



An Open Letter to Health Care Providers

April 24, 2006

This Open Letter discusses certain of my perspectives on compliance, the resolution of health care fraud cases, corporate integrity agreements (CIAs), and the OIG's Provider Self-Disclosure Protocol (SDP). I am also announcing an initiative that promotes the use of the SDP to resolve civil monetary penalty (CMP) liability under the physician self-referral and anti-kickback statutes for financial arrangements between hospitals and physicians.

In addition to working with our law enforcement partners to sanction companies and individuals who violate the law, OIG also commits substantial resources to promote voluntary compliance by the health care industry. Our guidance to the industry, in the form of Advisory Opinions, Special Fraud Alerts, Special Advisory Bulletins, and Compliance Program Guidance, offers substantive assistance to program participants committed to promoting ethical and lawful conduct in their organizations. Examples of recent guidance include a Special Advisory Bulletin concerning patient assistance programs for Medicare Part D enrollees, and a supplemental compliance program guidance for hospitals. All of our compliance materials may be found at OIG's Web site, <http://www.oig.hhs.gov>.

When a health care provider is alleged to have violated the law, OIG's first priority is to protect the Department's programs and their beneficiaries. OIG has several tools available for pursuing this goal, including program exclusion, CMPs, and integrity agreements. We will continue to seek the exclusion of providers that demonstrate a lack of integrity, or that provide substandard care to beneficiaries. For those providers that demonstrate the requisite level of trustworthiness and that also have in place, or are willing to develop, an effective compliance program, OIG will waive its exclusion authority concurrent with resolution of monetary liability under the False Claims Act and the CMP Law. Typically, these settlements include an integrity agreement between OIG and the provider.

Effective compliance systems are key to strengthening the integrity of the health care system. OIG integrity agreements have been a catalyst for change in corporate culture, and can result in the development of comprehensive internal control systems. Our communications with providers during the course of our compliance monitoring efforts have also enhanced compliance within their organizations.

While we are committed to working collaboratively with providers operating under integrity agreements, some providers fail to demonstrate a commitment to compliance even while operating under such agreements. Integrity agreements typically include contractual remedies

for breach of the agreement, including stipulated penalties and exclusion from Federal health care programs. Since 1999, OIG has imposed stipulated penalties totaling about \$300,000 in 21 cases where providers have failed to meet explicit requirements of their integrity agreements. In a recent case involving repeated and flagrant violations of a CIA, we excluded a hospital.

The OIG's November 2001 "Open Letter to Health Care Providers" continues to guide decisions about whether to require an integrity agreement and the specific terms of these agreements. Many providers have independently developed robust and effective compliance programs, which include internal auditing mechanisms. In appropriate cases, we have agreed to reduce the obligation on providers settling health care fraud matters by entering into Certification of Compliance Agreements (CCAs), rather than more extensive CIAs. CCAs require providers to certify that they will continue to operate their existing compliance programs for a fixed term, typically 3 years, rather than enter into a more extensive CIA with a 5-year term. CCAs do not require independent review organizations to conduct or verify audits or claims reviews.

A provider's self-disclosure of conduct continues to be an important factor in determining whether a CCA is appropriate, because detection and prompt disclosure of potential fraud are evidence of an effective compliance program. The OIG's 1998 SDP (available on our Web site) sets forth a mechanism for providers to investigate, quantify, and resolve potential fraud matters. Consistent with the 2001 Open Letter, we have required CIAs in only 27 of the 136 self-disclosures resolved with a monetary payment.

OIG has heard from hospitals that, through their compliance programs, they are discovering improper arrangements under the physician self-referral law (42 U.S.C. § 1395nn) and are seeking a way to resolve violations. The SDP is one vehicle to resolve this type of administrative liability. OIG has the authority to impose CMPs of up to \$15,000 for each service billed in knowing violation of the physician self-referral law, and assessments of up to 3 times the amount claimed for such services (see 42 U.S.C. § 1395nn(g)(3)). Hospitals and physicians also have potential liability for these arrangements under OIG's anti-kickback CMP (see 42 U.S.C. § 1320a-7a(a)(7)), which authorizes a penalty of \$50,000 for each kickback, plus an assessment of not more than 3 times the total amount of remuneration offered, paid, solicited, or received. In addition to CMPs, OIG may also seek exclusion under these authorities.

We are now seeking to increase awareness in the hospital and physician communities of a way to resolve conduct that may result in liability under the OIG's CMP authorities for physician self-referral and anti-kickback violations. This new initiative supplements the SDP by providing guidance on how these types of disclosures will be resolved. The initiative incorporates the SDP process, whereby OIG confers with the Department of Justice (DOJ) to ensure that it is aware of each disclosure and has an opportunity to opine before OIG accepts a provider into the Protocol and is presented with the results of OIG's review of the SDP matter before it is resolved under OIG's CMP authorities. It is important to stress that OIG's agreement to resolve an SDP matter is not binding upon DOJ.

The initiative is limited to matters that, in the provider's reasonable assessment, involve conduct that subjects the provider to CMP liability under the OIG's physician self-referral and anti-kickback authorities—in particular, situations involving a financial benefit knowingly conferred

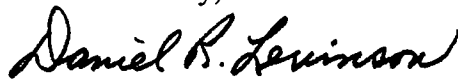
by a hospital upon one or more physicians. The financial benefit conferred upon a physician may take various forms, for example, an arrangement under which the physician pays the hospital below fair market value for a good or service (e.g., lease of office space).

Because multiple OIG authorities are implicated, a provider's liability in these cases typically falls along a continuum—the CMP damages calculation for physician self-referral violations is based on the number and dollar value of improper claims, while the CMP damages calculation for kickbacks is based on the number and dollar value of improper payments or remuneration. Subject to the facts and circumstances of the case, OIG will generally settle SDP matters for an amount near the lower end of this continuum, i.e., a multiplier of the value of the financial benefit conferred by the hospital upon the physician(s).

A provider's participation in the SDP is contingent upon full cooperation and complete disclosure of the facts and circumstances surrounding the violation. Providers will be removed from participation in the initiative unless they disclose in good faith and timely perform the required self-assessment, including quantifying the financial benefits conferred upon the physician(s) and quantifying the full amount of the overpayment. The degree of the provider's cooperation is considered when determining the appropriate terms of an administrative settlement. OIG will also consider the provider's existing compliance program when evaluating whether a CIA, CCA, or no additional compliance measures will be required.

This new self-disclosure initiative will serve as an additional opportunity for providers to work collaboratively with OIG and to take responsibility for further strengthening the integrity of our health care system. I look forward to continuing our joint efforts to promote compliance in the Federal health care programs.

Sincerely,



Daniel R. Levinson
Inspector General