



OIG NEWS

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VOLUNTARY COMPLIANCE GUIDANCE ISSUED FOR PHARMACEUTICAL MANUFACTURERS

The HHS Office of Inspector General (OIG) today issued final voluntary guidance for pharmaceutical manufacturers that outlines actions they can take to promote compliance with the rules and regulations of doing business with the Medicare, Medicaid and other federal health care programs.

“This guidance explains the value of compliance programs and details specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program,” Inspector General Janet Rehnquist said. “It is designed to help companies prevent health care fraud and abuse by promoting a high level of ethical and lawful corporate conduct.”

The voluntary guidance identifies potential risk areas for the drug industry and recommends various measures to guard against violating federal fraud and abuse laws, including implementing compliance programs, structuring business arrangements to fit in safe harbors, and utilizing OIG fraud alerts, bulletins and advisory opinions. While specific to pharmaceutical manufacturers, the guidance is also expected to be useful to hospitals, physicians and other health care providers that do business with pharmaceutical manufacturers, as well as health care providers that engage in similar financial arrangements.

The 56-page document, entitled *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, is available on the OIG Web site, and is to be published as a notice in the *Federal Register* the week of May 5. It is more expansive and detailed in its discussion of risk areas and compliance strategies than the draft version which was published in the *Federal Register* last October for public review and comment. That solicitation resulted in more than 140 responses, many of which are addressed in the final guidance.

The guidance identifies three major potential fraud and abuse risk areas for pharmaceutical manufacturers:

- integrity of data furnished by manufacturers;

- kickbacks and other illegal remuneration; and
- compliance with laws regulating drug samples.

The guidance emphasizes that drug companies are responsible for providing complete and accurate data to the government. Data reported by manufacturers are often used by the government to determine reimbursement under Medicare and Medicaid.

Drug companies are further cautioned about physician marketing activities, including making excessive payments for physician's consulting and research services, and offering inappropriate entertainment, recreation, travel, meals, gifts, gratuities, and other business courtesies to physicians and other health care providers who influence the prescribing of drugs. Payments by drug companies to physicians and pharmacists to switch patients to their drugs from a competitor's are cited as problematic, as are payments to a physician to listen to a drug representative's sales presentation.

The guidance notes that the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, adopted on April 18, 2002, provides useful and practical advice for reviewing and structuring relationships with physicians and that adherence to the Code will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements.

Also addressed in the guidance are manufacturer arrangements with pharmacy benefit managers (PBMs). The guidance acknowledges the potential benefits of PBM arrangements in controlling drug costs, but cautions that arrangements with PBMs should be properly structured. It further notes that the safe harbor for group purchasing organizations may be available to PBMs.

Another area of concern to the OIG is the improper sale of drug samples. These sales have emerged as a major risk because of violations revealed by recent enforcement activities and the widespread industry practice of providing free samples to physicians. While noting that the public derives significant benefit from the distribution of free drug samples, the guidance warns that both the anti-kickback statute and the False Claims Act may be implicated when the federal health care programs are billed for the samples in violation of the Prescription Drug Marketing Act of 1987. Companies are urged to educate their sales forces and customers about the strictures that govern the distribution of free drug samples and forbids their sale.

This is the eleventh set of voluntary guidelines to be developed by the OIG. Earlier guidance was issued for clinical laboratories, hospitals, home health agencies, third-party billing companies, the durable medical equipment, prosthetics, orthotics and supply industry, Medicare+Choice organizations offering coordinated care plans, hospices, nursing facilities, individual and small group physician practices, and ambulance suppliers. All of the guidances are available on the OIG Web site at <http://oig.hhs.gov/fraud/complianceguidance.html#1>.

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