

## LEGAL MATTERS

### PROVIDER SELF-DISCLOSURE PROTOCOL

by Bruce A. Smith, Esq.

To encourage health care providers to voluntarily disclose information on potential violations of laws relating to Federal health care programs, the United States Department of Health & Human Services Office of Inspector General (the "OIG") has released a Provider Self-Disclosure Protocol (the "Protocol"). The Protocol provides detailed guidance to health care providers that decide voluntarily to disclose irregularities in their dealings with the Federal health care programs. The Protocol is posted on the OIG's Internet site ([www.hhs.gov/progorg/oig](http://www.hhs.gov/progorg/oig)).

Unlike an earlier pilot voluntary disclosure program under its Operation Restore Trust demonstration project, the Protocol is open to all health care providers, whether individuals or entities, and is not limited to any particular industry, medical specialty or type of service. While not protected from civil or criminal action under the False Claims Act, providers disclosing fraud are advised in the Protocol that the self-reporting of wrongdoing could be a mitigating factor in OIG's recommendations to prosecuting agencies.

The Protocol explains what information the provider must gather and how to estimate the monetary impact of the disclosed problem, either by reviewing all affected claims or a statistically valid sample. The Protocol emphasizes the importance of random sampling and strongly recommends use of the OIG's Office of Audit Services' Statistical Sampling Software, known as "RAT-STATS", which can be download from the OIG web site.

If a health care provider chooses to make a self-disclosure under the Protocol, the provider must make a writ-

ten submission to the OIG that includes the following:

Name, address provider ID number(s), tax ID number(s), name and address of a designated representative, and a description or dia-



gram describing the relationships, and listing related entities, as well as, affected corporate divisions, departments or branches;

Whether the health care provider knows if the matter is under inquiry by the government, and if so, the government entities involved;

A description of the matter and why the provider believes it may have violated applicable laws and regulations;

The type of provider involved and a list of affected Federal health care programs; and

The provider's certification that the submission is truthful and a good faith effort to bring the mat-

ter to the Government's attention.

The provider must also submit a comprehensive report of its internal investigation and a financial self-assessment of the losses to the Federal health care program(s). The self-disclosure submission does not need to be finalized prior to the provider's initial disclosure to OIG. However, the provider needs to ensure that the submission, internal investigation and the financial self-assessment comply with the OIG's guidelines.

Once the OIG receives a completed disclosure submission (i.e., the disclosure submission plus the provider's internal investigation report and financial self-assessment), the OIG will verify the disclosure information. During this verification process, the OIG must have access to all of the provider's audit work papers and other supporting documents related to the disclosed matter. This requirement may result in the provider waiving certain privileges such as the attorney-client privilege or releasing documents covered by the work product doctrine.

The OIG is not bound by any findings made by the disclosing provider, nor is it obligated to resolve the matter in any particular manner. Indeed, any matters uncovered during the verification process which are outside the scope of the matter disclosed to OIG may be treated as separate matters that were not voluntarily disclosed which could lead to additional investigations.

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