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OIG Reports \$25.9 Billion in Savings and Expected Recoveries in FY 2010

In its *Semiannual Report to Congress*, the Department of Health & Human Services (HHS) Office of Inspector General (OIG) today announced recent successes in the fight against fraud, waste, and abuse. OIG reported savings and expected recoveries of \$25.9 billion for all of fiscal year (FY) 2010. The report highlights audit, investigation, and evaluation accomplishments for the second half of FY 2010 (April 1, 2010 – September 30, 2010) and for FY 2010 in total.

Specifically, OIG's \$25.9 billion in savings and expected recoveries includes \$21 billion in implemented recommendations to put funds to better use, \$3.8 billion in investigative receivables, and \$1.1 billion in audit receivables.

“Along with our significant work related to a variety of HHS agency programs during this reporting period, we are particularly encouraged by the success of our partnerships with HHS and the Department of Justice through the Health Care Fraud Prevention and Enforcement Action Team (HEAT),” said Inspector General Daniel R. Levinson. “For example, our HEAT Strike Force teams yielded 89 convictions and \$71.3 million in investigative receivables in the second half of FY 2010 alone.”

This past July, OIG's Special Agents participated in an unprecedented health care fraud takedown in seven cities that resulted in charges against 94 doctors, health care company owners, executives, and others for more than \$251 million in alleged false billing.

Additionally, in FY 2010, OIG excluded 3,340 individuals and organizations from participation in Federal health care programs. OIG reported 647 criminal actions against individuals or organizations that engaged in crimes against HHS programs and 378 civil actions, including False Claims Act and unjust enrichment suits filed in Federal district court, Civil Monetary Penalties Law settlements, and administrative recoveries related to provider self-disclosure matters. OIG work also prevents fraud and abuse through deterrence and by recommending actions to remedy program vulnerabilities.

Other OIG accomplishments during the semiannual reporting period include the following:

AstraZeneca Pays \$520 Million To Resolve False Claims Violations

AstraZeneca, LP, and AstraZeneca Pharmaceuticals, LP, (collectively, AstraZeneca) agreed to pay \$520 million plus interest and enter into a 5-year Corporate Integrity Agreement to resolve their civil False Claims Act liability in connection with the promotion of the atypical antipsychotic drug Seroquel. AstraZeneca was alleged to have

promoted Seroquel between January 2001 and December 2006 for uses that were not approved by the Food and Drug Administration (FDA) as safe and effective. AstraZeneca also was alleged to have violated the Federal anti-kickback statute by offering and paying illegal remuneration to doctors in connection with services rendered by the doctors relating to the unapproved uses of Seroquel.

Analysis of Errors Identified in Medicare Comprehensive Error Rate Testing Program

This analysis found that six types of Medicare health care providers accounted for \$4.4 million, or 94 percent, of the \$4.7 million in improper payments identified by the Centers for Medicare & Medicaid Services' (CMS) Comprehensive Error Rate Testing (CERT) contractor for FY 2009. The provider types were inpatient hospitals, durable medical equipment suppliers, hospital outpatient departments, physicians, skilled nursing facilities, and home health agencies. Analysis of the erroneous claims identified by the CERT contractor found that insufficient documentation, miscoded claims, and medically unnecessary services and supplies accounted for about 98 percent of the improper payments attributable to the six types of providers. CMS concurred with OIG's recommendation to use the results of the analysis in identifying (1) the types of payment errors indicative of programmatic weaknesses and (2) any additional corrective actions needed to strengthen the CERT program.

Challenges to FDA's Ability To Monitor and Inspect Foreign Clinical Trials

OIG found that in FY 2008, sponsors relied heavily on data from foreign clinical trials to support their marketing applications for drugs and biologics. The Food, Drug, and Cosmetic Act requires all new investigational drugs and biologics to undergo clinical trials on human subjects to demonstrate the safety and efficacy of these products prior to approval for sale in the United States. Sponsors may submit data from foreign and domestic clinical trials to support marketing applications. OIG found that 80 percent of approved marketing applications for drugs and biologics contained data from foreign clinical trials. Further, over half of clinical trial subjects and sites were located outside the United States. OIG found that FDA inspected less than 1 percent of foreign clinical trial sites. Challenges in conducting foreign inspections and data limitations inhibit FDA's ability to monitor foreign clinical trials.

Nine Health Care Employees Sentenced After Death of At-Risk Child

Nine employees at MultiEthnic Behavioral Health Services, Inc., (MEBH) were sentenced to prison terms ranging from 15 months to 17½ years and were ordered to pay joint and several restitution ranging from \$316,000 to \$1,216,000, resulting from charges related to health care fraud and the death of an at-risk child who was under MEBH's care. Federal and local investigators found that MEBH employees did not provide any services to the at-risk child with cerebral palsy, even though she was under their care. The child suffered severe bed sores and extreme weight loss as she slowly starved to death. MEBH employees then attempted to conceal the incident by destroying old records and creating new false records of the child's care. The defendants' fraudulent activity also included creating false documentation for visits that did not occur, forging guardian signatures, destroying records, and fabricating other medical documents.

FDA Inspections of Domestic Food Facilities

OIG identified significant weaknesses in FDA's inspections of food facilities. FDA inspects food facilities to ensure food safety and compliance with regulations. OIG found that FDA inspects less than a quarter of food facilities each year. In addition, more than half of all food facilities have gone 5 or more years without an FDA inspection. Moreover, for 36 percent of the facilities that received "official action indicated" (OAI) classifications, FDA took no additional steps to ensure that the violations were corrected. We recommended that FDA take regulatory action when an inspection identifies violations that are significant enough to warrant an OAI classification. This regulatory action could include issuing a warning letter; holding a regulatory meeting; or initiating an enforcement action, such as a seizure or an injunction.

Businesses Agree To Pay \$7.3 Million To Settle Stark Law Violations

Physician-owned United Shockwave Services, Ltd; United Urology Centers, LLC; and United Prostate Centers, LLC, (collectively, United) agreed to pay \$7,359,500 and, along with United Therapies, LLC, enter into a 5-year CIA to resolve their Civil Monetary Penalties Law liability. The settlement resolves allegations that United violated the anti-kickback statute by soliciting remuneration from hospitals in exchange for patient referrals. Specifically, it was alleged that United threatened hospitals that it would refer patients to competing hospitals if they did not agree to a contract with United, or promised additional referrals to hospitals that did contract with United Public Health.

Invalid Prescriber Identifiers on Medicare Part D Drug Claims

OIG found that Medicare drug plans and enrollees paid pharmacies \$1.2 billion in 2007 for more than 18 million prescription drug claims that contained 527,749 different invalid prescriber identifiers. These invalid identifiers either (1) were not listed as valid identifiers in the National Provider Identifier, Drug Enforcement Administration number, or Unique Physician Identification Number registry databases or (2) had been deactivated or retired before January 1, 2006. For 17 percent of the drug claims that contained invalid prescriber identifiers, the identifiers did not conform to length or format requirements. OIG's review also revealed that only 10 identifiers accounted for 17 percent of all drug claims with invalid prescriber identifiers in 2007. These drug claims represented \$237 million in payments by Medicare drug plans and enrollees. One of the top ten invalid prescriber identifiers was recorded on almost 1.8 million prescription drug event records for more than 150,000 beneficiaries enrolled with 248 different Medicare drug plan sponsors. These plan sponsors and enrollees paid pharmacies almost \$105 million for drug claims with this single invalid identifier. In addition, 5 of the top 10 invalid identifiers appeared on individual claims for very expensive drugs, with payment amounts totaling more than \$10,000 per claim.

To read the full *Semiannual Report to Congress*, go to the following link:

<http://oig.hhs.gov/publications/sar/2010/>