OIG NEWS

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OIG Reports Record $43 Billion in Savings and Recoveries

The Department of Health and Human Services (HHS) Office of Inspector General (OIG) Semiannual Report to Congress reported total fiscal year (FY) 2007 savings and expected recoveries of $43 billion; $5 billion more than last year and more than double the savings and recoveries of just five years ago.

OIG's FY 2007 $43.08 billion in savings encompasses $39 billion in implemented recommendations and other actions to put funds to better use; $1.9 billion in audit receivables, up from $789 million in FY 2006; and $2.18 billion in investigative receivables, an increase of $578 million from FY 2006.

"We will build on the work summarized in this report and continue to concentrate resources where challenges are greatest and benefits most advantageous to taxpayers and beneficiaries," said Inspector General Daniel R. Levinson. "Such challenges include continued attention to Medicare Part D; Medicare, Medicaid, and SCHIP payment integrity; Medicaid administration; quality of care; public health emergency preparedness and response; food, drug, and medical device safety; grants management; information technology systems and infrastructure; and ethics program oversight and enforcement."

Also for this reporting period, OIG reported exclusions of 3,308 individuals and entities for engaging in fraud or abuse with respect to Federal health care programs and/or their beneficiaries; 447 criminal actions against individuals or entities that engaged in crimes against departmental programs; and 262 civil actions, which include False Claims Act and unjust enrichment suits filed in district court, Civil Monetary Penalties Law settlements, and administrative recoveries related to provider self-disclosure matters.

Among OIG accomplishments in this reporting period:

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Purdue Companies and Three Executives to Pay Nearly $635 Million for Fraudulently Marketing OxyContin

As part of a global criminal, civil, and administrative settlement, the Purdue Frederick Company, Inc., and Purdue Pharma L.P. (collectively, the Purdue Companies), and three top executives agreed to pay almost $635 million to resolve a variety of Federal, State, and private liabilities.

Specifically, the settlement resolved allegations that the Purdue Companies waged a fraudulent and deceptive marketing campaign aimed at convincing doctors nationwide that OxyContin, because of its time-release formula, was less prone to abuse and that it was less likely to cause addiction or to produce other narcotic side effects than competing immediate release opioids.

The Purdue Frederick Company, Inc. is subject to a 25-year exclusion; Purdue Pharma L.P. agreed to enter into a 5-year corporate integrity agreement (CIA) with OIG.

South Florida Medicare Fraud

OIG has employed a multifaceted approach to fighting Medicare fraud in South Florida. Along with our partners and the U.S. Attorney's Office for the Southern District of Florida, we developed innovative methods to identify and prosecute fraud in a timely manner, resulting in $54.3 million in investigative receivables and a number of indictments.

Additionally, we analyzed the claims patterns of HIV/AIDS infusion therapy providers and beneficiaries in three South Florida counties and determined that in the last half of 2006, these counties accounted for half of the total amount, and 79 percent of the amount for drugs, billed nationally for Medicare beneficiaries with HIV/AIDS. We also found that the approaches CMS and its contractors have used to control these aberrant billing practices have not proven effective.

We recommended that CMS treat South Florida as a high-risk area, mandate site visits for certain providers, adjust contractor standards for processing new applications, modify the Statement of Work for the jurisdiction that includes South Florida, review all reassignments in high-risk areas, and strengthen revocations.

FDA's Oversight of Clinical Trials through Its Inspection Processes

We identified data limitations and other factors that affect the Food and Drug Administration's (FDA) ability to effectively manage the Bioresearch Monitoring (BiMo) program.

For example, FDA is unable to identify all clinical trials and institutional review boards (IRB), and it lacks a single database for tracking its own inspections. Furthermore, the three FDA centers and the Office of Regulatory Affairs inconsistently classify some inspections.

In addition, FDA's guidance and regulations do not reflect current clinical trials practices. Finally, we estimate that FDA inspected about 1 percent of clinical trials for the fiscal year 2000–2005 period.

We recommended that FDA take the following steps to improve its information systems and processes: (1) develop a clinical trial database that includes all clinical trials, (2) create an IRB registry, (3) create a cross-center database that enables complete tracking of BiMo inspections, (4) establish a mechanism to provide feedback to BiMo investigators on their inspection reports and findings, and (5) seek legal authority to provide oversight that reflects current clinical trial practices.

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Maximus, Inc., Entered Into a $42.65 Million Settlement
Maximus, Inc., a revenue maximization consulting business for State and local jurisdictions throughout the country, agreed to a $42.65 million settlement with the Government to resolve its liability under the FCA. Maximus allegedly filed false claims for Medicaid-funded targeted case management services, which assist foster children with their medical, social, and educational needs.

As part of the global settlement agreement, Maximus entered into a 5-year CIA and into a 24-month deferred prosecution agreement. In a novel provision, the CIA requires that OIG's Office of Audit Services perform the claims and contract reviews that are ordinarily performed by an Independent Review Organization.

Advanced Neuromodulation Systems, Inc., Entered into a $2.95 Million Settlement
To resolve its liability under the CMPL, Advanced Neuromodulation Systems, Inc. (ANS), a medical device manufacturer, paid $2.95 million and entered into a 3-year CIA to settle allegations that it engaged in a marketing program in which physicians were paid kickbacks for patient referrals.

Specifically, ANS allegedly paid illegal remunerations for the purchase or lease of its medical devices and for patient trials using ANS's spinal cord simulator.

Use of Health Information Technology in State Medicaid Programs
We found that 12 State Medicaid agencies have implemented 16 health information technology (HIT) initiatives for Medicaid beneficiaries and participating providers including claims-based electronic health records initiatives, electronic prescribing initiatives, remote disease-monitoring initiatives, and personal health records initiatives We also found that 25 State Medicaid agencies are currently involved in planning an developing statewide health information exchange (HIE) networks.

Lastly, we found that 13 State Medicaid agencies are incorporating the Medicaid Information Technology Architecture (MITA) into their HIT and HIE planning. We recommended that CMS continue to support the goals of MITA, collaborate with other Federal agencies an offices to assist State Medicaid agencies with developing privacy and security policies and continue to work with the Office of the National Coordinator for HIT to ensure that State Medicaid initiatives are consistent with national goals.

The Semiannual report describes OIG investigations and evaluation and audit reports finalized during the reporting period. This publication is a significant indicator of the progress OIG has made and the challenges the Department faces in achieving even greater economy and efficiency.

To read more about OIG activities to identify fraud and abuse involving HHS programs, go to:
http://oig.hhs.gov/publications/docs/semiannual/2007/SemiannualFinal2007.pdf

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