



OIG NEWS

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Office of Inspector General
Department of Health
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330 Independence Ave., SW
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OIG Reports More Than \$20.4 Billion in Savings and Recoveries

In its Semiannual Report to Congress, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) announced significant audit, evaluation, and investigation accomplishments for the second half of fiscal year (FY) 2008 (April 1, 2008–September 30, 2008). OIG reported savings and expected recoveries of more than \$20.4 billion for all of FY 2008.

Specifically, OIG’s \$20.4 billion in savings and expected recoveries includes \$16.72 billion in implemented recommendations to put funds to better use, \$1.33 billion in audit receivables, and \$2.35 billion in investigative receivables.

“OIG has achieved significant results in the fight against fraud, waste, and abuse in HHS programs,” said Inspector General Daniel R. Levinson. “While these programs continue to grow in size, scope, and complexity, the dedicated efforts of our professional staff nationwide, in collaboration with our government partners, have once again yielded notable accomplishments in program savings, program integrity and efficiency, and quality of care.”

In FY 2008, OIG excluded from participation in Federal health care programs 3,129 individuals and organizations for convictions for health-care-related crimes and for patient abuse or neglect or as a result of license revocation. In addition, OIG reported 775 criminal actions brought against individuals or organizations that engaged in crimes against HHS programs and pursued 342 civil actions, which include False Claims Act (FCA) and unjust enrichment suits filed in district court, Civil Monetary Penalties Law settlements, and administrative recoveries related to provider self-disclosure matters.

OIG significant accomplishments during this period include:

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Cephalon To Pay \$425 Million Plus Interest for Marketing Three of its Drugs for Uses Not Approved by the Food and Drug Administration

As part of a global criminal, civil, and administrative settlement, Cephalon, Inc., agreed to pay \$375 million plus interest to resolve its FCA liability for the off-label marketing (that is, marketing for uses not approved by the Food and Drug Administration (FDA)) of the drugs Actiq, Gabitril, and Provigil; plead guilty to a misdemeanor violation of the Federal Food, Drug, and Cosmetic Act; and pay a \$50 million criminal fine. Cephalon also agreed to enter into a comprehensive 5-year corporate integrity agreement (CIA) that contains several unique provisions, including a requirement that Cephalon notify doctors about the settlement and establish a way for them to report questionable conduct by sales representatives.

Marketing Materials for Medicare Prescription Drug Plan

In our review of marketing materials developed by stand-alone Medicare prescription drug plans (PDP) in 2007, we found that the Centers for Medicare & Medicaid Services (CMS) provided limited oversight of the materials and that 85 percent of the materials failed to meet at least one element of the agency's guidelines. These deficiencies ranged from omitting required information about PDP benefits and rules to not using the required font size for footnotes. We found that, among other problems, CMS's model documents were not fully consistent with the agency's own guidelines, which in turn resulted in problems with PDP marketing materials. We recommended that CMS ensure that model documents are consistent with the guidelines, develop protocols for reviewing marketing materials, conduct more frequent retrospective reviews of file-and-use materials, enforce the use of the materials tracking system, and enhance the tracking system to include an identifier for marketing materials written in non-English languages and alternative formats. CMS agreed with our recommendations. (OEI-01-06-00050)

Merck Agrees To Pay More Than \$650 Million To Resolve Claims of Fraudulent Price Reporting and Kickbacks

Merck and Company, Inc. (Merck), agreed to pay more than \$650 million to resolve allegations that it failed to pay proper rebates to Medicaid and other Government health care programs and paid illegal remuneration to health care providers to induce them to prescribe the company's products. The allegations were brought in two separate lawsuits filed by whistleblowers under the qui tam provisions of the FCA. According to the allegations, Merck offered hospitals deep discounts on its products Pepcid, Vioxx, Zocor, and Mevacor, then overcharged Government programs by failing to properly include these discounts in the "best prices" reported to CMS under the Medicaid drug rebate program.

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Hospital Agrees To Pay \$88.9 Million in One of the Largest Civil Fraud Recoveries Ever Against an Individual Hospital

In one of the largest civil fraud recoveries ever against a single U.S. hospital, Staten Island University Hospital agreed to pay nearly \$89 million to resolve allegations that it defrauded Medicare, Medicaid, and TRICARE (the military's health insurance program). The settlement resolves two separate lawsuits filed in the U.S. District Court for the Eastern District of New York under the qui tam provisions of the FCA and two investigations conducted by the United States, including one initiated under OIG's Self-Disclosure Protocol. As part of the settlement, the hospital entered into a 5-year CIA.

Medical Review of Claims in the Comprehensive Error Rate Testing Program

In our review of CMS's Comprehensive Error Rate Testing (CERT) program, we estimated the error rate in the FY 2006 CERT durable medical equipment (DME) sample at 17.3 percent or 28.9 percent, depending on the extent of documentation reviewed. CMS established the CERT program to produce a Medicare fee-for-service paid claim error rate, which it reports annually to Congress pursuant to the Improper Payments Act of 2002. Our two-part review, performed by an independent medical review contractor, initially used the same procedures and limited medical records as CMS's CERT contractor and produced an error rate of 17.3 percent. The second part of our review, which used additional medical records from physicians and other health care providers and information from beneficiaries and providers, produced the higher error rate of 28.9 percent. We recommended that CMS require the CERT contractor to review all available supplier documentation and all medical records necessary to determine compliance with applicable requirements on medical necessity and contact the beneficiaries named on high-risk claims to determine whether the DME items were received and were medically necessary. CMS generally concurred. (A-01-07-00508)

The Food and Drug Administration's Generic Drug Review Process

In our review of generic drug applications reviewed by FDA in 2006, we determined that FDA had opportunities to better manage current reviews and to potentially increase the number of submissions reviewed and approved within 180 days. To market a generic drug, a pharmaceutical company must obtain FDA's approval of an Abbreviated New Drug Application (ANDA) and the agency is required by Federal law to approve or disapprove original ANDAs within 180 days of receipt. Of the original ANDAs that FDA reviewed in 2006, 96 percent did not meet review standards and were disapproved. FDA exceeded the 180-day statutory review requirement for nearly half of the ANDAs. We recommended that FDA identify common ANDA deficiencies and offer more guidance to the industry to decrease the percentage of disapproved original ANDAs, increase the percentage of original ANDAs that are reviewed by all divisions within 180 days, and implement new prioritization practices. FDA agreed with the first recommendation but did not indicate concurrence with the other two. (OEI-04-07-00280)

To read the full Semiannual Report:

http://www.oig.hhs.gov/publications/docs/semiannual/2008/semiannual_fall2008.pdf