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Congressional Requesters

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MEDICARE FRAUD AND ABUSE

DOJ Has Made Progress in Implementing False Claims Act Guidance

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Health care fraud in the United States costs taxpayers billions of dollars every year. As a result, fighting fraud and abuse in the health care industry is a top priority of the Department of Justice (DOJ). A key enforcement tool in the fight against health care fraud is the False Claims Act (31 U.S.C. sec. 3729 to 3733). Under the act, DOJ can bring civil enforcement actions and seek significant damages and penalties against providers who knowingly submitted false or fraudulent bills to Medicare, Medicaid, or other federal health programs. In 1999, the federal government collected more than $490 million from health care fraud settlements, judgments, and administrative actions.

DOJ's use of the False Claims Act has sometimes been controversial. In particular, the hospital industry has alleged that DOJ, in a series of nationwide investigations of hospitals, known as national health care initiatives,[1] has been unfair and overzealous in its application of the act. In June 1998, responding to hospital and congressional concerns, DOJ issued guidance to its attorneys and all U.S. Attorneys[2] on the appropriate use of the act in civil health care matters, including national initiatives.

[1]DOJ defines a national initiative as a nationwide investigation stemming from an analysis of national claims data, indicating that numerous similarly situated health care providers have engaged in similar conduct to improperly bill government health care programs.

[2]U.S. Attorneys, under the direction of the Attorney General, prosecute individuals charged with violations of federal criminal law, represent the government in civil cases, and collect money and property owed the government. There are 93 U.S. Attorneys stationed throughout the United States, Puerto Rico, the Virgin Islands, Guam, and the Northern Mariana Islands.

Concerns about DOJ's use of the False Claims Act in health care investigations prompted the Congress to add a provision to the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (P.L. 105-277) requiring us to monitor the compliance of DOJ attorneys and U.S. Attorneys with the guidance. In accordance with this requirement, we issued two reports in 1999 on the results of our monitoring.[3] In the second report, we concluded that DOJ's process for assessing compliance at U.S. Attorneys' Offices appeared superficial. In addition, we found that implementation of the guidance varied among the U.S. Attorneys' Offices we visited. Consequently, we recommended that DOJ take steps to improve its oversight. The Congress subsequently directed us to continue our monitoring by including a provision in the Consolidated Appropriations Act of 2000 (P.L. 106-113). This provision requires us to report no later than April 1, 2000, on DOJ's compliance with its guidance and again by April 1 in each of the 2 succeeding years. This is our first report in response to this new requirement.

For this report, we looked at two issues. First, we determined what had been done in response to our prior recommendations. To make this determination, we met with officials from DOJ's Executive Office for U.S. Attorneys. Second, we focused on the most controversial of the four national initiatives—Laboratory Unbundling.[4] To determine the status of the initiative, we met with representatives from the working group, established in part to oversee its implementation at U.S. Attorneys' Offices. We also returned to the four U.S. Attorneys' Offices that we previously reported had been slow in incorporating DOJ's guidance into their ongoing Laboratory Unbundling investigations. At these offices, we discussed the progress that had been made in their investigations since our previous visits. To corroborate officials' statements, we reviewed selected case files and other relevant documents.

As in our earlier work, our access to materials related to open investigations was limited because of DOJ's concern that public disclosure

[3]See *Medicare Fraud and Abuse: Early Status of DOJ's Compliance With False Claims Act Guidance* (GAO/HEHS-99-42R, Feb. 1, 1999) and *Medicare Fraud and Abuse: DOJ's Implementation of False Claims Act Guidance in National Initiatives Varies* (GAO/HEHS-99-170, Aug. 6, 1999).

[4]The Laboratory Unbundling initiative identifies excess payments for laboratory tests that were performed concurrently on automated equipment but improperly billed or "unbundled" as separate tests. The other three national initiatives were discussed in our two 1999 reports.

of this information could adversely affect pending law enforcement matters. Although we were not granted complete access, we were permitted to select specific open case files for review. DOJ officials then screened the files and provided us with redacted documents that they deemed appropriate. Despite these limitations, we believe we were able to more fully assess these four offices' compliance than during our earlier review because many of their Laboratory Unbundling investigations had been closed since the issuance of our August 1999 report.

We conducted our work between December 1999 and March 2000. Except for the access restrictions described above, our work was performed in accordance with generally accepted government auditing standards.

Results in Brief

Since our August 1999 report was issued, DOJ has taken actions to improve its oversight of the U.S. Attorneys' Offices participating in national health care initiatives. It plans to place more emphasis on offices' compliance with the False Claims Act guidance in its periodic evaluations of these offices and has initiated a requirement for offices to certify their compliance annually. DOJ officials also told us that the role of the working groups has been expanded. Originally, these groups—composed of DOJ attorneys and Assistant U.S. Attorneys—concentrated on coordinating the development and implementation of national initiatives. Now enhanced emphasis is being placed on monitoring compliance with the guidance.

In addition, DOJ has given special attention to the most problem-prone initiative, Laboratory Unbundling. Offices participating in this initiative at the time the guidance was issued were recently required to document their compliance. Finally, the four U.S. Attorneys' Offices that we previously reported as being slow to incorporate the guidance into their ongoing Laboratory Unbundling investigations now appear to have addressed their shortcomings.

Background

The False Claims Act imposes civil liability on anyone who "knowingly" presents false or fraudulent claims for payment to the United States. The act defines "knowingly" to mean that a person (1) has actual knowledge of the false claim, (2) acts in deliberate ignorance of the truth or falsity of the information, or (3) acts in reckless disregard of the truth or falsity of the information. Anyone who submits false claims is liable for damages up to three times the amount of the erroneous payment in addition to civil

monetary penalties. Until recently, these penalties were $5,000 to $10,000 for each false claim. In August 1999, these penalties increased by 10 percent to $5,500 to $11,000 per false claim.

On June 3, 1998, DOJ issued "Guidance on the Use of the False Claims Act in Civil Health Care Matters." The guidance emphasizes the fair and responsible use of the act in all civil health care matters, including all current and future national initiatives. It instructs DOJ attorneys and U.S. Attorneys to determine, before they allege violations of the act, that the facts 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 relied on—to ensure that allegations are supported.

The guidance also contains requirements specifically applicable to national initiatives. U.S. Attorneys are generally required to notify a provider of potential exposure under the False Claims Act and to offer the provider an opportunity to discuss the matter before a specific demand for payment is made. In addition, the requirements specify that working groups of DOJ attorneys and Assistant U.S. Attorneys be established to provide guidance and oversight to U.S. Attorneys' Offices participating in each initiative.

In February 1999, DOJ began including assessments of compliance with the False Claims Act guidance in the periodic evaluations it conducts of U.S. Attorneys' Offices. Under this evaluation program, DOJ conducts a broad review of the operations of each U.S. Attorney's Office every 3 years. These broad reviews are conducted by evaluation teams composed of Assistant U.S. Attorneys from offices other than the one under review.

Actions Taken by DOJ to Strengthen Its Oversight of U.S. Attorneys' Offices

DOJ has made improvements in its oversight of U.S. Attorneys' Offices participating in national initiatives since August 1999. At that time, we reported that DOJ's assessments of the offices' compliance with False Claims Act guidance appeared superficial and provided little assurance that the offices complied with the guidance. DOJ agreed with our recommendation to improve its oversight by developing specific steps for assessing U.S. Attorneys' Offices' compliance and has begun implementing it. DOJ's approach consists of three components involving staff who conduct periodic evaluations of U.S. Attorneys' Offices, officials in the U.S. Attorneys' Offices, and national initiative working groups. In addition, DOJ acknowledged that its Laboratory Unbundling "transition offices"—offices where investigations were ongoing at the time the guidance was issued—

needed special attention and required these offices to document their compliance with the guidance.

Evaluation Process Revamped

DOJ recently made two changes to its process for assessing compliance with the False Claims Act guidance during the evaluations that are conducted every 3 years at each U.S. Attorney's Office. First, DOJ has developed a new pre-evaluation process to help evaluators prepare for their on-site reviews. Starting in January 2000, the evaluators began receiving information in advance of their visits regarding offices' participation in national initiatives. This information includes comments from national initiative working groups and the Executive Office for U.S. Attorneys regarding the offices' compliance with the guidance. We examined the 10 pre-evaluations that had been prepared as of March 7; they cited no concerns about the offices' compliance.

Second, the interview questions used by the evaluators to assess an office's compliance with the guidance were revised and expanded in March 2000. Previously, the review consisted of a single interview question in which officials from a U.S. Attorney's Office were asked to identify the steps being taken to ensure compliance. Although DOJ later added a few additional questions, we concluded in our August 1999 report that these questions would not provide a more meaningful assessment of compliance and that DOJ's limited approach provided little assurance that offices complied with the guidance. The interview questions added in March 2000 are more comprehensive and require the evaluators to ask detailed questions about an office's compliance with the guidance. However, we were unable to judge the effect of these new questions because evaluators will not begin using them until late March 2000, according to DOJ officials.

Annual Compliance Reviews Initiated

To stress the importance of its False Claims Act guidance, DOJ recently began requiring U.S. Attorneys' Offices participating in national initiatives to conduct annual reviews of their compliance with the guidance. To ensure independence, each office is expected to designate an Assistant U.S. Attorney not assigned to the national initiative cases to perform this internal review. The offices should use the results to annually certify their compliance with the guidance. The first certifications were due on January 30, 2000. DOJ officials told us that all required certifications had been submitted and that these certifications indicated that all the offices were complying with the guidance. In the future, DOJ plans to assess the annual compliance review process during its periodic evaluations of U.S.

Attorneys' Offices. We intend to more fully examine this process for our April 1, 2001, report.

Working Groups' Role Enhanced

To strengthen oversight of U.S. Attorneys' Offices participating in national initiatives, DOJ has enhanced the role of the working groups. Previously, working group members were primarily responsible for coordinating the overall development and implementation of national initiatives. They were expected to maintain regular contact with offices working on national initiative investigations, obtain updates on the progress of these investigations, and provide the offices advice and assistance. More recently, DOJ has expanded the responsibilities of working group members to place more emphasis on monitoring compliance with the guidance. For example, in November 1999, DOJ issued instructions requiring working group members to informally monitor the compliance of their assigned U.S. Attorneys' Offices for the duration of these offices' participation in the initiative. These instructions also outlined the steps to be taken when a working group member identifies an unresolved compliance issue. Finally, DOJ increased the size of three of the four working groups so that each member has responsibility for monitoring fewer offices.[5]

Oversight of Laboratory Unbundling Strengthened

DOJ required Laboratory Unbundling transition offices to document their compliance on each open investigation by November 1, 1999, because of concerns regarding their compliance with the guidance. Offices were required to describe how they had complied with the key components of the guidance in each Laboratory Unbundling investigation. According to DOJ officials, there were 20 transition offices still participating in the initiative as of the required reporting date. They also said that all 20 offices submitted the required reports and, based on those submissions, the officials concluded that all the offices were in compliance. As discussed in the next section, we did not find any evidence in the case files we examined to contradict the information contained in the transition reports we reviewed.

[5]According to DOJ officials, because a single U.S. Attorney's Office is conducting one of the initiatives, increasing the size of its working group was not considered necessary.

U.S. Attorneys' Offices Have Addressed Shortcomings in Laboratory Unbundling

We found that four of the U.S. Attorneys' Offices participating in the Laboratory Unbundling initiative that we previously visited have addressed the shortcomings in their investigations that we identified in our August 1999 report. They now appear either to be conducting their investigations in accordance with DOJ's False Claims Act guidance or have decided to discontinue pursuing False Claims Act violations under this national initiative.

As stated in our August 1999 report, these offices had begun participating in the Laboratory Unbundling initiative before DOJ's guidance was issued. We found that their actions were, to varying degrees, inconsistent with the subsequent guidance. Specifically, these offices, without having the evidence later required by the guidance, had sent letters that alleged or implied False Claims Act violations to many hospitals. The letters warned that the hospitals could be liable for three times the amount of any overpayment plus penalties of between $5,000 and $10,000 for each false claim. In the letters, DOJ offered to settle the claims if the hospitals conducted an independent self-audit and paid two times the amount of overpayments identified. However, at the time these letters were sent, most of the offices had not determined if the pervasiveness and magnitude of the apparent errors were sufficient to warrant allegations of False Claims Act violations. Moreover, these offices also lacked evidence that each of the hospitals had submitted the alleged false claims knowingly.

Because DOJ's guidance was issued while these investigations were ongoing, the U.S. Attorneys' Offices were faced with the problem of identifying what could be done to promptly remedy the actions they had taken that were inconsistent with the guidance. We reported that more than 1 year after the guidance was issued False Claims Act allegations against more than 100 hospitals remained pending. However, the offices had not obtained sufficient evidence to justify their allegations as required by the guidance.

When we revisited these four offices, we found that they had taken actions that, in our view, were reasonable remedies for the problems we previously reported. The following describes what we found when we returned to these offices. The offices appear in the same order as in our August 1999 report.

- The first U.S. Attorney's Office decided to allow hospitals to forgo self-audits and instead hired an auditing firm to assist with its own analysis

of claims data. As we reported in August 1999, this office lacked the evidence to support its False Claims Act allegations against about two dozen hospitals as would have been required if the guidance had been in force. Rather, the hospitals were originally selected for investigation primarily because they were the largest billers of Medicare in the state, rather than because evidence showed they had unbundled laboratory claims. Since our last report, officials have analyzed claims data and found that overpayments had occurred. They concluded that most of the hospitals appeared to have errors significant enough to justify continuing with False Claims Act investigations. The officials have shared their concerns with the hospitals and have asked them to respond. For about one-quarter of the hospitals, however, the officials determined that the overpayments were too small to pursue as False Claims Act violations. Instead, the office now intends to ask these hospitals to repay the overpayments with interest.

- The second U.S. Attorney's Office has terminated all its False Claims Act investigations. This office had made allegations in 1997 against about 75 hospitals and, at the time of our August 1999 report, more than 60 were still pending. Officials acknowledged that letters to hospitals were sent out before evidence of False Claims Act violations had been established, contrary to what the guidance now requires. They told us that opening so many investigations at the same time had strained their resources. Officials also acknowledged that obtaining evidence needed to establish False Claims Act violations would be time consuming and difficult in light of resource constraints. When we returned to this office, officials told us that they were no longer pursuing hospitals for violations of the act, citing the continuing lack of resources. The office instead offered the hospitals the alternative of settling these matters by asking them to return overpayments identified during the investigation. By the time we revisited this office, about one-quarter of the hospitals had agreed to repay these amounts. Investigations against several others had been terminated because of financial hardship. Negotiations with the remaining hospitals were continuing. We inquired about settlements made with a few hospitals before the False Claims Act investigations were terminated. In addition to recovering the amounts overpaid, these settlements included False Claims Act damages. Officials told us that, to avoid disparate treatment, they have reopened these investigations and said they intend to issue refunds for the amount of False Claims Act damages that were previously assessed.
- Officials at the third U.S. Attorney's Office also have decided to terminate their False Claims Act investigations and no longer expect hospitals to complete self-audits. We previously reported that this office

had alleged that about 10 hospitals had violated the act, but the office had not determined the pervasiveness and magnitude of the hospitals' billing errors before making these allegations. At the time of our August 1999 report, most of the hospitals had completed self-audits. According to the officials, the overpayments identified in these audits were not significant enough to constitute False Claims Act violations. They still planned, however, to continue False Claims Act investigations against the remaining hospitals. When we returned to this office, we learned that officials had reached agreements with the hospitals to return the overpayments identified in their self-audits. The hospitals that had not completed self-audits were no longer expected to do so and were no longer being investigated for violating the act. The officials told us that they decided to discontinue the False Claims Act investigations against these hospitals because they do not have resources to fully develop the evidence necessary to establish whether false claims were knowingly submitted. Instead, they currently are negotiating the recovery of suspected overpayments as identified by the office's original analysis of claims data. Officials have reached an agreement with one of the hospitals and expect that the others will be resolved soon.

- At the fourth office, most of the investigations that were open at the time of our August 1999 report have been closed. At that time, False Claims Act investigations were pending at almost 30 hospitals and officials were developing overpayment estimates for these hospitals. They were also attempting to collect evidence to prove the "knowing" element necessary to establish that the claims were false under the False Claims Act. By the time we returned, officials had conducted further analysis and concluded that the hospitals' billing errors did not warrant False Claims Act damages and penalties. Consequently, the office used its overpayment estimates as a starting point to negotiate repayment amounts for each of the hospitals. Only a few of the cases remain to be resolved.

Finally, we examined the transition reports prepared by these four offices. These reports indicated that the offices were in compliance with DOJ's False Claims Act guidance in each investigation. Based on our work at these offices, which included reviewing selected case files, we did not find any evidence that would contradict the information contained in these reports.

Conclusions

DOJ has made a concerted effort to implement our previous recommendation to strengthen its oversight of U.S. Attorneys' Offices

participating in national initiatives. It has changed the evaluation process by advising evaluators of potential compliance problems before they begin their assessments and by adding more detailed questions to be asked during these reviews. It also has required offices to conduct annual reviews of their compliance with the guidance. In addition, it has enhanced the working groups' role in monitoring offices' compliance. Finally, it provided special attention to the Laboratory Unbundling transition offices to help ensure that they were in compliance with the guidance.

Our follow-up at four U.S. Attorneys' Offices that we previously identified as having shortcomings in their Laboratory Unbundling investigations seems to indicate that they have addressed these problems. Our work indicates that they have made a reasonable attempt to take the steps necessary to bring their investigations into compliance with the False Claims Act guidance.

Agency Comments

We provided a draft of this report to DOJ for comment. DOJ officials generally concurred with our findings. They also provided several technical comments, which we incorporated.

We are sending a copy of this report to the Honorable Janet Reno, Attorney General of the United States, and other interested parties. We will also make copies available to others upon request. Please call me at (202) 512-7114 or Leslie G. Aronovitz at (312) 220-7600 if you or your staff have any questions about this report. The other major contributors to this report are Robert T. Ferschl and Geraldine Redican-Bigott.

William J. Scanlon
Director, Health Financing and
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