

CMS-Related Legal and Investigative Activities

Acronyms and Abbreviations for Selected Terms:

CIA—corporate integrity agreement
CMP—civil monetary penalty
CMS—Centers for Medicare & Medicaid Services
CPG—compliance program guidance

DOJ—Department of Justice
HEAT—Health Care Fraud Prevention and Enforcement
Action Team
MFCU—[State] Medicaid Fraud Control Unit

Legal Activities

OIG's resolution of civil and administrative health care fraud cases includes litigation of program exclusions and civil monetary penalties (CMPs) and assessments. OIG also negotiates and monitors corporate integrity agreements (CIAs) and issues fraud alerts, advisory bulletins, and advisory opinions. OIG develops regulations within its scope of authority, including safe harbor regulations under the anti-kickback statute, and provides compliance program guidance (CPG). OIG encourages health care providers to promptly self-disclose conduct that violates Federal health care program requirements and provides them a self-disclosure protocol and guidance.

Exclusions From Program Participation

OIG may exclude individuals and entities from participation in Medicare, Medicaid, and all other Federal health care programs for many reasons, some of which include program-related convictions, patient abuse or neglect convictions, licensing board disciplinary actions, or other actions that pose a risk to beneficiaries or programs. (Social Security Act, § 1128, § 1156, and other statutes.) Exclusions are generally based on referrals from Federal and State agencies. We work with these agencies to ensure the timely referral of convictions and licensing board and administrative actions. In FY 2014, OIG excluded 4,017 individuals and entities from participation in Federal health care programs. Searchable exclusion lists are available on OIG's Web site at:

- <http://exclusions.oig.hhs.gov/>

Civil Monetary Penalties

OIG pursues CMP cases, when supported by appropriate evidence, on the basis of the submission of false or fraudulent claims; the offer, payment, solicitation, or receipt of remuneration (kickbacks) in violation of the Social Security Act, § 1128B(b); violations of the Emergency Medical Treatment and Labor Act of 1986; items and services furnished to patients of a quality that fails to meet professionally recognized standards of health care; and other conduct actionable under the Social Security Act, § 1128A, or other CMP authorities delegated to OIG.

False Claims Act Cases and Corporate Integrity Agreements

When adequate evidence of violations exists, OIG staff work closely with prosecutors from the Department of Justice (DOJ) to develop and pursue Federal false claims cases against individuals and entities that defraud the Government. Authorities relevant to this work come from the False Claims Amendments Act of 1986 and the Fraud Enforcement and Recovery Act of 2009. We assist DOJ prosecutors in litigation and settlement negotiations arising from these cases. We also consider whether to invoke our exclusion authority on the basis of the defendants' conduct. When appropriate and necessary, we require defendants to implement CIAs aimed at ensuring compliance with Federal health care program requirements.

Providers' Compliance With Corporate Integrity Agreements

OIG often negotiates compliance obligations with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false claims statutes. Subsequently, OIG assesses providers' compliance with the terms of the CIAs. For example, we conduct site visits to entities that are subject to CIAs to verify compliance, to confirm information submitted to us by the entities, and to assess the providers' compliance programs. We review a variety of types of information submitted by providers to determine whether their compliance mechanisms are appropriate and identify problems and establish a basis for corrective action. When warranted, we impose sanctions, in the form of stipulated penalties or exclusions, on providers that breach CIA obligations. Current CIAs and other integrity agreements are listed on OIG's Web site at:

- http://oig.hhs.gov/fraud/cia/cia_list.asp

Advisory Opinions and Other Industry Guidance

To foster compliance by providers and industry groups, OIG responds to requests for formal advisory opinions on applying the anti-kickback statute and other fraud and abuse statutes to specific business arrangements or practices. Advisory opinions provide meaningful advice on statutes in specific factual situations. We also issue special fraud alerts and advisory bulletins about practices that we determine are suspect and CPG for specific areas. Examples are available on OIG's Web site at:

- Advisory Opinions: <http://oig.hhs.gov/fraud/advisoryopinions.asp>
- Fraud Alerts: <http://oig.hhs.gov/compliance/alerts/index.asp>
- Compliance Guidance: <http://oig.hhs.gov/fraud/complianceguidance.asp>
- Open Letters: <http://oig.hhs.gov/fraud/openletters.asp>
- Other Guidance: <http://oig.hhs.gov/compliance/alerts/guidance/index.asp>

Provider Self-Disclosure

OIG is committed to assisting health care providers and suppliers in detecting and preventing fraud and abuse. Since 1998, we have made available comprehensive guidelines describing the process for providers to voluntarily submit self-disclosures to OIG of fraud, waste, or abuse. The Provider Self-Disclosure Protocol gives providers an opportunity to minimize the potential costs and disruption that a full-scale OIG audit or investigation might entail if fraud is uncovered. The self-disclosure also

enables the provider to negotiate a fair monetary settlement and potentially avoid being excluded from participation in Federal health care programs.

The protocol guides providers and suppliers through the process of structuring a disclosure to OIG about matters that constitute potential violations of Federal laws (as opposed to honest mistakes that may have resulted in being overpaid by a Federal program). The provider or supplier is expected to thoroughly investigate the nature and cause of the matters uncovered and make a reliable assessment of their economic impact (e.g., an estimate of the losses to Federal health care programs). OIG evaluates the reported results of each internal investigation to determine the appropriate course of action. The self-disclosure guidelines are available on the OIG Web site at:

- <http://oig.hhs.gov/fraud/selfdisclosure.asp>.

On April 17, 2013, OIG updated its Provider Self-Disclosure Protocol, which is available at:

- <http://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf>

Investigative Activities

OIG conducts and coordinates criminal, civil, and administrative investigations of fraud, waste, abuse, and misconduct related to more than 100 HHS programs and operations. The investigations include Medicare and Medicaid fraud, failure-of-care cases, child support enforcement violations, grant and contract fraud, network intrusions, and employee misconduct. Investigations can lead to criminal prosecutions and program exclusions; recovery of damages and penalties through criminal, civil, and administrative proceedings; and corrective management actions, regulations, or legislation. Each year, thousands of complaints from various sources are brought to OIG's attention for review, investigation, and resolution. The nature and volume of complaints and priority of issues vary from year to year. We describe some of the more significant investigative outcomes in OIG's *Semiannual Report(s) to Congress*, which are available on our Web site at:

- <http://oig.hhs.gov/publications.asp>.

See OIG's Consumer Alerts at:

- <http://oig.hhs.gov/fraud/consumer-alerts/index.asp>.

Medicare Fraud Strike Force Teams and Other Collaboration

OIG devotes significant resources to investigating Medicare and Medicaid fraud. We conduct investigations in conjunction with other law enforcement entities, such as the Federal Bureau of Investigation, the U.S. Postal Inspection Service, the Internal Revenue Service, and MFCUs.

The Health Care Fraud Prevention and Enforcement Action Team (HEAT) was started in 2009 by HHS and DOJ to strengthen programs and invest in new resources and technologies to prevent and combat health

care fraud, waste, and abuse. Using a collaborative model, Medicare Fraud Strike Force teams coordinate law enforcement operations among Federal, State, and local law enforcement entities. These teams, now a key component of HEAT, have a record of successfully analyzing data to quickly identify and prosecute fraud.

Strike Force teams were formed in March 2007 and are operating in nine major cities. The effectiveness of the Strike Force model is enhanced by interagency collaboration within HHS. For example, we refer credible allegations of fraud to CMS so it can suspend payments as appropriate. During Strike Force operations, OIG and CMS work to impose payment suspensions that immediately prevent losses from claims submitted by Strike Force targets. In support of Strike Force operations, OIG:

- investigates individuals, facilities, or entities that, for example, bill or are alleged to have billed Medicare and/or Medicaid for services not rendered, claims that manipulate payment codes to inflate reimbursement amounts, and false claims submitted to obtain program funds;
- investigates business arrangements that allegedly violate the Federal health care anti-kickback statute and the statutory limitation on self-referrals by physicians; and
- examines quality-of-care and failure-of-care issues in nursing facilities, institutions, community-based settings, and other care settings and instances in which Federal programs may have been billed for services that were medically unnecessary, were not rendered, or were not rendered as prescribed or in which the care was so deficient that it constituted “worthless services.”

Other areas of investigation include Medicare and Medicaid drug benefit issues and assisting CMS in identifying program vulnerabilities and schemes, such as prescription shorting (a pharmacy’s dispensing of fewer doses of a drug than prescribed, but charging the full amount).

Working with law enforcement partners at the Federal, State, and local levels, we investigate schemes that illegally market, obtain, and distribute prescription drugs. In doing so, we seek to protect Medicare and Medicaid from making improper payments, deter the illegal use of prescription drugs, and curb the danger associated with street distribution of highly addictive medications.

We assist MFCUs in investigating allegations of false claims submitted to Medicaid and will continue to strengthen coordination between OIG and organizations such as the National Association of Medicaid Fraud Control Units and the National Association for Medicaid Program Integrity. Highlights of recent enforcement actions to which OIG has contributed are posted to OIG’s Web site at <http://oig.hhs.gov/fraud/enforcement/criminal/>.