GAO Evaluates Implementation of False Claims Act Guidance

by Sue Prophet, RRA, CCS

With the increased attention to healthcare fraud and abuse in recent years, the Department of Justice (DOJ) has been using the False Claims Act to prosecute healthcare providers for practices that, in the past, might have been dealt with by seeking repayment. The damages and penalties invoked by this act make it a powerful enforcement tool. Hospitals have charged that they have been unfairly targeted with respect to the DOJ's nationwide civil fraud investigations and that the DOJ has been overzealous in its application of the False Claims Act.

In response to concerns expressed by the hospital community and Congress, the DOJ issued guidance in June 1998 on the appropriate use of the False Claims Act in civil healthcare matters, including national healthcare fraud initiatives. This guidance emphasizes the fair and responsible use of the act in all civil healthcare matters, including all current and future national healthcare initiatives. It instructs all DOJ attorneys to determine—before alleging violations of the act—that the facts and the law sufficiently establish that a claimant knowingly submitted false claims. The guidance requires the attorneys to take a number of steps, including reviewing relevant statutes and regulations and verifying the accuracy of the data that the attorneys relied upon, to ensure that they support the allegations.

Regarding national initiatives, the guidance generally requires that US Attorneys' offices use contact letters to notify providers of their potential exposure under the False Claims Act and to offer the providers an opportunity to discuss the matter before a specific demand for payment is made. Workgroups must be established for each current and future national initiative in order to coordinate the development and implementation of the initiatives. The workgroups are expected to prepare initiative-specific guidance, such as a legal analysis of pertinent issues, a summary of relevant claims data, and an investigative plan to guide the US attorneys' offices participating in the national initiatives.

Concerns about the DOJ's implementation of the guidance prompted Congress to add a provision to the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (PL 105-277) that requires the General Accounting Office (GAO) to monitor the DOJ's and the US Attorneys' offices' compliance with the guidance. The GAO was required to issue two reports on the results of this monitoring effort. In the first report (issued in February 1999), the GAO reported that the DOJ designated four national initiatives involving hospitals—laboratory unbundling, 72-hour window, prospective payment system transfers, and pneumonia upcoding—and had established workgroups for each. These workgroups consisted of representatives from the DOJ and selected US Attorneys' offices.

At that time, the DOJ began taking steps to ensure that the US Attorneys' offices complied with the guidance. The DOJ incorporated the guidance into its training programs and was planning to include an assessment of compliance with the guidance in its ongoing reviews of the US Attorneys' offices. The GAO's initial report also noted that several US Attorneys' offices had closed a large number of investigations related to any one of the four national initiatives without taking action against any providers.

The GAO's second report, "Medicare Fraud and Abuse: DOJ's Implementation of False Claims Act Guidance in National Initiatives Varies," issued in August 1999, described the results of the monitoring of the DOJ's and selected US Attorneys' offices' compliance with the guidance. The GAO examined the following:

- the status of the workgroups' efforts and the initiative-specific guidance they prepared
- the DOJ's efforts to assess US Attorneys' offices' compliance with the guidance
- implementation of the guidance at selected US Attorneys' offices
- state hospital associations' concerns regarding the DOJ's use of the False Claims Act

The GAO visited 10 US Attorneys' offices as part of their monitoring activities. Eight of these 10 offices were participating in at least one of the national initiatives.

The GAO report noted that the DOJ's national initiative workgroups continue to make progress in implementing the False Claims Act guidance since the February report was issued. All four workgroups have completed their examination of the legal and factual basis for their initiatives and have prepared initiative-specific guidance for the US Attorneys' offices participating in the initiatives. The GAO determined that the guidance prepared by these workgroups is consistent with the requirements in the DOJ's guidance. The GAO noted that all of the workgroups developed model contact letters for notifying providers that they were subjects of False Claims Act investigations. These letters were carefully worded to avoid any inference that the providers had violated the False Claims Act. The new letters do not include a specific demand for payment and the GAO feels that they do not contain the type of language that many hospitals previously found to be intimidating and coercive.

The documents prepared by the laboratory unbundling, PPS transfer, and pneumonia upcoding workgroups included investigative plans containing specific suggestions for conducting investigations of individual hospitals. These plans outline procedures to determine whether claims submitted by these hospitals were false and, if so, whether the hospitals knowingly submitted them. The workgroups' materials also addressed the source, limitations, and reliability of the claims data to be used in the investigations. The GAO concluded that the documentation prepared by these three workgroups was consistent with the requirements outlined in the DOJ's guidance.

The 72-hour window workgroup prepared a report that assessed the initiative's activities in light of the DOJ's guidance, rather than the detailed guidance prepared by the other workgroups. Unlike the other three national initiatives, which are being conducted by multiple US Attorneys' offices, a single US Attorneys' office is conducting the 72-hour window initiative. For this reason, and because this initiative was more than two-thirds complete at the time the guidance was issued, this workgroup did not develop the same step-by-step instructions that were developed by the other workgroups. However, the GAO concluded that the report of this workgroup satisfied the requirements established by the DOJ's guidance. The report evaluated the accuracy of the data used in the initiative, the clarity of the relevant billing rules, and the appropriateness of the US Attorneys' office's approach for completing the initiative.

The GAO's review concluded that the implementation of the DOJ guidance by US Attorneys' offices varied among the national initiatives. For example, offices participating in the laboratory unbundling initiative took action in their investigations prior to the issuance of the False Claims Act guidance that were, to varying degrees, inconsistent with the guidance (e.g., demand letters alleging violations of the False Claims Act were sent to hospitals, insufficient analysis of claims data to determine if pervasiveness and magnitude of errors were enough to warrant alleging a False Claims Act violation). The GAO found that most of these US Attorneys' offices had not yet completed actions to bring their investigations into compliance with the DOJ guidance. The GAO found that the US Attorneys' office conducting the 72-hour window investigation was doing so in compliance with the guidance. The DOJ could not fully assess compliance with the guidance with regard to the PPS transfer and the pneumonia upcoding initiatives. Most investigations related to these initiatives were pending at the time of the GAO's review, which restricted the GAO's access to information. Many of the pending pneumonia upcoding investigations were related to a *qui tam* lawsuit that the GAO had agreed to exclude from the scope of its review. However, although the GAO could not fully assess compliance in these areas, it determined that these initiatives were apparently being developed in accordance with the DOJ's guidance.

Although the DOJ indicated that compliance with its False Claims Act guidance is an ongoing priority, the GAO concluded that the DOJ's process for assessing the US Attorneys' offices' compliance may be superficial. These assessments appeared to involve little more than reviewers asking supervisors what actions they have taken to ensure compliance with the guidance. The GAO recommended that DOJ take additional steps to improve its oversight of national healthcare fraud initiatives. The report also noted that the DOJ stated that reviews of the assessment of US Attorneys' offices' compliance has been undertaken at a number of offices. The DOJ also has instructed reviewers to ask additional questions regarding compliance with the guidance in future reviews. The DOJ also indicated that it is taking a number of additional steps to ensure the guidance is being followed.

A GAO survey showed that the issuance of the DOJ's False Claims Act guidance has lessened state hospital associations' concerns about national DOJ investigations. Half of the associations expressing concerns with the DOJ's use of the False Claims Act prior to the issuance of the guidance responded that the guidance had fully addressed their concerns. The 15 state hospital associations that still have concerns reported a range of issues, including:

- some associations felt that the guidance should have established a minimum threshold of alleged overpayments before a False Claims Act investigation would be initiated
- some associations did not believe the guidance was being followed in a national initiative in their state

In all but one of these responses, the concerns raised were related to the laboratory unbundling initiative. The most often voiced criticism was that this initiative lacked a legal basis.

Reference

US General Accounting Office. *Medicare Fraud and Abuse: DOJ's Implementation of False Claims Act Guidance in National Initiatives Varies*, August 1999. Available at www.gao.gov/new.items/he99170.pdf.

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Article Citation:
Prophet, Sue. "GAO Evaluates Implementation of False Claims Act Guidance." *Journal of AHIMA* 70, no. 10 (1999): 19-20.