidance document released by IHI and is intended to disseminate practical information about the tool for use by those involved with the skilled nursing industry.

- **Medicare Hospice Benefit Vulnerabilities and Recommendations for Improvement.** The OIG has identified vulnerabilities in payment, compliance and oversight, as well as quality-of-care concerns related to Medicare hospice benefits. The OIG will summarize evaluations, audits and investigate work on Medicare hospices and highlight key recommendations for protecting beneficiaries and improving the program.

- **Review of Hospices' Compliance with Medicare Requirements.** When a beneficiary elects hospice care, the hospice agency assumes the responsibility for medical care related to the beneficiary's terminal illness and related conditions. Federal regulations address Medicare conditions of and limitations on payment for hospice services (42 CFR Part 418, Subpart G). The OIG will review hospice medical records and billing documentation to determine whether Medicare payments for hospice services were made in accordance with Medicare requirements.

- **Hospice Home Care – Frequency of Nurse On-Site Visits to Assess Quality of Care and Services.** The OIG will determine whether registered nurses made required on-site visits to the homes of Medicare beneficiaries in hospice care. Medicare requires that a registered nurse make an on-site visit to a patient's home at least once every 14 days to assess the quality of care and services provided by the hospice aide, as well as to ensure that services ordered by the hospice interdisciplinary group meet the patient's needs.

- **Comparing HHA Survey Documents to Medicare Claims Data.** Home health agencies (HHAs) supply patient information (i.e., rosters and schedules) to state agencies during the recertification survey process, but state agencies do not have access to Medicare claims data to verify this information. As a result, fraudulent HHAs might intentionally omit certain patients from information supplied to state agencies to avoid scrutiny. Previous OIG work has shown that the home health program is prone to fraud, waste and abuse. The OIG will determine whether HHAs are accurately providing patient information to state agencies for recertification surveys.

- **Part B Services During Non-Part A Nursing Home Stays: Durable Medical Equipment.** A July 2009 OIG report found that Medicare Part B allowed inappropriate payments of $30 million in 2006 for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) provided during non-Part A stays in SNFs. Thus, the OIG will conduct a study to determine the extent of inappropriate Medicare Part B payments for DMEPOS provided to nursing home residents during non-Part A stays in 2015. The OIG will also determine whether CMS has a system in place to identify inappropriate payments for DMEPOS and recoup payments from suppliers.

- **Medicare Market Share of Mail-Order Diabetic Testing Strips: April 1 through June 30, 2016 – Mandatory Review.** The OIG will review the market share of diabetic testing strips in 2016 to determine how the national mail order re-compete may have impacted shifts in the market.

- **Positive Airway Pressure Device Supplies – Supplier Compliance with Documentation Requirements for Frequency and Medical Necessity.** The OIG will review claims for frequently replaced continuous positive airway pressure or respiratory assist device therapy (PAP) device supplies to determine whether documentation requirements for medical necessity, frequency of replacement and other Medicare requirements are met. Medicare payments for these supplies in 2014 and 2015 were approximately $953 million, and prior OIG reviews have discovered that suppliers sometimes automatically shipped PAP device supplies when no physician orders for refills were in effect.

- **Monitoring Medicare Payments for Clinical Diagnostic Laboratory Tests – Mandatory Review.** The OIG will analyze, pursuant to Section 216 of the Protecting Access to Medicare Act of 2014, the top-25 laboratory tests by Medicare payments to determine the implementation and effect of the new system that determines payment rates for Medicare Part B clinical diagnostic laboratory tests that use rates paid to laboratories by a private payer. The OIG will review Medicare payments for clinical diagnostic laboratory tests performed in 2016 and monitor CMS's implementation of the new Medicare payment system for these tests.

- **Medicare Payments for Transitional Care Management.** The OIG will determine whether payments for transitional care management – which includes services provided to a patient whose medical and/or psychosocial problems require moderate or high-complexity medical decision-making during transitions in care from an inpatient hospital setting to the patient's community setting – were made in accordance with Medicare requirements.

- **Medicare Payments for Chronic Care Management.** The OIG will determine whether payments for chronic care management (CCM) services were made in accordance with Medicare requirements. CCM services are non-face-to-face services provided to Medicare beneficiaries who have multiple significant chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation or functional decline.
- **Data Brief on Financial Interest Reported Under the Open Payments Program.** The OIG will analyze 2015 data extracted from the open payments website to determine the number and nature of reported financial interests from manufactures that made payments to physicians and teaching hospitals. It will determine how much Medicare paid for drugs and DMEPOS ordered by physicians who had financial relationships with manufacturers and group purchasing organizations.
- **Power Mobility Devices Equipment – Portfolio Report on Medicare Part B Payments.** The OIG will compile the results of prior OIG audits, evaluations and investigations of power mobility device equipment to identify trends in payment, compliance and fraud vulnerabilities and offer recommendations to improve detected vulnerabilities.
- **Drug Waste of Single-Use Vial Drugs.** The OIG will determine the amount of waste for the 20 single-use vial drugs with the highest amount paid for waste as identified by the JW modifier and provide specific examples of where a different size vial could significantly reduce waste.
- **Potential Savings from Inflation-Based Rebates in Medicare Part B.** The OIG will build on earlier work that examined existing inflation-based rebates in the Medicaid program and potential rebates in Medicare Part B. The OIG will examine the amount the federal government potentially could collect from pharmaceutical manufacturers if inflation-based rebates were required in Medicare Part B. Currently, Medicare Part B spends billions annually on prescription drugs without a statutorily mandated inflation-based rebate methodology. The study is expected to be issued in FY2017 and will sample 50 to 100 Part B drugs.
- **Medicare Payments for Service Dates after Individuals' Dates of Death.** Section 502 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires CMS to establish policies and implement claim edits to ensure that payments are not made for Medicare services ostensibly rendered to deceased individuals. Prior reviews have identified Medicare payments for services ostensibly rendered to deceased individuals. OIG will review CMS's policies and procedures that ensure that payments are not made for Medicare services ostensibly rendered to deceased individuals.
- **Management Review: CMS's Implementation of the Quality Payment Program.** The OIG will review CMS's planning and early implementation of a new quality payment program (QPP), which is a Medicare physician payment system enabling clinicians either to receive positive or negative Medicare payment adjustments depending on their performance across a range of measures or participate in the advanced alternative payment model, another program offering quality and payment incentives. The QPP was established by MACRA and together with other payment reforms, is intended to control Medicare expenditures and promote high-value, high-quality care and shift how Medicare calculates compensation for clinicians. The OIG will describe the key milestones and timelines, identify the key challenges and report on potential vulnerabilities CMS faces during implementation of the QPP.

CMS: Medicare Parts C & D

- **Medicare Part C Payments for Service Dates after Individuals' Dates of Death.** The OIG will build on a prior review of improperly made Medicare Part C payments, occurring one year following a beneficiary's death. Although CMS prospectively makes payments to Medicare Advantage (MA) organizations, federal regulations require

MA organizations to disenroll beneficiaries from plans on the first day of the calendar month following the month a beneficiary dies. The OIG will determine whether Medicare requirements were followed for any reported prospective payments made after a beneficiary's date of death.

- **Extent of Denied Care in Medicare Advantage and CMS Oversight.** The OIG will examine national trends and rates related to denials of care, appeals and overturns with MA plans, out of concern that MA plans may be financially incentivized to underserve beneficiaries because of capitated payment systems. Capitated payment systems are based on a payment per person rather than a payment per service and are supposed to be monitored by CMS. The OIG will evaluate CMS's efforts to prevent inappropriate denials of care in MA plans, and in the future, may review medical records to examine the appropriateness of any denials.

- **Medicare Part D Rebates Related to Drugs Dispensed by 340B Pharmacies.** The OIG will determine the highest potential savings if pharmaceutical manufacturers paid rebates for drugs dispensed at contract pharmacies and 340B covered entities through the Medicare Part D program. Currently, these manufacturers do not pay rebates at contract pharmacies and 340B covered entities because the locations already receive a discount on the purchase of the drugs. However, the OIG believes there may be a potential for savings to beneficiaries and the government within the Medicate Part D program, similar to the Medicaid drug rebate program.

- **Questionable Billing for Compounded Topical Drugs in Part D.** The OIG will review billing for topical compounded drugs under Medicare Part D, since spending for compounded topical drugs reached $224 million in 2015, and there has been an increasing number of OIG investigative cases related to compounded topical drugs. The OIG will identify pharmacies and associated prescribers with questionable Part D billing for these drugs.

- **Medicare Part D Payments for Service Dates After Individuals' Dates of Death.** To offer prescription drug benefits to eligible individuals, CMS contracts with prescription drug plan and MA organizations (collectively known as sponsors). CMS prospectively makes payments to the prescription drug plan organizations for Part D benefits, and the sponsors are required by federal regulations to disenroll beneficiaries from plans on the first day of the calendar month following the month a beneficiary dies. The OIG will build on a prior review of improperly made Medicare Part D payments, occurring the same year following a beneficiary's death, by determining whether Medicare requirements were followed for any reported prospective payments made after a beneficiary's date of death.

CMS: Medicaid

- **States' MCO Medicaid Drug Claims.** States contract with managed care organizations (MCOs) to provide Medicaid services to enrollees, such as certain covered outpatient drugs. States are required to use a quarterly Medicaid drug tape – which essentially lists the covered outpatient drugs and indicates applicable drugs' termination dates – to verify coverage of any drugs for which the states may claim reimbursement. The OIG will determine whether reimbursements for drugs that are not covered under the Medicaid program are being included in the MCO capitation payments.

- **Data Brief on Fraud in Medicaid Personal Care Services.** The OIG has conducted numerous audits, evaluations and investigative work involving personal care services (PCS). Much of this work is summarized in a November 2012 portfolio report to CMS. Through data collected from the 50 State Medicaid Fraud Control Units and OIG's Office of Investigations, OIG will issue a brief that provides an overview of PCS statistical data collected since the 2012 portfolio. The brief will provide information on state and federal investigations, indictments, convictions and recoveries involving fraud and patient abuse or neglect in Medicaid PCS. The data presented in this brief is intended to illustrate the prevalence and magnitude of fraud, patient abuse or neglect involving PCS and will be especially important for OIG's future work with CMS to combat these issues.

- **Delivery System Reform Incentive Payments.** The OIG will ensure that select states adhere to the applicable federal and state requirements when it issues delivery system reform incentive payments. States must be able to demonstrate outcomes and ensure accountability for allocated funding.

- **Accountable Care in Medicaid.** The Medicaid program is experiencing a shift toward models that promote accountability for the cost and quality of care delivered to patients and focus on more efficient coordination of care. Several delivery system reform initiatives in Medicaid, including medical homes and accountable care organizations, focus on accountable care and include elements such as implementing value-based payment structures, measuring quality improvement and collecting and analyzing data. The OIG will review selected accountable care models in Medicaid for compliance with relevant state and federal requirements.

- **Third-Party Liability Payment Collections in Medicaid.** Medicaid beneficiaries may have additional health insurance through third-party sources. Previous OIG reviews described problems that state Medicaid agencies had in identifying and collecting third-party payments. The OIG will determine if states have taken action to ensure that Medicaid is the payer of last resort by identifying whether a third-party payer exists and if the state correctly reports the third-party liability to CMS.

- **Medicaid Overpayment Reporting and Collections.** Prior OIG audits identified Medicaid overpayments in various states and included recommendations for recouping sg those overpayments. If a federal audit indicates that a state has failed to identify an overpayment, CMS considers the overpayment as discovered on the date that the federal official first notifies the state in writing of the overpayment and specifies a dollar amount subject to recovery (42 CFR § 433.316(e)). Federal regulations require that states report overpayments to CMS. For OIG audits in which CMS concurred with recommendations to collect overpayments, OIG will determine whether the overpayments have been recouped and properly reported to CMS.

- **Overview of States' Risk Assessments for Medicaid-Only Provider Types.** The OIG will review states' assignment of Medicaid-only providers to the federally designated risk categories of high, moderate and limited and any challenges states face in screening Medicaid-only provider types. The ACA requires enhanced screening for providers and suppliers seeking initial enrollment, reenrollment or revalidations in Medicare, Medicaid and CHIP according to risk. In 2016, the OIG found opportunities for improvement with enhanced provider screenings in Medicare and Medicaid. When only Medicaid recognizes a provider type (e.g., nonemergency transportation services), states are responsible for assessing the provider type's risk for fraud, waste and abuse and assigning the risk category.

- **Health Care-Related-Taxes: Medicaid MCO Compliance with Hold-Harmless Requirements.** Many states finance a portion of their Medicaid spending by imposing taxes on health care providers. A health care-related tax is permissible if the tax, among other standards, avoids hold-harmless arrangements that return collected taxes directly or indirectly to taxpayers. The OIG is currently reviewing state tax programs for hospitals and nursing homes to test for compliance with the hold-harmless requirement. The OIG will determine if health-care-related tax programs for MCOs meet federal hold-harmless requirements in 42 CFR § 433.68 by examining the tax programs in large states that tax MCOs.

- **Health Care-Acquired Conditions – Medicaid Managed Care Organizations.** Previous OIG reviews found that some states continued to make fee-for-service Medicaid payments for hospital care associated with health care-acquired conditions and provider-preventable conditions. Provider-preventable conditions are certain reasonably preventable conditions caused by medical accidents or errors in the health care setting. The ACA, § 2702, and implementing regulations at 42 CFR § 447.26, prohibit federal payments for provider-preventable conditions. Because the OIG found problems with states making fee-for-service payments associated with provider-preventable conditions, the OIG is expanding its review to managed care arrangements. Additionally,

the OIG will determine whether Medicaid MCOs have continued to make payments to providers for inpatient hospital services related to treating certain provider-preventable conditions.

Food & Drug Administration

- **Hospitals' Reliance on Drug Compounding Facilities.** Larger-scale facilities that compound without a patient-specific prescription are regulated under section 503B of the Food, Drug and Cosmetic Act and referred to as outsourcing facilities. The OIG will determine the extent to which hospitals obtain compounded sterile preparations from compounders, including outsourcing facilities that have registered with the U.S. Food and Drug Administration (FDA). The OIG will also determine the extent to which compounders that produce compounded sterile preparations without a patient-specific prescription have registered with the FDA.

Other New HHS-Related Reviews

- **Review of CMS Action on CERT Data.** Since 2003, CMS has utilized the Comprehensive Error Rate Testing (CERT) program to establish a national error rate for Medicare fee-for-service payments as mandated by the Improper Payments Information Act of 2002. The OIG issued a report in 2010 identifying error-prone providers and recommended that CMS target these specific providers that contributed significantly to payment errors in the CERT program for provider-based reviews. Improper error rates and payments have not decreased in recent years. The FY2015 reported national error rate for Medicare fee-for-service payments was approximately 12.1 percent, with improper payments estimated at $43.3 billion. The OIG will determine if CMS took action on its previous recommendation to use CERT data to target error-prone providers and reduce payment errors. Additionally, the OIG will analyze CERT data to identify errors and potential patterns where further interventions could reduce payment errors.

- **Compliance with the Digital Accountability and Transparency Act (DATA Act) – Mandatory Review.** On May 9, 2014, President Obama signed the DATA Act, which mandated the establishment of government-wide data standards for financial and payment data by May 2015 and agency reporting of consistent, reliable and searchable financial and payment data by May 2017, to be displayed for taxpayers and policymakers on USASpending.gov. The DATA Act also requires the OIG to review a statistically valid sampling of the spending data submitted under this act by HHS and submit to Congress and make publicly available a report assessing the completeness, timeliness, quality and accuracy of the data sampled and the implementation and use of data standards by HHS.

- **Audit of HHS Information System Security Controls to Track Prescription Drug Disbursements.** Prior OIG audits have reported that HHS lacks sufficient security controls to track the disbursement of prescription drugs in National Institutes of Health (NIH) and Indian Health Service (IHS) hospitals. Thus, the OIG will determine whether HHS applications that track the disbursement of prescription drugs meet federal information security standards. Additionally, for selected NIH and IHS hospitals, the OIG will review application controls and use automated assessment tools to assess the security of the networks, databases and web-facing applications.

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