OIG Issues 2008 Work Plan

On October 1, 2007, 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 2008 ("2008 Work Plan"). The 2008 Work Plan outlines the areas of special concern to the OIG and describes those enforcement initiatives the OIG will pursue in FY 2008 in connection with its oversight of the Centers for Medicare & Medicaid Services ("CMS") and other agencies of HHS. Accordingly, health care suppliers and providers should be aware of these areas and initiatives in planning their business strategies and compliance efforts for the year.

The 2008 Work Plan includes several new themes in addition to the areas that historically have been of concern to the OIG, namely physician payments, physician referrals, health information security and operation of the Medicare Part D benefit. The OIG has indicated that it will pursue a number of audits and evaluations focusing on Medicare payments to physicians, including instances where the services are provided in institutions with which the physician has a financial relationship. Such reviews will include a look at Medicare Part B payments for diagnostic imaging services provided in hospital emergency departments and a review of financial arrangements where magnetic resonance imaging ("MRI") services are provided and paid for under the Medicare Physician Fee Schedule ("PFS").

The OIG will review the extent to which Medicare physicians reassign their benefits to other entities. Government investigations have revealed fraudulent schemes in which physicians obtain identifying information for legitimate physicians and request reassignments on their behalf. As a result, the OIG intends to examine a national sample of Medicare physicians to determine the frequency with which they reassign their benefits and the extent to which the physicians are aware of reassignments requested on their behalf.

The OIG will continue to monitor physician-owned specialty hospitals for patient care and safety issues. Physician-owned specialty hospitals have been the subject of intense scrutiny as to the adequacy of staffing levels and appropriateness of care. The 2008 Work Plan indicates that this level of scrutiny will continue.

Not surprisingly, given previous OIG studies of improper payments to independent diagnostic testing facilities ("IDTFs"), the OIG has indicated that it will focus on IDTFs and examine billing patterns in relation to provider and beneficiary profiles. In addition to IDTFs, the OIG indicates that it will review billing patterns for unusually high utilization rates for ultrasound and chiropractic services.

Finally, in FY 2008, the OIG will ensure continued proper implementation of the Medicare Part B drug pricing regulations and Part D drug benefit provisions.

MEDICARE

Major Issues

Part B Drug Reimbursement

The OIG will continue to focus on certain pharmaceuticals reimbursed under the Medicare Part B program. In addition, the OIG will address the drug pricing methodologies under the Part B program.

- Payment to Dialysis Facilities for Epogen. The OIG will determine whether claims submitted for Epogen (“EPO”) administered at dialysis facilities were supported and billed in accordance with Medicare requirements. The OIG also will assess the EPO claim oversight by CMS and the fiscal intermediaries.

- Monitoring Medicare Part B Drug Prices: Comparing Average Sales Prices to Widely Available Market Prices and Average Manufacturer Prices. The OIG will review the appropriateness of Medicare Part B drug prices by comparing average sales prices (“ASP”) to widely available market prices (“WAMP”) and to average manufacturer prices (“AMP”). Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), the OIG will notify the Secretary of HHS of drugs with an ASP that exceeds the WAMP or the AMP by a threshold of 5 percent.

- Changes in Average Sales Price for Part B Drugs. The OIG will review the extent to which ASPs for Medicare Part B drugs fluctuate from quarter to quarter and identify the ASPs with the greatest quarterly variations.

Part D Administration

The OIG continues to monitor the implementation of the Medicare Part D drug benefit program, specifically with respect to fraud and abuse issues, as well as duplicate and aberrant payments for drugs. The OIG also will review the CMS methodology for reviewing bids from Part D plan sponsors to determine whether the process is adequate and whether the benefits of Part D negotiated drug prices and concessions are passed on to enrollees.

- Reconciliations. The OIG will assess whether CMS, the prescription drug plans (“PDPs”) and Medicare Advantage Prescription Drug Plans (“MA-PDs”) have established adequate controls over the Medicare Part D payment reconciliation process. The OIG intends to determine whether the PDPs, MA-PDs and CMS are complying with the applicable regulations (e.g., requiring the PDPs and MA-PDs to submit to CMS timely and accurate information).

- Negotiated Drug Prices and Price Concessions. The OIG will review Part D sponsors’ implementation of and compliance with requirements for passing on negotiated drug prices to the Medicare program and/or its beneficiaries.

- Implementation of Part D in Nursing Facilities. The OIG will review the implementation of Medicare Part D for dual-eligible (Medicare and Medicaid) residents in a sample of nursing homes by assessing whether they are receiving medically necessary drugs and the factors contributing to the drugs they receive. The OIG also will identify concerns of nursing home with long-term care pharmacy staff regarding the implementation of Part D in nursing homes.
Other Significant Areas of Focus

The 2008 Work Plan covers a broad array of projects related to CMS programs, organized by type of provider and by federal reimbursement scheme. Further highlights of the 2008 Work Plan include the following:

**Hospitals**

- **Long Term Care Hospital ("LTCH") Payments for Interrupted Stays.** The OIG will review payments made to certain LTCHs. Interrupted stays occur when a beneficiary is discharged from an LTCH and then returns within a certain period of time. The OIG will determine whether such payments were accurate.

- **Special Payment Provisions for LTCHs Discharging Beneficiaries to Co-located or Satellite Providers.** The OIG will determine whether special payment provisions were appropriately applied to LTCHs discharging beneficiaries to co-located hospitals or satellite providers. The special payment provisions apply if an LTCH’s or an LTCH satellite facility’s discharged Medicare inpatient population admitted from the co-located hospital exceeds the applicable threshold.

- **Medicare Disproportionate Share ("DSH") Payments.** In light of steady increases in DSH payments and previously identified overpayments, the OIG will review Medicare DSH payments to hospitals and determine whether these payments met Medicare criteria. The OIG also will examine components of the calculation methodology to determine whether hospitals were classified appropriately and to verify the hospitals’ total uncompensated care costs.

- **Payments for Diagnostic X-Rays in Hospital Emergency Departments.** The OIG will review a sample of Medicare Part B paid claims and medical records to determine the appropriateness of payments for diagnostic x-rays in hospital emergency departments. This action is in response to the Medicare Payment Advisory Commission’s concerns about the increasing cost and potential overuse of diagnostic imaging services and a marked increase in payments for imaging services since 2001.

- **Physician-Owned Specialty Hospitals.** The OIG will review indicators of patient care and safety in physician-owned specialty hospitals and review compliance by these hospitals with Medicare Conditions for Participation. In addition, the OIG will also examine policies related to staffing requirements at these hospitals. As part of the MMA, an 18-month moratorium was imposed on referrals to new physician-owned specialty hospitals. In June 2005, CMS issued a memorandum suspending the processing of provider enrollment applications for new specialty hospitals, which Congress extended under the Deficit Reduction Act of 2005 ("DRA") until August 8, 2006.

**Home Health**

- **Medicare Home Health Resource Groups.** The OIG will evaluate Medicare claims submitted by home health agencies ("HHAs") to determine the extent to which the home health resource groups that are used in determining payments to HHAs are accurate and supported by documentation in the medical record.
Nursing Homes

- Skilled Nursing Facility (“SNF”) Resource Utilization Groups’ (“RUGs”) Claims. The OIG will review a national sample of Medicare claims submitted by SNFs to determine the accuracy of RUGs included on SNF claims for Medicare reimbursement. This will address an OIG finding that 22 percent of such claims were upcoded, resulting in overpayments. The OIG also will identify areas for improvement in SNF coding.

Medicare Physicians and Other Health Professionals

- Place of Service Errors. The OIG will determine whether physicians have properly coded the place of service on claims for services provided in ambulatory surgical centers (“ASCs”) and hospital outpatient departments.

- Evaluation and Management Services During Global Surgery Periods. The OIG will determine whether industry practices related to the number of evaluation and management services provided during the global surgery period have changed since the global surgery fee concept was developed in 1992.

- Medicare “Incident to” Services. The OIG will examine Medicare services that physicians bill “incident to” their professional services for medical necessity, documentation and quality of care. The study also will examine the qualifications and appropriateness of the staff that perform the “incident to” services.

- Payments for Polysomnography. The OIG will examine the appropriateness of Medicare payments and factors contributing to the rise in payments for polysomnography, a diagnostic test in which a number of the patient’s physical parameters, such as heart rate and brain activity, are measured during sleep.

- Billing Violations of Medicare Providers. The OIG will determine the extent to which providers may be billing beneficiaries in excess of amounts allowed by Medicare requirements and assess beneficiary awareness of the potential violations.

- Business Relationships and the Use of MRI Under the Medicare Physician Fee Schedule. The OIG will review arrangements under which MRI is provided under the Medicare PFS. The OIG also will determine whether relationships among physicians, billing providers and others who work together to provide imaging services affect levels of utilization.

- Billing Patterns for Ultrasound Services, Independent Diagnostic Testing Facilities and Chiropractic Treatments. The OIG will examine service profiles, provider profiles and billing patterns in geographic areas with high utilization of ultrasound services paid under the PFS and geographic areas with high concentrations of IDTFs. The OIG also will review chiropractor billings for high-frequency treatments to determine whether they comply with Medicare coverage criteria and documentation requirements.

Medical Equipment and Supplies

- Medicare Part B Payments for Home Blood Glucose Testing Supplies. The OIG will review Medicare Part B payments to durable medical equipment suppliers for home blood glucose test strips and lancet supplies based on applicable local medical review policies and local coverage determinations.
Part B Pricing of Enteral Nutrition Therapy. The OIG will examine Part B pricing of enteral nutrition therapy (“ENT”) by comparing Medicare’s fee schedule for ENT to prices available to nursing homes, individuals and other purchasers.

Other Medicare Services

• Pricing of Clinical Laboratory Tests. The OIG will examine Medicare payment rates for certain laboratory tests and compare them with the rates of other federal, state and private plan payers. The OIG also will analyze claims data and survey large public and private payers to determine the extent of variation in payment rates among contractors for the most commonly performed tests.

• Ambulatory Surgical Center Payment System. The OIG will determine the appropriateness of the methodology for setting the ASC payment rates under the revised ASC payment system.

Medicare Advantage

• Marketing Practices. Medicare Advantage ("MA") plans are prohibited from misleading or confusing Medicare beneficiaries and from misrepresenting plans. To assess CMS oversight of MA marketing and sales practices, the OIG will evaluate the sanctions (including civil monetary penalties, suspension of beneficiary enrollment, or suspension of payments) imposed by CMS for marketing abuses, CMS attempts to collaborate with state governments to address these abuses and the extent of beneficiary complaints about MA marketing and sales practices.

• Lock-In Provision. The lock-in provisions restrict the number of times and the time of year beneficiaries are permitted to change health plans. Other regulations require MA plans to provide beneficiaries with written explanations of plan rules, policies, benefits, fees and other information needed for informed enrollment decisions (including information on the lock-in provisions). The OIG will examine CMS and MA plan communications to beneficiaries on these topics and will evaluate beneficiaries’ comprehension of the lock-in provisions.

• MA Plan Bids. The OIG will assess Medicare Advantage Organization ("MAO") bids and supporting documentation to determine whether such information was supported by the MAOs’ accounting records and was prepared in compliance with CMS instructions. In this effort, the OIG will consider whether CMS payments to MAOs were correct and supported for the level of service claimed.

• Special Needs Plans. The OIG will evaluate any differences in operation between traditional MA plans and special needs plans ("SNPs"), which were designed to care for institutionalized beneficiaries, dual eligible beneficiaries and beneficiaries with severe or disabling chronic conditions. The OIG will examine how SNP benefit packages differ from other MA plan packages, assess SNP coordination of care and determine the adequacy of SNP provider networks.

• Encounter Data. The OIG will review the accuracy of Part A encounter data on Medicare beneficiaries that MA plans are required to submit to CMS. CMS uses encounter data to develop the risk-adjusted portion of each organization’s monthly capitation rate. The risk-adjusted portion has increased from 10 percent of the monthly rate in 2003 to 75 percent in 2006, and it will eventually be 100 percent of the monthly rate. Accordingly, incomplete or inaccurate encounter data could have a substantial impact on future Medicare reimbursement.
• **Other Provisions.** The OIG will undertake each of the following tasks: determination of the accuracy of payments made by CMS to MAOs after enrollees’ deaths; consideration of the adequacy, appropriateness and timeliness of CMS’ procedures for assessing MA plan proposals and awarding plan stabilization funds (where applicable); evaluation of CMS efforts to address problems identified in past audits of adjusted community rate proposals (“ACRPs”), including the promotion of accuracy in future ACRPs and the repayment or provision of enhanced benefits as necessitated by audit findings; and assessment of the accuracy of the functional impairment data underlying the frailty payment adjustments made for Programs of All-Inclusive Care for the Elderly (“PACE”) Organizations.

**Contractor Operations**

• **Accuracy and Completeness of National Provider Identifier (“NPI”).** The OIG will review accuracy and completeness of the NPI and whether CMS has met program goals for its implementation. In place of legacy provider identifiers, by May 23, 2008, all providers must include their NPI with claims or risk losing their ability to receive Medicare and Medicaid payments.

• **Recovery Audit Contractors: Reducing Medicare Improper Payments.** The OIG will review CMS oversight and monitoring of recovery audit contractors (“RACs”) to determine whether the agency meets the contractual requirements outlined in the RAC Task Orders.

**Other Priority Issues**

• **Health Information Security.** The OIG will review oversight and enforcement by CMS of the HIPAA Security Rule. Specifically, the agency will determine whether CMS has implemented controls adequate to ensure protection of the confidentiality, integrity and availability of electronic health information under the HIPAA Security Rule, focusing on all aspects of electronic security of health information while it is being stored or transmitted between entities.

• **Quality Information Technology Initiatives.** CMS contracts with Quality Improvement Organizations (“QIOs”) to assist independent physician practices (“IPGs”) with improving clinical performance. One aspect of this effort is to assist IPGs with the adoption and implementation of interoperable health information technology (“IT”), including electronic health records. The OIG will assess CMS efforts in this regard and whether QIOs are meeting their contractual obligations. The OIG aims to also identify variations in achievements and obstacles facing IPGs in adopting health IT.

• **Serious Medical Errors (“Never Events”).** The OIG will conduct a number of never event studies over the next two years, as mandated by Congress. Included in these reviews will be a focus on incidence, facility response and payments relating to never events. The OIG also will focus on the adequacy of CMS administrative process for detecting never events and recouping or denying payments for services furnished in connection with an identified never event.
MEDICAID

Prescription Drugs

• **Average Manufacturer Price Calculation.** The OIG will survey certain manufacturers to assess whether their methodologies for calculating AMP comply with their rebate agreements and with all applicable statutes, regulations and Drug Manufacturer Releases (issued by CMS).

• **State Medicaid Drug Claims.** The OIG will determine the accuracy of the Medicaid drug claims submitted by states to CMS for reimbursement and will evaluate whether the payments made by CMS to states for these claims are accurate and supported by the data. The OIG will also assess the completeness of the lists of Medicaid-covered drugs (and their termination dates, where applicable) that are provided quarterly by CMS to states, since CMS guidance directs states to use these lists to confirm that the drugs for which they claim reimbursement are in fact covered.

• **Pharmacy Reimbursement.** In follow-up to its previous finding that most states had not decided as of October 2006 whether to use AMP data for pharmacy reimbursement, the OIG will consider whether and how states are currently using the AMP data that are made available to them on a monthly basis.

• **Pharmacy Purchases.** Previous OIG studies found that pharmacy payments to manufacturers (“pharmacy acquisition costs”) were substantially lower than the average wholesale prices on which most states based pharmacy reimbursement. In the 2008 Work Plan, the OIG notes that Congress expects the AMP provisions of the DRA to increase transparency and competition in drug pricing. Accordingly, the OIG will compare AMPs to pharmacy acquisition costs to evaluate pharmacies’ ability to purchase Medicaid-covered drugs at or near the AMP.

• **Federal Upper Limits.** After the new Medicaid federal upper limits (“FULs”) for certain multiple source drugs are implemented in January 2008, the OIG will evaluate the impacts of these changes on pharmacy Medicaid reimbursement. To follow up on previous OIG and Government Accountability Office findings that the new FULs may fall below pharmacy acquisition costs for some drugs, the OIG will collect data from wholesalers on high-expenditure FUL drugs to determine whether pharmacies are able to obtain drugs at or below the new FULs.

COMMENT

The above represents just a sampling of major OIG initiatives for FY 2008 as found in the 2008 Work Plan. The 2008 Work Plan is extensive and touches upon numerous issues of concern to the OIG. Health care providers and suppliers should pay close attention to those items outlined in the 2008 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 training for personnel. A careful review of the 2008 Work Plan should be undertaken in conjunction with an annual monitoring of each provider’s compliance program.

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