OIG ISSUES 2007 WORK PLAN

On September 25, 2006, the Office of the Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”) issued its Work Plan for Fiscal Year 2007 (“2007 Work Plan”).¹ The 2007 Work Plan outlines the areas of special concern to the OIG and describes those enforcement initiatives the OIG will pursue in FY 2007 in connection with its oversight of the Centers for Medicare & Medicaid Services (“CMS”), and other agencies of HHS. Accordingly, health care providers should be aware of these areas and initiatives in planning their business strategies and compliance efforts for the year.

The 2007 Work Plan includes several new themes that weave throughout the major program areas. First, the OIG seeks to ensure the compliance of state false claims acts and programs with the Deficit Reduction Act of 2005 (“DRA”). For instance, in FY 2007, the OIG will investigate whether inpatient rehabilitation facilities are complying with admissions and billing regulations based upon the DRA’s alterations to the compliance threshold criteria. The OIG will also evaluate methodologies used by drug manufacturers to calculate their Average Manufacturer Price for the Medicaid drug rebate in light of DRA modifications.

Second, in FY 2007, the OIG will ensure continued proper implementation of Medicare Part B drug pricing regulations and Part D drug benefit provisions. Finally, the 2007 Work Plan expresses the OIG’s desire to determine whether long-term care hospitals are complying with average length of stay criteria and long-term care hospital reimbursement rates and whether physician-owned specialty hospitals are providing safe and adequate care to patients.

This advisory will provide an overview of the 2007 Work Plan and will summarize some of the major areas of focus for the OIG in FY 2007.

MAJOR ISSUES

CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare Part D

The OIG continues to monitor the implementation of the Medicare Part D drug benefit program, specifically with regard to fraud and abuse issues in the Part D drug program. While the 2006 Work Plan focused on the marketing and enrollment of persons in Part D drug programs, the 2007 Work Plan primarily focuses on drug pricing schemes. The 2007 Work Plan outlines a number of Part D issues that the OIG will monitor and evaluate, including:

- **Comparisons of Part D Drug Pricing.** OIG will compare prescription drug prices under Part D with the prices of those same drugs under Part B and will compare the prices of particular Part D drugs to Medicaid payment amounts.

- **Monitoring Part D Drug Prices.** OIG will study the history of Part D drug prices, comparing fluctuations in prices due to price variations during the open enrollment period to fluctuations after enrollment closed.

- **Drug Benefit Payments.** OIG will evaluate CMS’s new Part D implementation policies and computerized payment systems to discover whether effective controls have been instituted to guarantee that benefits are paid on behalf of eligible beneficiaries and that Medicare and beneficiaries are paid the proper amounts.

Medicare Part B

The OIG focuses primarily on pharmaceuticals in the Medicare Part B program in the 2007 Work Plan, including:

- **Computation of Average Sales Price.** OIG will evaluate drug manufacturers’ methodologies for calculating the average sales price (“ASP”), which is both required by the Medicare Modernization Act (“MMA”) and used to determine Part B reimbursement of specific classes of drugs.

- **Part B Drug Reimbursement Methodology.** OIG will assess the potential benefit for the federal government if CMS reimburses multi-source Part B drugs based on the ASP of individual National Drug Codes (“NDC”) rather than based on the Healthcare Common Procedure Coding System (“HCPCS”).

- **Payments to Independent Dialysis Facilities for Epogen.** OIG will determine whether independent dialysis facilities are billing Medicare for administering Epogen in instances beyond what is medically necessary and ordered by physicians.
Other Significant Areas of Focus

The 2007 Work Plan covers a broad array of projects related to CMS programs, broken down by type of provider and by federal reimbursement scheme. Further highlights of the 2007 Work Plan include the following:

Hospitals

- **Inpatient Rehabilitation.** OIG will assess the extent of compliance by inpatient rehabilitation facilities with regulatory requirements for admissions and billing in light of the modifications in the DRA of the compliance threshold criteria to be categorized as a rehabilitation hospital.

- **Dialysis Services.** OIG will determine whether payments were made for inpatient admissions for dialysis services when physicians had designated the level of care as “admission to observation status,” so as to identify inappropriate payments for treatment at the higher inpatient rates when only observation services are performed.

- **Long Term Care Hospitals.** OIG will assess whether payments under the long term care hospital (“LTCH”) PPS complied with Medicare regulations and whether early discharges to home and interrupted stays were appropriate.

- **Oversight of Specialty Hospitals.** OIG will evaluate CMS oversight of physician-owned specialty hospitals to ensure patient safety and quality of care at these hospitals. To this end, OIG will investigate staffing requirements at these hospitals.

- **Rebates Paid to Hospitals.** OIG will determine whether hospitals are properly identifying purchase credits rebates as a separate line item in their Medicare cost reports.

- **Outpatient Department Payments.** OIG will review payments to hospital outpatient departments under the outpatient hospital PPS to determine the extent to which they were made in accordance with Medicare laws and regulations.

- **Diagnostic X-Rays in Hospital Emergency Departments.** OIG will determine the extent of inappropriate payments for diagnostic x-rays performed in hospital emergency departments. Interpretations by emergency room physicians of diagnostic x-rays should not be billed separately.

Home Health

- **Outlier Payments.** OIG will review outlier payments to home health agencies (“HHA”) to determine the frequency and distribution of these payments and to assess whether the payments are equitable.
• **Rehabilitation Therapy Services.** OIG will assess the extent to which HHA rehabilitation therapy services were provided by proper staff and were medically necessary. OIG will determine whether the care given met patients' needs and to what extent HHAs were reimbursed for medically unnecessary therapy.

**Nursing Homes**

• **Skilled Facility Rehabilitation and Infusion Therapy Services.** OIG will examine whether rehabilitation and infusion therapy services provided by skilled nursing facilities (“SNFs”) were medically necessary and sufficient for patients’ needs.

• **Consecutive Inpatient Stays.** OIG will analyze the medical reasonableness and necessity of SNF care provided to beneficiaries with consecutive inpatient stays. An inpatient hospital stay must precede all SNF stays, and OIG will focus on beneficiaries who have made three or more consecutive stays, including at least one SNF stay.

• **Imaging and Laboratory Services.** OIG will determine the nature and extent of any medically unnecessary imaging and laboratory services provided to nursing home residents. OIG will also calculate any excessive billing associated with these services.

• **Implementation of Medicare Part D.** OIG will gauge the extent of Part D implementation in nursing homes. OIG will study the ways dual eligible nursing home residents select and enroll in Medicare prescription drug plans and will determine whether these residents receive the drugs they need.

• **Psychotherapy Services.** OIG will determine the extent to which psychotherapy services are provided and medically necessary for Medicare beneficiaries residing in nursing homes.

**Physicians and Other Health Professionals**

• **Billing Service Companies.** OIG will identify the types of relationships that physicians and other providers have with billing services and will evaluate the impact of these relationships on physicians’ billings.

• **Physician Pathology Services.** OIG will examine whether billings for pathology laboratory services comply with Part B requirements, focusing on services performed in physicians’ offices. OIG will review the arrangements between physicians who furnish these services in their offices and outside pathology companies.
Evaluation of “Incident to” Services. OIG will identify services performed “incident to” physicians’ professional services and will assess the extent to which these services comport with Medicare standards for medical necessity, documentation, and care quality.

Medical Equipment and Supplies

Durable Medical Payments. OIG will determine whether durable medical equipment (“DME”) items and supplies furnished to beneficiaries receiving HHA services were reasonable and necessary for the patients’ conditions. OIG will also determine whether payments for specified DME items (e.g., wound care equipment) were accurately documented, medically necessary, and actually received by the beneficiaries.

Other Medicare Services

End Stage Renal Disease Drug Reimbursement. OIG will explore the difference between the Medicare reimbursement amounts for specified separately billable end-stage renal disease (“ESRD”) drugs and the amounts ESRD facilities pay to obtain the drugs. OIG will also examine the variability of acquisition costs among providers. OIG will also assess whether independent dialysis facilities are billing Medicare for administering Epogen in instances beyond what is medically necessary and ordered by physicians.

Medicaid Hospitals

Hospital Outlier Payments. OIG will determine whether methods employed by state Medicaid agencies for computing inpatient hospital cost outlier payments result in reasonable payments. Prior OIG work involving Medicare claims for hospital outliers identified vulnerabilities in the Medicare payment methodology.

Medicaid Long Term and Community Care

Billing for Medicaid Nursing Home Patients Transferred to Hospitals. OIG will examine state Medicaid claims data to determine whether Medicaid made duplicate payments to nursing facilities and hospitals for the same patients and whether hospitals are receiving payments for Medicaid patients who have been discharged.

Assisted Living Facilities. In several states, OIG will determine whether providers were improperly reimbursed for services provided to residents of assisted living facilities and determine the associated financial impact on the Medicaid program.
• **Medicaid Payments for Medicare-Covered Home Health Services.** Medicare pays a prospective payment rate for each 60-day episode of home health coverage for a beneficiary. Most states pay for Medicaid home health services on a fee-for-service basis. OIG will determine the appropriateness of Medicaid payments for Medicare-covered home health services.

**Medicaid Prescription Drugs**

• **Review of the Average Manufacturer Price.** OIG will review selected drug manufacturers to evaluate the methodologies that manufacturers used to calculate their AMPs for the Medicaid drug rebate program and determine whether the methodologies were consistent with statute, their rebate agreements, and CMS Releases. The DRA makes changes that involve revisions to the calculation of the AMP and the best price.

• **Review of CMS’s Oversight of the Medicaid Drug Rebate Program.** OIG will review CMS’s oversight of the Medicaid drug rebate program to determine whether AMP data are accurate and timely.

• **Overprescribing of OxyContin and Other Prescription Drugs.** OIG will analyze Medicaid paid claims data to identify beneficiaries who have received significant amounts of OxyContin and other drugs with potential for abuse, such as Hydrocodone, Xanax, Diazepam, and Soma.

**Investigation Priorities**

• **Health Care Fraud.** OIG will continue its vigorous investigation of fraud committed against the Medicare and Medicaid programs. OIG will investigate individuals, facilities, or entities that bill Medicare and/or Medicaid for services not rendered, claims that manipulate payment codes, claims for care not provided to nursing home residents, and other false claims submitted to obtain program funds. The OIG will also continue to investigate business arrangements that may violate the federal Anti-Kickback Statute.

• **Prescription Drugs.** Working in conjunction with federal, state, and local law enforcement officials, the OIG will continue to identify and investigate illegal schemes to market, obtain, use, and distribute prescription drugs, as well as scams involving identify theft related to the prescription drug discount card program.
PUBLIC HEALTH AGENCIES

Centers for Disease Control and Prevention

• Pandemic Flu Registry and System. OIG will assess the CDC’s progress in deploying a pandemic flu system that will track and manage the distribution of influenza vaccine and other measures from the point of manufacture to the point of delivery.

• Strategic National Stockpile. OIG will evaluate the Strategic National Stockpile, the primary resource to help state and local governments respond to public health emergencies, to ensure its security, product integrity, and ability to control regulated products.

Food and Drug Administration

• Implementation of Clinical Trials Data Bank. OIG will evaluate the integrity of the Clinical Trials Data Bank, including the completeness of individual registration records, what barriers may exist that prevent complete information from getting to the Data Bank, and what problems, if any, the FDA faces in managing the Data Bank.

• FDA Generic Drug Approval Process. OIG will determine the extent to which FDA reviews applications for generic drugs in a thorough and timely manner within statutory requirements. FDA is required by law to approve or disapprove applications for generic drugs within 180 days of submission. However, average review time exceeds 20 months, and as of 2006, the agency had a backlog of approximately 1,000 generic drug applications, 250 of which had exceeded the 180-day statutory time limit.

COMMENT

The above represents just a sampling of the major OIG initiatives for FY 2007 as found in the 2007 Work Plan. The 2007 Work Plan is extensive and touches upon numerous issues of concern to the OIG. Health care providers should pay close attention to those items outlined in the 2007 Work Plan and seek to update their compliance programs to ensure that they address the issues of particular concern to the OIG. If gaps are detected in a provider’s compliance program, it may be necessary to develop additional written compliance policies and procedures and/or to provide additional training to personnel. A careful review of the 2007 Work Plan should be undertaken in conjunction with an annual monitoring of each provider’s compliance program.

This advisory was prepared by Tamara Carty, Keith Harvey and Bharath Parthasarathy.
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