Work Plan Part IV:
Legal and Investigative Activities
Related to Medicare and Medicaid

Table of Contents

Note: selected acronyms and abbreviations of terms, titles, organizations, and laws used in the Work Plan are spelled out in Appendix B.

Legal and Investigative Activities Related to Medicare and Medicaid

Legal Activities

OIG's resolution of civil and administrative health care fraud cases includes litigation of program exclusions and civil monetary penalities (CMP) and assessments. OIG also negotiates and monitors corporate integrity agreements (CIA) 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 issues 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

Pursuant to the Social Security Act, § 1128, § 1156, and other statutes, 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. 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 fiscal year (FY) 2009, OIG excluded 2,556 individuals and entities from participation in Federal health care programs. The total for FY 2010 will be published in OIG's Fall FY 2010 *Semiannual Report to Congress*. 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, based on 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 MedicalTreatment and Labor Act of 1986 (EMTALA); 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.

Resolution of False Claims Act Cases and Negotiation of Corporate Integrity Agreements

When adequate evidence of violations exists, OIG staff members 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 based on 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 integrity agreements. For example, we conduct site visits to entities that are subject to integrity agreements to verify compliance efforts, to confirm information submitted to us by the entities, and to assess the providers' compliance programs. We review a variety 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 integrity agreement obligations. Active CIAs, Certification of Compliance Agreements, and settlement agreements with integrity provisions are listed on OIG's Web site at: http://www.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. For example, in FY 2008, we issued a revised supplemental CPG for nursing facilities, updating the original CPG that was published in 2000 to reflect OIG's focus on quality-of-care issues, including staffing, care plan development, and patient neglect and abuse. Examples are available on OIG's Web site at:

- Advisory Opinions: http://www.oig.hhs.gov/fraud/advisoryopinions.asp
- Fraud Alerts: http://www.oig.hhs.gov/fraud/fraudalerts.asp
- Compliance Guidance: http://www.oig.hhs.gov/fraud/complianceguidance.asp
- Open Letters: http://www.oig.hhs.gov/fraud/openletters.asp

Provider Self-Disclosure

OIG encourages health care providers to promptly self-disclose conduct that violates Federal health care program requirements. In October 1998, OIG announced a self-disclosure protocol for all health care providers. The protocol offers steps, including a detailed audit methodology, that providers may use if they choose to work openly and cooperatively with us. Many

providers, including hospitals, laboratories, and physicians, make disclosures using the protocol.

In a 2006 Open Letter, OIG encouraged health care providers to disclose improper arrangements under the anti-kickback statute and the physician self-referral law and committed, in appropriate cases, to settling liability under OIG's authorities, generally for an amount near the lower end of the damages continuum, i.e., a multiplier of the value of the financial benefit. On April 15, 2008, OIG issued another Open Letter that discussed certain refinements and clarfications of our policies to increase the efficiency of the self-disclosure protocol and benefit providers that self-disclose. The 2008 Open Letter stated that OIG would generally not require compliance obligations in exchange for a release of exclusion authorities. A March 2009 Open Letter further refined the protocol by stating that OIG would no longer accept self-disclosures solely alleging violations of the physician self-referral law.

The self-disclosure protocol is designed only for providers who believe a potential violation of the law has occurred. Matters exclusively involving overpayments or errors that do not indicate violations of the law are brought directly to the attention of the entity responsible for claim processing and payment. Self-disclosure information is available on OIG's Web site at: http://www.oig.hhs.gov/fraud/selfdisclosure.asp.

Investigative Activities

To safeguard programs, protect beneficiaries, and ensure that personnel and contractors uphold the highest level of integrity, the Office of Inspector General (OIG) reviews and investigates allegations of fraud and misconduct. Investigations lead to criminal prosecutions and program exclusions; recovery of damages and penalties through 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://www.oig.hhs.gov/publications.asp.

Health Care Fraud

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 (FBI), the United States Postal Inspection Service (USPS), the Internal Revenue Service (IRS), and State Medicaid Fraud Control Units (MFCU).

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.

We also investigate business arrangements that allegedly violate the Federal health care anti-kickback statute and the statutory limitation on self-referrals by physicians.

OIG examines quality-of-care issues such as in nursing facilities, institutions, community-based settings, and other care settings and instances in which the programs may have been billed for medically unnecessary services, for services either not rendered or not rendered as prescribed, or for substandard care that is so deficient that it constitutes "worthless services."

Other areas of investigative activity include Medicare and Medicaid drug benefit issues and assisting the Centers for Medicare & Medicaid Services (CMS) in identifying program vulnerabilities and schemes such as prescription shorting (a pharmacy dispensing fewer doses of a drug than prescribed, charging the full amount, and then instructing the customer to return to pick up the remainder). Working with law enforcement partners at the Federal, State, and local levels, we investigate schemes to illegally market, obtain, and distribute prescription drugs. In doing so, we seek to protect the Medicare and Medicaid programs from making improper payments, deter the illegal use of prescription drugs, and to curb the danger associated with street distribution of highly addictive medications.

OIG applies lessons learned through our Strike Force work related to fraudulent durable medical equipment (DME). The Strike Force model brings together a multiorganizational and multidisciplinary team that uses real-time analysis of Medicare billing data, as well as findings from earlier investigations, to identify, investigate, and prosecute individuals and companies that have committed DME fraud. Strike Force teams operate in South Florida, Detroit, Houston, Los Angeles, Brooklyn, Tampa, and Baton Rouge.

We assist State MFCUs to investigate 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 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://www.oig.hhs.gov/fraud/enforcement/criminal/.