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Client Alert

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OIG Publishes Work Plan for Fiscal Year 2010 Affecting FDA-regulated Industry

The Office of Inspector General (OIG) released its Work Plan for Fiscal Year 2010. The Work Plan outlines the specific audits and evaluations that the agency has either initiated or intends to begin in 2010. It also addresses the general focus areas for the agency's investigative, enforcement, and compliance activities.

Although a large number of topics identified in the 2010 Work Plan involve Medicare and Medicaid issues affecting hospitals, home health agencies and nursing homes, the OIG identifies some initiatives that are relevant to industries regulated by the Food and Drug Administration. This bulletin will address only those issues that concern FDA and FDA-regulated industry, in addition to the OIG's general investigative plans.[1] Among the many issues that the OIG has identified, the following areas should be of particular interest to the FDA-regulated industry.

FDA-Specific Public Health Programs

- Examination of FDA's food facility inspection process, including its methods for selecting facilities for inspection and the extent to which FDA identifies and addresses any violations.
- Assessment of FDA's oversight of food facility inspections which are conducted through contracts and partnership agreements and its use of information from State inspections, in order to determine if the agency's performance has improved since the OIG's review in 2000.
- Review of FDA's oversight related to imported pet food and feed products and its policies to determine if the agency requires adherence to the same safety standards for domestic production of such items. In addition, the OIG will assess FDA's policies regarding the sampling of these products for chemicals and microbial pathogens.
- Evaluation of FDA's complaint investigation process for foods, feed, drugs, cosmetics, medical devices, and biological products and its processes for categorizing and using complaints to identify potentially significant trends or patterns in reported illnesses or injuries.

1 This Client Alert provides a general overview of the 2010 Work Plan and is not intended to be an in-depth analysis of how the OIG's initiatives may affect specific sectors or types of companies. In addition, for a summary of those initiatives affecting physicians, please click here to see the AGG Client Alert by Sidney Welch and Meredith Burris.

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- Assessment of the extent to which drug manufacturers use foreign clinical trials to support new drug applications and biologics license applications and the agency's process for reviewing such data.
- Evaluation of FDA's process for evaluating investigational new drug applications to identify challenges in the review process and assess the agency's timeliness with such applications.
- Assessment of FDA oversight of licensed blood establishments to determine whether the agency's inspection of such facilities and monitoring of blood deviations meet statutory requirements to ensure the safety of national blood supply.

Medicare Part B Payments for Prescription Drugs

- Assessment of renal dialysis facility protocols for erythropoiesis-stimulating agents to ensure adherence to FDA labeling recommendations.
- Review of Medicare Part B immunosuppressive drug reimbursement claims to ensure appropriate billing, in accordance with FDA-approved labels.
- Evaluation of Medicare payments for drugs and biologicals used off-label in anticancer chemotherapeutic regimens to determine whether patients were prescribed FDA-approved anticancer drugs for such indications prior to use of anticancer drugs used on off-label basis.

Medicare Contractor Operations and Part D Prescription Drug Program

- Examination of Durable Medical Equipment claims to assess the extent of supplier influence on physicians' prescription of certain brands or modes of delivery of covered items.
- Comparison of pharmaceutical manufacturer rebates collected by Medicare Part D sponsors and Pharmaceutical Benefit Managers with the rebate amounts that were negotiated for any discrepancies.
- Analysis of potential savings to the Part D program if the Medicaid percentage rebate amount is applied to Part D covered brand-name drugs.
- Review of price concessions obtained by Part D sponsors and their method of reporting such concessions.

General Investigative and Legal Activities Affecting the FDA-Regulated Industry

- Healthcare fraud investigations to identify false claims and, specifically, program vulnerabilities in the Medicare Part D drug benefit, including enrollment and marketing plans and prescription "shorting" (e.g., dispensing fewer doses of a drug than prescribed but still charging the full amount).
- Ongoing efforts to exclude individuals and entities from participation in Federal health care programs as necessary and encourage provider self-disclosure of improper conduct.
- Continued development and resolution of False Claims Act cases against individuals and entities that defraud the U.S. Government.

- Negotiation and assessment of Corporate Integrity Agreements through site visits, verification of compliance efforts, and systems review processes.
- Issuance of advisory opinions, fraud alerts, and other industry guidance to foster compliance efforts by providers and industry groups.
- Ongoing pursuit of civil monetary penalty cases for false or fraudulent claims or other violations triggering the OIG's authority to impose such sanctions.