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Client Alert

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# OIG Publishes Fiscal Year 2012 Work Plan

Last week, the U.S. Department of Health and Human Services' Office of Inspector General (OIG) published its work plan for the 2012 fiscal year in which it described its primary objectives for the year. We identify below, by industry sector, certain key objectives that are likely to raise issues for companies and providers during the coming year. All activities identified in the 2012 work plan will not be completed within 2012; however, they are traditional indicators of where the federal government will be focusing efforts to study and prevent fraud, waste, and abuse for the foreseeable future.

## I. Pharmaceutical Industry

The OIG has identified a number of 2012 objectives that could potentially impact the pharmaceutical industry. Among these objectives are items relating to pricing of and payment for pharmaceuticals, rebates offered on pharmaceuticals, and actions taken by government agencies including plans to:

Pricing and Payments

- Review Medicare Part B drug prices by comparing Average Sales Prices (ASP) to Average Manufacturer Prices (AMP) and Widely Available Market Prices (WAMP) to determine if the ASP exceeded either the AMP or WAMP by a designated threshold of 5%;

- Determine the percentage of manufacturers that complied with the AMP reporting requirements to evaluate if increased enforcement by OIG and the Centers for Medicare and Medicaid Services (CMS) impacted reporting rates;

- Review annual changes in prices for brand-name prescription drugs used by Medicare Part D beneficiaries to determine if the prices are rising faster than inflation and if the prices affect Part D payment amounts;

- Review methodologies used by selected drug manufacturers to calculate the AMP and the best price for the Medicaid drug rebate program and for drug reimbursement. OIG will analyze

For more information, contact:

**Seth H. Lundy**
+1 202 626 2924
slundy@kslaw.com

**Patrick Morrisey**
+1 202 626 3740
pmorrisey@kslaw.com

**Preeya Noronha**
+1 202 626 5547
pnoronah@kslaw.com

**John Shakow**
+1 202 626 5523
jshakow@kslaw.com

**Joanne H. Chan**
+1 202 626 2914
jchan@kslaw.com

**Terrence Burek**
+1 202 626 2992
tburek@kslaw.com

**King & Spalding**
***Washington, D.C.***
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500
Fax: +1 202 626 3737

**www.kslaw.com**

whether the methodologies are consistent with statutes, regulations, manufacturers' rebate agreements, and CMS *Drug Manufacturer Releases* and potentially levy penalties against non-compliant manufacturers;

- Compare Federal Upper Limit (FUL) amounts under the Patient Protection and Affordable Care Act methodology to estimate pharmacy acquisition costs for selected drugs to ensure that FULs more accurately reflect pharmacy acquisition costs;

- Review changes to base-date AMPs, including manufacturers' rationales and supporting data, and assess their impact on Medicaid rebates; and

- Compare Medicare and Medicaid payments for commonly used physician-administered drugs and biologicals to determine whether changes in the reimbursement methodologies for the Part B drug program would result in significant savings for the federal government (this recommendation is particularly important in light of CMS' new price setting authorities under the Accountable Care Act).

Rebates

- Review contracted pharmaceutical manufacturer rebates collected by Part D sponsors and pharmacy benefit managers, compare the rebate negotiated to the actual rebates received, and analyze any discrepancies;

- Review drug pricing and rebate data to determine the extent to which manufacturers are reporting pricing data and paying rebates for authorized generic drugs, and whether the number of authorized generic drugs has changed since the implementation of various provisions of the Deficit Reduction Act of 2005;

- Determine whether states are effectively collecting drug rebates from manufacturers for drugs with zero-dollar unit rebate amounts (URA), that is, where the manufacturer has failed to provide CMS with data necessary to calculate URA, and determining the financial impact of zero-dollar URAs; and

- Review drug manufacturers' compliance with Medicaid drug rebate requirements for new drug formulations and determine whether manufacturers have correctly identified all their drugs that are subject to the "new formulation" provision in the Patient Protection and Affordable Care Act.

Agency Actions

- Review CMS's processes for reopening final payment determinations. This review is based on CMS's decision to reopen payment determinations for 2006 and 2007 Part D reconciliations after CMS had previously reopened the 2006 payment determinations for all Part D sponsors;

- Review FDA's process for evaluating Investigational New Drug (IND) applications and assessing FDA's timeliness and identifying challenges in the IND review process;

- Examine the extent to which FDA ensures that drug manufacturers comply with the Risk Evaluation and Mitigation Strategies (REMS) program requirements and review drug manufacturer assessments of the program's efficacy in minimizing risk; and

- Determine the extent to which Drug and Safety Monitoring Boards (DSMB) monitor data in clinical trials and the extent to which NIH is ensuring that grantees are complying with data and safety monitoring requirements.

## II. Medical Device Industry

- At the request of the Senate Finance Committee, determine the extent to which physician-ownership of medical device distributors (physician-owned distributors or PODs), with a particular focus on distributors of spinal implants, results in higher utilization of devices purchased by hospital customers than in cases where physicians have no financial ties to the distributor;

- Review Medicare payments for Part B imaging services to determine whether they reflect the expenses incurred and whether the utilization rates reflect industry practices; and

- Review Medicare payments for high-cost diagnostic radiology tests and clinical laboratory tests to determine whether they were medically necessary.

## III. Home Use Medical Devices: Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Industry

Among OIG's objectives for 2012 are a number of goals that could potentially impact the medical device industry. OIG continues to focus significant resources on fraud, waste, and abuse controls for the DMEPOS sector and is planning a number of new activities, including plans to:

- Review Medicare contractors' processes for enrolling and monitoring DMEPOS suppliers to identify applicants that pose fraud risk or omit ownership information in enrollment applications, which in turn will likely result in increased activity by such contractors, including longer time periods to enroll new suppliers, more supplier audits and larger numbers of revocations of existing supplier privileges;

- Review the credentials of providers submitting claims for custom-fabricated orthotics and prosthetics to determine the extent to which Medicare paid unqualified practitioners in 2009 and provided oversight of orthotist and prosthetist credentialing (*e.g.*, by state licensing boards), which may result in forthcoming overpayment demands;

- Review supplier compliance with Medicare requirements for frequently replaced DMEPOS supplies to determine if payment met Medicare requirements relating to the Certificate of Medical Necessity, and whether beneficiary requests for refills appropriately are being received before refills are dispensed;

- Review the appropriateness of Part B payments made to DMEPOS suppliers for claims with certain modifiers to determine if the provider has furnished necessary information (such as requested documentation) to receive payments, which may result in overpayment demands against suppliers;

- Review Medicaid claims to determine the extent to which state agencies utilize controls to identify claims associated with inactive or invalid national provider identifiers;

- Review performance evaluation reports submitted by the National Supplier Clearinghouse (NSC) to CMS to determine whether and how the NSC performs all contractually-required activities and assess CMS's oversight of NSC to ensure that DMEPOS suppliers are appropriately qualified for payment under the Medicare program; and

- Examine claims for replacement medical devices. OIG will investigate whether hospitals have received a warranty or other credit from device manufacturers, in which case Medicare should not pay the full cost of the device. Such claims should contain a modifier indicating a manufacturer credit.

Diabetic Testing Supplies

OIG has shown particular interest in Medicare payments for glucose test strips and lancets and is planning a number of activities in that area including: (1) a review to determine whether payments were made in accordance with requirements in Local Coverage Determinations (LCDs); (2) a review of the effectiveness of claims processing edits used by Durable Medical Equipment Medicare Administrative Contractors (DME MACS) to prevent payments to multiple suppliers of home blood-glucose testing strips and lancets during overlapping service dates; and (3) a review of claims for diabetic testing strips and lancets to identify questionable supplier billing and characteristics that may be indicative of fraud, waste, and abuse. All three of these activities are likely to bring even more scrutiny to this area, including an increase in pre- and post-payment claims reviews and overpayment demands.

DMEPOS Competitive Bidding Program

OIG also appears to be interested in the competitive bidding program that was implemented for certain types of DME and will be reviewing the process used by the CMS to conduct competitive bidding and pricing determinations for certain DMEPOS items and services in Rounds 1 and 2 of the competitive bidding program. OIG plans to interview physicians to determine if competitive bidding suppliers are soliciting physicians to prescribe profitable brands of modes of delivery of covered items and examine billing patterns for changes resulting from competitive bidding. This process will be ongoing as CMS begins the bidding process for Round 2 of the DMEPOS competitive bidding program and a national competitive bidding program for mail order diabetic supplies, both of which are targeted to commence sometime in 2013.

## IV. End-Stage Renal Disease (ESRD) Industry

Among OIG's planned activities in 2012 are a number of objectives relating to the bundled ESRD prospective payment system (ESRD PPS). The work plan includes plans to:

- Review Medicare pricing and utilization under the ESRD PPS and determine whether payments made under the ESRD PPS are in accordance with Medicare requirements;

- Compare facility acquisition costs for certain drugs to OIG's inflation-adjusted costs estimates to determine how drug costs have changed since OIG's last assessment of drug costs;

- Review claims for ESRD beneficiaries entitled to Medicare coverage due to special circumstances (*e.g.*, due to kidney transplant or termination of dialysis) to determine the extent to which the beneficiaries continue to obtain benefits after coverage should have ended; and

- Assess Medicare's oversight of facilities providing outpatient maintenance dialysis services, including CMS's methods for holding state survey and certification agencies and ESRD networks accountable for assessment of facilities.

**V. Other General OIG Objectives and Activities**

In the 2012 work plan, OIG also identifies a number of broad objectives that affect federal health care programs generally, with potential impacts on numerous industries. These objectives relate to the practices of Medicare contractors, complaint handling by various agencies, and OIG's legal and enforcement priorities.

Medicare Contractor Practices

- Review the variation in Medicare spending and coverage due to differences in LCDs and CMS's monitoring and oversight of LCDs. OIG will also examine the evidence that Medicare contractors use to determine LCDs; and

- Review the process used and the timeliness of Medicare contractors in making determinations on requests for reconsideration at the first level of Medicare appeals.

Complaint Handling

- Review and describe cases decided by Medicare administrative law judges (ALJs) in FY 2010 and determine the extent to which CMS and its contractors participate in ALJ hearings; and

- Determine the adequacy of FDA's complaint investigation process. OIG will examine whether complaints are properly recorded and expeditiously investigated and examine FDA's processes for utilizing complaints to identify potentially significant trends in reported illnesses/injuries to protect the public against injury and illness from contaminated or harmful foods, feed, drugs, cosmetics, medical devices and biological products.

Legal and Enforcement Priorities

OIG will continue its extensive legal and enforcement activities:

- Exclude individuals and entities from participation in Medicare, Medicaid, and all other federal health care programs for participating in prohibited activities identified in the Social Security Act;

- Impose civil money penalties (CMP) for submitting false or fraudulent claims; offering, paying, soliciting, or receiving illegal remuneration; violating EMTALA; or participating in other prohibited activities identified in the Social Security Act; and

- Pursue false claims against individuals and entities who attempt to defraud the government. OIG will also review entities that settled fraud cases with the government but declined to enter into a corporate integrity agreement (CIA). OIG's review may be similar to or more extensive than those that would be performed by Independent Review Organizations under CIAs to assess the entity's compliance with Federal health care program standards.

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The 2012 work plan reveals areas in which OIG will likely have increased activity. Industry members are well advised to examine their practices in these identified areas to ensure compliance with requirements and avoid increased governmental scrutiny. The full OIG 2012 work plan can be accessed at: http://oig.hhs.gov/reports-and-publications/workplan/index.asp.