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Office of Inspector General's Work Plan Outlines 2017 Priorities

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The ***United States Department of Health and Human Services ("HHS") Office of Inspector General ("OIG")*** released its Fiscal Year 2017 Work Plan ("2017 Plan") on November 10. OIG releases a work plan annually to identify the new and ongoing investigative, enforcement, and compliance activities that it will undertake during that fiscal year ("FY").

Takeaways from OIG's Work Plan

Healthcare organizations are well-advised to review their internal audit and compliance plans on a regular basis, and the 2017 Plan is a valuable resource in that effort insofar as the Plan outlines where OIG will focus its investigative resources. New initiatives indicate OIG's impending priorities, and audit and compliance continuing initiatives emphasize OIG's continued—and potentially heightened—interest in certain areas. OIG's stated priorities (including the degree of specificity of OIG's focus) can help an organization shape its compliance program for the coming year.

While the 2017 Plan covers a lot of territory, healthcare organizations should pay particular attention to those priorities involving hyperbaric oxygen therapy services, pharmaceutical and device pricing and reimbursement, and a renewed focus on post-acute care services.

OIG has noted that its work plan is an ongoing and evolving process, and the 2017 Plan may be updated throughout the year. The new administration will also likely have an effect on HHS and OIG priorities.

Initiatives for FY 2017

As explained below, the 2017 Plan includes many new initiatives, including review of incorrect medical assistance days claimed by hospitals, a focus on skilled nursing facilities ("SNF") and several post-acute reviews, and attention to prescription drugs including pricing and 340B rebates. The 2017 Plan also contains reviews of hyperbaric oxygen therapy billing and services, new laboratory payment structures, drug waste, managed care organization and provider compliance with federal billing requirements. This *Update* summarizes new initiatives and highlights of the 2017 Plan.

Medicare Parts A and B

OIG notes that its Medicare oversight efforts have been focused on identifying and offering recommendations to reduce improper payments, prevent and deter fraud, and foster economical payment policies. The 2017 Plan notes that OIG's future planning efforts will include additional oversight of hospice care, SNF compliance with admission requirements, and evaluation of the Centers for Medicare and Medicaid Services ("CMS") Fraud Prevention System.

Hospitals and Institutional Providers

The 2017 Plan contains several new initiatives for hospitals and institutional providers as well as continuing initiatives:

- Hyperbaric Oxygen ("HBO") Therapy Services. As a new focus this year, OIG will determine whether certain Medicare payments related to HBO outpatient therapy were reimbursed consistent with federal requirements. OIG explained that CMS is concerned with beneficiaries receiving HBO therapy for non-covered conditions, medical documentation that did not support HBO therapy, and beneficiaries who received more HBO treatments than were medically necessary.

- Incorrect Medical Assistance Days. New this year, OIG will assess whether Medicare Administrative Contractors are properly settling Medicare costs reports for Medicare disproportionate share hospital ("DSH") payments. According to OIG, risk of overpayment for Medicare DSH payments result from the complex factors and variable required for calculations.

- Inpatient Psychiatric Facility Outlier Payments. New for FY 2017, OIG will study outlier payments from inpatient psychiatric facilities to determine whether those payments complied with Medicare documentation, coverage, and coding.

- Inpatient Rehabilitation Hospital Patients Not Suited For Intensive Therapy. Also new, OIG will study a sample of rehabilitation hospitals to determine whether patients participated in and benefited from intensive therapy. This study is a result of a medical review evaluation that found a small number of cases where patients appeared ill suited for intensive therapy.

- Nursing Home Complaint Investigation. OIG will assess whether state agencies investigate nursing home complaints categorized as immediate jeopardy and actual harm within the requisite 2- and 10-day timeframe.

- Skilled Nursing Facilities. OIG's focus on SNFs in FY 2017 will include: (i) investigation of incidence of abuse and neglect of Medicare beneficiaries receiving treatment in SNFs; (ii) review of select SNFs to determine whether documentation for higher levels of therapy meet billing requirements; and (iii) issuance of the SNF Adverse Event Screening Tool and practical information about the tool.

- Hospice, Home Health, and Long-Term Care. OIG's priorities for hospice and long-term care providers include the following initiatives for FY 2017: (i) examination of states' procedures for background checks on long-term care employees and providers, (ii) investigation of hospice providers' medical records for billing compliance, (iii) investigation of vulnerabilities in payment to hospice programs, including payment, compliance, and quality of care, (iv) examination of hospice home care nurse on-site visits in compliance with 14-day requirement, and (v) assessment of home health agency accurate reporting of patient

information for recertification survey.

In FY 2017, OIG will also continue its review of outpatient outlier payments for short-stay claims, provider-based reimbursement, reconciliations of outlier payments, hospitals' use of outpatient and inpatient stays under the two-midnight rule, adverse events in post-acute care, and potentially avoidable hospitalizations of dual eligible nursing facility residents.

Medical Equipment and Supplies

OIG will continue to study competitive bidding and payments and compliance for specific items, including orthotic braces, osteogenesis stimulators, power mobility devices, and nebulizer machines. OIG will add review of other items, including durable medical equipment, prosthetics, orthotics and supplies, along with mail-order diabetic testing strips and positive airway pressure device supplies.

Other Providers and Suppliers

The 2017 Plan outlines five new enforcement priorities among other revised and continuing reviews:

- Clinical Diagnostic Laboratory Tests. New for FY 2017, OIG will review Medicare payments for clinical diagnostic laboratory tests performed in 2016. The review will assess CMS implementation of the new Medicare payment system, which is a market-based system using rates paid to laboratories by private payers.

- Chronic Care Management ("CCM") and Transitional Care Management ("TCM"). New this year, OIG will review payments for CCM services, which cannot be billed during the same period as TCM, home health supervision, hospice care, or certain end-stage renal disease services. OIG will also investigate compliance with TCM requirements, including the requirement that certain services (chronic care management, end-stage renal disease, and prolonged services without direct patient contact) were not covered during the same service period as TCM.

- Financial Interests Reported Under the Open Payments Program. OIG plans to examine how much Medicare paid for drugs and whether DMEPOS were ordered by physicians who had financial relationships with manufacturers and group purchasing organizations.

- Power Mobility Devices ("PMD") Equipment. OIG will continue its assessment of inappropriate payments for PMDs due to incorrect documentation, lack of medical necessity, and failure to rent when it is less expensive than purchasing.

- Inpatient Rehabilitation Facility ("IRF") Payment System Requirements. OIG will assess whether IRFs billed claims in compliance with Medicare requirements, such as specific documentation that supports a reasonable expectation regarding beneficiary need for multiple intensive therapies (one of which is physical or occupational), ability to actively participate, demonstrable measureable improvement, and required active supervision during rehabilitation.

- Histocompatibility Laboratories Payment Requirements. New this year, OIG will review whether Medicare payments to histocompatibility laboratories were made in accordance with

federal requirements.

Continuing in FY 2017, OIG will review financial interests reported under the open payments program, high use of sleep-testing procedures, outpatient physical therapy, chiropractic services, quality oversight of the ambulatory surgical centers, anesthesia services, and prolonged services. OIG will also continue to monitor payments for Medicare services, supplies, and durable medical equipment, prosthetics/orthotics and supplies referred or ordered by physicians.

Prescription Drugs

The 2017 Plan contains two new initiatives for FY 2017:

- Drug Waste of Single-Use Vial Drugs. OIG will review the amount of waste for the 20 single-use-vial drugs with the highest amount paid for waste as identified by the JW modifier. OIG will provide specific examples of where a different size vial could significantly reduce waste.

- Potential Savings from Inflation-Based Rebates in Part B. New this year, OIG will study the amount the Federal Government could collect from pharmaceutical manufacturers if inflation-indexed rebates were required under Medicare Part B, similar to the mandated rebates enabling Medicaid to collect some of the fees paid for prescription drugs.

OIG will also continue to review the difference between average sales prices and average manufacturer prices of Part B drugs as well as Part B payments for immunosuppressive drugs billed with specific modifiers.

Part A and B Management Issues

- Accountable Care Organizations ("ACOs"). OIG will review the Medicare Shared Savings Program ("MSSP") to determine whether beneficiary assignment to ACOs and shared savings payments for assigned beneficiaries complied with federal requirements. OIG will also examine CMS shared savings payments to ensure no duplication of payments for the same beneficiaries by other savings programs or initiatives. OIG will also (i) describe ACO performance on quality measures and cost savings over the first 3 years of the MSSP and (ii) review the extent to which providers participating in ACOs in the MSSP use electronic health records ("EHRs") to exchange health information to achieve care coordination goals and identify best practices.

- Payments for Service Dates After Individuals' Death. New for FY 2017, OIG will investigate CMS policies and procedures to ensure payments are not made for services rendered to deceased individuals, which has been identified in previous studies.

- MACRA. Also new for FY 2017, OIG will describe timeliness and key milestones CMS has established for implementing the new Quality Payment Program under MACRA.

Medicare Parts C and D

The 2017 Plan contains a number of new and revised initiatives for FY 2017. Most of the OIG

initiatives focus on CMS administration and oversight of Parts C and D. However, these items are often the source of increased CMS scrutiny on plans and vendors (e.g., first-tier, downstream, and related entities).

- Part C and D Payments for Service Dates After Individuals' Dates of Death. Like Part A and Part B, new for FY 2017, OIG will determine whether Part C and D payments are properly made after a beneficiaries' date of death, where federal regulations require Medicare Advantage ("MA") organizations to disenroll a beneficiary from its MA plan on the death of the individual, effective the first day of the calendar month following death.

- Extent of Denied MA Care and CMS Oversight. Also new, OIG will examine the possibility of MA organizations underserving beneficiaries based on capitated payments systems, which base payment on a per person (PMPM) rather than a per service basis.

- Part D Rebates For Drugs Dispensed by 340B Pharmacies. According to OIG, manufacturers frequently do not pay rebates for Part D prescriptions filled at 340B covered entities and contract pharmacies since they are already providing a discount on the purchase of the drug. As a new focus, OIG will review potential savings if requirements similar to those of the Medicaid Drug Rebate Program were adopted by the Part D program.

- Questionable Billing for Compounded Topical Drugs in Part D. As a result of a 3,400 percent increase for compounded topical drugs between 2006 and 2015, OIG will begin a new review potential fraud surrounding compounded topical drugs.

OIG also plans to continue its audits and reviews of conflicts of interest in Medicare prescription drug decisions, access by dual eligible beneficiaries to drugs under Part D, and review CMS oversight of Medicare Eligibility Verification transactions (E1 transactions) processed by contractors.

Medicaid

OIG's focus on the Medicaid program for FY 2017 continues OIG's interest on fraud, waste, and abuse as Medicaid continues to expand and long-term initiatives address new payment and delivery models, state financing mechanisms, drug diversion and abuse, and Medicaid managed care. As with Part C and D, a number of OIG priorities for FY 2017 focus on state and CMS management and administration. However, providers may see increased state and CMS interest related to these initiatives.

- Prescription Drug Reviews. New this year, OIG will determine whether managed care organizations ("MCOs") received capitation payments that included reimbursement for outpatient drugs not covered on the CMS list of outpatient drugs. OIG also has a number of continuing Medicaid-related prescription drug reviews for FY 2017, including: (i) copayments and rebates related to physician administered drugs, (ii) state action for inappropriate dispensing and potential abuse of prescription drugs, and (iii) provider compliance with Medicaid billing requirements for use of Herceptin (used to treat breast cancer), as previous OIG audits found Medicare billing non-compliance for Herceptin.

- Fraud in Medicaid Personal Care Services ("PCS"). Also new for FY 2017, OIG will release a data brief with an overview of PCS statistical data since 2012, based on data collected from the 50 State Medicaid Fraud Control Units ("MFCUs") and OIG's Office of

Investigations.

- Delivery System Reform. New for FY 2017, OIG has two delivery system reform priorities: (i) ensuring that states are adhering to federal and state requirements for receiving Section 1115 incentive payments to increase quality of services and (ii) reviewing accountable care models in Medicaid for compliance with federal and state requirements.

- State Management. FY 2017 initiatives include: (i) investigation whether states are taking all necessary action to ensure that Medicaid is the payer of last resort by identifying whether any third-party payers exist, (ii) analyzing whether states are properly and timely reporting overpayments to CMS, and (iii) continuing examination as to whether states made prohibited Medicaid payments for hospital care associated with health-care acquired conditions and provider preventable conditions.

- Medicaid Managed Care. In FY 2017, OIG will examine: (i) whether health care related tax programs for MCOs meet federal hold harmless and other requirements and (ii) whether Medicaid MCOs are making prohibited payments for provider preventable conditions.

Also continuing for FY 2017 is OIG review of adult day health care services, room-and-board costs associated with the Home and Community Based Services waiver program, benefits and challenges of Express Lane Eligibility, provider compliance with Medicaid billing requirements for billing required dental services for children, payments for Community First Choice services and required institutional level of care and financial eligibility criteria, rate of and reasons for transfer from group homes or nursing facilities to hospital emergency departments, state Medicaid agency (and contractors) HIPAA breach notification procedures, and reimbursement made to managed long-term care plans. OIG will also continue to perform onsite reviews of MFCUs.

Health Insurance Marketplaces

OIG will continue its review of health insurance marketplaces and related programs (e.g., financial assistance payments and premium stabilization programs) in FY 2017. Specifically, OIG reports that it will focus on payment accuracy, eligibility, management and administration, IT security risks, and consumer fraud.

For FY 2017, OIG will focus on the following to facilitate the health insurance marketplace: a revised review of CMS oversight and issuer compliance in ensuring data integrity for the risk adjustment program, HHS Establishment Grants, accuracy of financial assistance payments for individual enrollees, inconsistencies in marketplace applicant data, and a revised review of CMS monitoring activities for the Consumer Operated and Oriented Plan.

Electronic Health Records

The 2017 Plan includes a continued focus on compliance with the Health Information Technology for Economic and Clinical Health Act ("HITECH") and the EHR incentive programs HITECH established. The 2017 Plan notes that more than $30 billion in incentives have been paid thorough the Medicare and Medicaid EHR incentive programs; improper incentive payments is the primary risk to the programs, and these programs may be at greater risk of improper payments because of the complex requirements.

For FY 2017, OIG will review past Medicare EHR incentive program payments to look for errors and will assess CMS's plans to oversee incentive payments for the program. OIG will also continue to assess whether eligible providers and hospitals have successfully implemented appropriate technical capabilities to fulfill meaningful use objectives. OIG notes that it will perform audits throughout the year to ensure that entities receiving incentive payments are complying with the objectives.

CMS-Related Legal and Investigative Activities

In the 2017 Plan, OIG notes that it will continue to leverage its authority under the False Claims Act, Civil Monetary Penalties statute, the Anti-Kickback statute, and the Stark law, among other statutes and regulations, to combat fraud against federal health care programs. The 2017 Plan specifically indicates a focus on health care fraud schemes related to:

- Controlled and non-controlled prescription drugs;
- Home health agencies, personal care, and home and community based services;
- Ambulance transportation;
- Durable medical equipment; and
- Diagnostic radiology and laboratory testing.

Other HHS-Related Reviews

OIG reports that it will continue to address Department-wide matters, such as financial statements, financial accounting, information systems management, and other departmental issues. One such Department-wide initiative for FY 2017 includes a review of CMS Action on Comprehensive Error Rate Testing ("CERT") Data. OIG reports that the national error rate for Medicare fee-for-service payments is at around 12.1% with improper payments of approximately $43.3 billion. OIG plans to review CERT data to identify patterns to reduce payment errors and determine whether CMS took action to target error-prone providers.

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