

Report to Congressional Committees

**April 2002** 

# MEDICARE FRAUD AND ABUSE

DOJ Continues to Promote Compliance with False Claims Act Guidance



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#### **Abbreviations**

AHA	American Hospital Association
DOJ	Department of Justice
HCFA	Health Care Financing Administration
HHS-OIG	Department of Health and Human Services Office of
	Inspector General
PPS	prospective payment system

# United States General Accounting Office Washington, DC 20548

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#### Congressional Committees

In fiscal year 2001, the Department of Justice (DOJ) reported recoveries of more than \$1.2 billion related to civil health care fraud. Identifying improper payments and ferreting out fraud in Medicare—the federal health insurance program serving approximately 40 million elderly and disabled Americans—is one of DOJ's top enforcement priorities. DOJ's recoveries have been bolstered by the use of the False Claims Act,¹ a powerful enforcement tool, which enables the government to seek significant damages and penalties against providers who knowingly submit false or fraudulent bills to Medicare, Medicaid, or other federal health programs.

DOJ's use of its False Claims Act authority has included several nationwide investigations of hospitals—projects known as national initiatives.<sup>2</sup> These investigations resulted in significant concerns from hospital industry representatives in the late 1990s. They criticized DOJ for overzealously pursuing hospitals for improper Medicare billings by conducting unwarranted investigations and demanding large penalties for unintentional errors. Amid growing concerns from both the industry and the Congress, DOJ issued guidance on the appropriate use of the act in civil health care matters, including national initiatives, in June 1998. The guidance was intended to emphasize the importance of using the act in a fair and even-handed manner and to implement new procedures regarding national initiatives.

<sup>&</sup>lt;sup>1</sup>31 U.S.C. sec. 3729(a) to 3733: Anyone who "knowingly" presents false claims for payment to the United States may be found to be in violation of the False Claims Act. The act defines "knowingly" to include a person who (1) has actual knowledge of the false claim, (2) acts in deliberate ignorance of the truth or falsity of the claim, or (3) acts in reckless disregard of the truth or falsity of the claim.

<sup>&</sup>lt;sup>2</sup>DOJ defines a national initiative as a nationwide investigation stemming from an analysis of national claims data, indicating that numerous, similarly situated providers have engaged in similar conduct to improperly bill government health care programs.

The Congress subsequently required us to monitor DOJ's implementation of the guidance, which has resulted in a series of reports (see appendix I).<sup>3</sup> While our initial reviews identified concerns with a DOJ initiative that had commenced before the guidance was issued, our more recent work shows that DOJ has made progress in ensuring that the guidance is followed.

This report represents our final required evaluation of DOJ's efforts to ensure compliance with the guidance. It focuses on DOJ's efforts to monitor compliance at its U.S. Attorneys' Offices and the application of the guidance in three national initiatives. These three initiatives all focus on hospitals that may have received greater reimbursement from the Medicare program than they were entitled to receive. The Prospective Payment System (PPS) Transfer initiative examines whether hospitals have improperly reported patient transfers between hospitals as discharges. The Pneumonia Upcoding initiative assesses whether Medicare has been billed improperly on behalf of beneficiaries hospitalized with pneumonia. Finally, the Laboratory Unbundling initiative reviews potentially improper billings for laboratory tests.

Our specific objectives were to: (1) review the actions taken by DOJ to ensure U.S. Attorneys' Offices compliance with the guidance, (2) determine whether the PPS Transfer, Pneumonia Upcoding, and Laboratory Unbundling projects are being conducted in a manner consistent with the guidance, and (3) determine whether the hospital industry has concerns with DOJ's current use of the False Claims Act.

Although DOJ's guidance applies to all civil health care matters, we focused this review, as we have our prior reports, on DOJ's implementation of the guidance in national initiatives. To evaluate DOJ's oversight of U.S. Attorneys' Offices, we discussed ongoing monitoring and compliance efforts with DOJ officials, including those responsible for periodic evaluations of the operations of each U.S. Attorney's Office. In addition, we confirmed that all offices involved in civil health care matters had certified their compliance with the guidance for the period ending December 31, 2001, as required by DOJ. We also reviewed relevant documentation supporting these certifications and interviewed members

<sup>&</sup>lt;sup>3</sup>These requirements were contained in the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (P.L. 105-277) and the Consolidated Appropriations Act of 2000 (P.L. 106-113).

of DOJ's working groups that coordinate each initiative to discuss their oversight of U.S. Attorneys' Offices participating in the initiatives.

To determine if the PPS Transfer, Pneumonia Upcoding, and Laboratory Unbundling projects are being conducted in a manner consistent with the guidance, we visited 4 of the 94 U.S. Attorneys' Offices. The offices we visited were participating in at least one national initiative. At these offices we reviewed investigative files pertaining to PPS Transfer, Pneumonia Upcoding, and Laboratory Unbundling matters. We reviewed correspondence and other materials to determine whether these offices were conducting their investigations in accordance with the guidance. We chose the offices to visit to be able to review examples of both open and closed matters from the three initiatives. In total, we reviewed 35 investigative files—19 closed matters and 16 open matters. To identify industry concerns with DOJ's implementation of the guidance, we spoke to representatives of the American Hospital Association (AHA) and representatives from eight state hospital associations.

We were provided access to documents through an agreement with DOJ to ensure that confidentiality of ongoing matters and DOJ's internal review process would not be compromised. This agreement did not materially affect our review because we were able to document compliance with specific elements of the guidance in both open and closed matters. We conducted our work from October 2001 through March 2002. Except for these restrictions on our access, our work was performed in accordance with generally accepted government auditing standards.

#### Results in Brief

DOJ continues to take actions to foster compliance with its False Claims Act guidance. First, DOJ has successfully integrated an assessment of compliance with the guidance in its periodic evaluations of all U.S. Attorneys' Offices. In addition, all U.S. Attorneys' Offices involved in pursuing civil health care fraud matters must annually certify their compliance with the guidance. Although not required to do so, DOJ officials told us that some offices have implemented procedures to support their annual certifications by documenting their compliance with the guidance in individual investigative files or by establishing a review process under the direction of their civil chiefs. All of the offices we visited this year that are resolving matters with the use of the False Claims Act had, in fact, instituted such procedures. The national initiative working groups also have encouraged compliance with the guidance. Their efforts have helped ensure that claims data are accurate and that offices do not open more investigations than resources can support. Offices are therefore

better able to devote individualized attention to each hospital's circumstances, as the guidance requires. In our view, these activities have helped to promote compliance with the guidance.

DOJ appears to be conducting its three national initiatives in a manner that is consistent with the guidance. Our work continues to show that the U.S. Attorneys' Offices we visited had coordinated their activities with the national initiative working groups and, as the guidance requires, took each hospital's unique circumstances into consideration in resolving these matters. We noted one of the offices we visited that was participating in the Laboratory Unbundling initiative had simultaneously opened many matters in 1995, prior to the issuance of the guidance. According to an official in this office, a lack of resources to handle this workload ultimately resulted in delays in resolving these matters. The office found it could not resolve all of these matters soon enough to utilize the damages provision available under the False Claims Act. According to an official in this office, approximately 12 matters remained open at the time of our March 2002 visit. In addition, this office was unable to resolve 4 of the recently closed matters we reviewed as false claims. Instead, it collected the amount of any overpayment plus interest.

Representatives from the AHA and the state hospital associations we spoke to were generally satisfied that U.S. Attorneys' Offices were adhering to DOJ's False Claims Act guidance in the national initiatives. Although a few hospital association representatives expressed continuing concerns with the use of the act in health care matters, none of the representatives we contacted identified specific instances of noncompliance with the guidance—either by a particular U.S. Attorney's Office or in one of DOJ's national initiatives. Many of these representatives provided us with examples of DOJ's compliance with the guidance. Officials from DOJ's Executive Office for U.S. Attorneys and its Civil Division generally concurred with our findings and concluding observations.

#### Background

The False Claims Act provides that anyone who "knowingly" submits false claims to the government is liable for damages up to three times the amount of the erroneous payment plus mandatory penalties between \$5,500 and \$11,000 for each false claim submitted. In the health care setting, where providers submit thousands of claims annually, the potential damages and penalties provided under the act for violators can quickly add up.

DOJ's use of the False Claims Act currently includes three national initiatives involving hospitals. 4 The two initiatives that currently have the most active investigations are the PPS Transfer and Pneumonia Upcoding projects. The PPS Transfer<sup>5</sup> initiative was developed from a series of audits and joint recovery projects by DOJ, the Department of Health and Human Services Office of Inspector General (HHS-OIG), the Health Care Financing Administration (HCFA), the agency within the Department of Health and Human Services that administers the Medicare program—and the contractors to HCFA that process and pay Medicare claims. This effort sought to identify improperly coded transfers and recover associated overpayments from hospitals. The Pneumonia Upcoding initiative targets inpatient hospital claims inappropriately coded as stays for a relatively rare bacterial form of the disease that is more costly to treat approximately \$2,500 more per claim—than the more common viral pneumonia. DOJ's older national initiative—Laboratory Unbundling—is nearly completed. The Laboratory Unbundling initiative, which began in 1994 prior to the issuance of the False Claims Act guidance, identifies excess payments for laboratory tests that were performed concurrently on automated equipment but improperly billed or "unbundled" as separate tests.

DOJ issued "Guidance on the Use of the False Claims Act in Civil Health Care Matters" on June 3, 1998. The guidance, which applies to all civil health care matters, emphasizes fair and responsible use of the act and

<sup>&</sup>lt;sup>4</sup>Another project, the 72-Hour Window, was previously designated as a national initiative, but according to DOJ, is now complete. This project, begun in 1995, centered on improper claims for payments for outpatient services received within 72 hours of a hospital admission. Payments for the inpatient admission cover these services in addition to services during a patient's stay.

<sup>&</sup>lt;sup>5</sup>Under Medicare's Prospective Payment System, hospitals are reimbursed a single amount to cover an entire inpatient stay. When a patient is transferred from one inpatient hospital to another, the transferring hospital is only entitled to receive a prorated payment based upon the patient's diagnosis and the number of days at the transferring hospital.

<sup>&</sup>lt;sup>6</sup>On June 14, 2001, the secretary of Health and Human Services announced that the name of the Health Care Financing Administration had been changed to the Centers for Medicare and Medicaid Services. In this report, we will refer to HCFA where our findings apply to operations that took place under that organizational structure and name.

<sup>&</sup>lt;sup>7</sup>See, for example, reports issued by the Department of Health and Human Services Office of Inspector General, *Medicare Hospital Patient Transfers Incorrectly Paid as Discharges—January 1992-December 1994* (A-06-95-0083), November 1996; and *Medicare Hospital Patient Transfers Improperly Reported and Paid as Hospital Discharges* (A-06-93-00095), February 1995.

instructs DOJ attorneys and U.S. Attorneys to determine, before they allege violations of the act, that the facts and the law sufficiently establish that the claimant knowingly submitted false claims. The guidance also contains provisions that specifically address the use of the act in DOJ's national initiatives. Prior to alleging a violation of the act in connection with a national initiative, attorneys should use contact letters to notify a provider of a potential liability and give the provider an opportunity to respond before a demand for payment is made. The guidance contains other safeguards to ensure the fair treatment of hospitals. For example, U.S. Attorneys' Offices must consider alternative remedies to the False Claims Act, including administrative remedies such as recoupment of overpayments, program exclusions, and other civil monetary penalties. In addition, they must also consider a provider's ability to pay; the effect on the community served by the provider—particularly for rural and community hospitals; and the extent of provider cooperation in the matter.

According to the guidance, working groups must be established to coordinate each national initiative. These groups, comprised of DOJ attorneys and assistant U.S. Attorneys with expertise in health care fraud control, must develop "initiative-specific guidance" to provide direction and support to the U.S. Attorneys' Offices that are participating in the initiatives. This initiative-specific guidance may include a legal analysis of pertinent issues, an investigative plan, and a summary of Medicare claims data indicating potentially significant billing errors for specific providers to assist individual U.S. Attorneys' Offices participating in the initiatives. As we reported in August 1999, the PPS Transfer, Pneumonia Upcoding, and Laboratory Unbundling working groups developed extensive guidance and memoranda for their respective initiatives outlining relevant legal and regulatory requirements. The working groups are also tasked with tracking the participating offices' progress, responding to their questions, and monitoring compliance with the guidance, as each initiative proceeds.

This is the fifth and last in a series of reports we have issued regarding DOJ's implementation of its False Claims Act guidance and its efforts to oversee compliance. In February 1999, we issued an early status report on

<sup>&</sup>lt;sup>8</sup>U.S. General Accounting Office, *Medicare Fraud and Abuse: DOJ's Implementation of False Claims Act Guidance in National Initiatives Varies*, GAO/HEHS-99-170 (Washington, D.C.: Aug. 6, 1999).

DOJ's initial efforts to implement the guidance. In our August 1999 report we concluded that DOJ's process for reviewing implementation of the guidance appeared superficial and that U.S. Attorneys' Offices were not consistent in their application of the guidance. However, in March 2000, we reported that DOJ had taken steps to improve compliance with its False Claims Act guidance. Our March 2001 report concluded that DOJ seemed to have made substantive progress in ensuring compliance with the guidance by strengthening its oversight of U.S. Attorneys' Offices. In that report, we also pointed out that both the PPS Transfer and Pneumonia Upcoding initiatives appeared to be conducted in a manner that was consistent with the guidance.

## DOJ's Oversight Aims to Foster Compliance with False Claims Act Guidance

DOJ continues to promote compliance with the False Claims Act guidance at its U.S. Attorneys' Offices. We believe that the oversight mechanisms it has put in place help ensure that the guidance will be followed and, that if instances of noncompliance occur, there are procedures in place to detect them.

DOJ's periodic evaluation of compliance with the guidance at U.S. Attorneys' Offices continues to be substantive. Two years ago DOJ revamped this process to provide a more meaningful assessment of compliance, in response to our prior recommendations. As we reported last year, these evaluations include detailed interviews regarding the activities and procedures each office has in place to ensure that the attorneys are informed of the guidance and that the office is in compliance. Of the 28 evaluations that took place in 2001, none resulted in a determination that an office was out of compliance with the guidance. DOJ officials indicated that offices found to be out of compliance in future evaluations will be required to develop a plan of corrective action. DOJ's Executive Office for U.S. Attorneys would then be tasked with monitoring the offices' implementation of these plans.

 $<sup>^9\</sup>mathrm{U.S.}$  General Accounting Office, Medicare Fraud and Abuse: Early Status of DOJ's Compliance with False Claims Act Guidance, GAO/HEHS-99-42R (Washington, D.C.: Feb. 1, 1999).

<sup>&</sup>lt;sup>10</sup>U.S. General Accounting Office, Medicare Fraud and Abuse: DOJ Has Made Progress in Implementing False Claims Act Guidance, GAO/HEHS-00-73 (Washington, D.C.: March 31, 2000).

<sup>&</sup>lt;sup>11</sup>U.S. General Accounting Office, Medicare Fraud and Abuse: DOJ Has Improved Oversight of False Claims Act Guidance, GAO-01-506 (Washington, D.C.: March 30, 2001).

Similarly, DOJ's requirement that all U.S. Attorneys' Offices involved in civil health care fraud matters annually certify their compliance with the guidance, a process also instituted 2 years ago in response to our recommendations, appears to have continued to promote compliance. According to DOJ officials, all U.S. Attorneys' Offices participating in civil health care matters had attested to their compliance for the period ending December 31, 2001. Although DOJ has not required offices to document their compliance with the guidance as part of the certification process, the offices we visited this year, like those we visited the year before, had either specifically documented their compliance in individual investigative files, instituted a review process under the direction of their office's civil chief, or developed a process to document compliance in a particular stage of an investigation. For example, closed investigative files we reviewed in one office contained certifications that the investigations had been conducted in accordance with the guidance. Another office conducted an annual review of all open national initiative matters to assess compliance. A third office documented its justification for opening investigations before hospitals were notified of potentially false claims. Based on our review of the materials supporting these certifications, and our analysis of the files we reviewed, we found no basis to dispute any office's certifications.

The working groups have continued to be involved in the development and implementation of the national initiatives. They have also continued to monitor the progress of the offices participating in them. Particularly for DOJ's two newer initiatives, the working groups have helped ensure the accuracy of the data on which the investigations are premised. By obtaining and analyzing national and hospital-specific claims data and subsequently sharing them with U.S. Attorneys' Offices to use as a basis for initiating their investigations, the working groups' review has helped ensure the validity of the analysis, thus addressing a problem which we noted in a prior report. <sup>12</sup> In addition, substantially fewer matters are being pursued under the two newer initiatives, which we believe is attributable to the working groups' oversight and their limiting the data provided to participating offices. This approach helps ensure that the offices do not simultaneously open more matters than resources can support. It also

<sup>&</sup>lt;sup>12</sup>This report noted that data used for the basis of unbundling investigations by certain offices were seriously flawed and had not been adequately analyzed and verified before these offices made allegations. U.S. General Accounting Office, *Medicare Fraud and Abuse: DOJ's Implementation of False Claims Act Guidance in National Initiatives Varies*, GAO/HEHS-99-170 (Washington, D.C.: Aug. 6, 1999).

enables offices to devote individualized attention to each hospital's unique circumstances, such as its efforts to comply with billing rules and its financial condition, as the guidance requires. In addition, we found that U.S. Attorneys' Offices participating in the initiatives consulted with working group members throughout the development of their investigations and shared proposed settlement agreements with them. This exchange of information allows the working groups to monitor compliance with the guidance on an ongoing basis.

## National Initiatives Are Being Conducted in Accordance with the Guidance

Our review of files at the U.S. Attorneys' Offices we visited suggests that the interactions between these offices and the hospitals they investigated were consistent with the guidance, in all three national initiatives. However, we also found that one of the offices that was participating in the Laboratory Unbundling initiative had simultaneously opened more matters than could be processed expeditiously. It subsequently found that it could not resolve all of these matters soon enough to utilize the damages provision available under the False Claims Act.

In reviewing correspondence and other documentation pertaining to the PPS Transfer, Pneumonia Upcoding, and Laboratory Unbundling investigations and settlements, we observed that the offices conducted detailed examinations of each hospital's billing patterns and circumstances, as the guidance requires. They also considered hospitals' individual circumstances and varied their actions accordingly, as required by the guidance. For example, one office reviewed the data supplied by the PPS Transfer working group and found that billing patterns for five hospitals indicated that some improper billings had been submitted. However, the office chose not to pursue False Claims Act actions because in its view, the amounts of the overpayments were not of a magnitude to warrant the use of the act. This office also recognized that resolving these matters as false claims could adversely affect the hospitals' financial conditions and impair their ability to provide services to their rural communities. Both considerations are consistent with proper use of the guidance. Another office participating in the Pneumonia Upcoding project reduced its proposed settlement offer because the hospital was able to demonstrate that it was in dire financial condition and was currently billing Medicare properly. The office also considered that the hospital's improper billings occurred while it was under different management. In a different office participating in the Laboratory Unbundling initiative, the office closed a matter without recovering any monies because of the hospital's poor financial condition and the community's dependence on it

as a sole source of medical care. The hospital, however, instituted new procedures to prevent improper billings in the future.

However, we found that one office we visited that was participating in the Laboratory Unbundling initiative is currently facing a challenge comparable to one we previously identified at another office in our August 1999 report—simultaneously opening more matters than the office's resources could ultimately support. As that report noted, the office was unable to close most of its matters as false claims and instead collected overpayments only.<sup>13</sup>

In March 2002, we visited an office that had opened approximately 60 matters in June 1995, prior to the issuance of the guidance. Although many of these matters had been settled, an official told us that approximately 12 were still open at the time of our visit. When matters remain open for many years the government may jeopardize its ability to recover damages under the False Claims Act. In order to settle or litigate allegations as False Claims Act violations, the government must resolve these matters within the timeframe specified by the act's statute of limitations. At the office we visited, the statute of limitations had expired for some of the office's closed matters, including 4 of the recently closed matters we reviewed. The office collected the amount of the overpayments plus interest, but could not assess any damages or penalties available under the False Claims Act.

Officials there largely attributed the delay in resolving these matters to the complexity of the investigations as well as the office's workload and an accompanying lack of resources. The resulting delays may also have kept the hospitals in a state of prolonged uncertainty regarding their liability.

<sup>&</sup>lt;sup>13</sup>Officials had made False Claims Act allegations against 75 hospitals in 1997. Officials at that office told us that obtaining evidence needed to establish violations of the act would be time consuming and difficult and that opening so many matters at the same time strained their resources. Ultimately, the office opted to not pursue hospitals for violation of the act and instead offered them the alternative of returning the overpayments identified during the investigation.

 $<sup>^{14}</sup>$ The statute of limitations applicable to the False Claims Act requires that a civil action may not be brought more than 6 years from the date the false claim was made or 3 years from the date that the government could have reasonably discovered the facts about the claim but not to exceed 10 years from the date the claim was made.

However, since the guidance was issued, scrutiny by the working groups and more careful selections of matters by offices has made it less likely that offices will open more matters than they can resolve in a timely fashion.

## Hospital Associations Express Few Concerns Regarding DOJ's Compliance with the Guidance

Representatives from the AHA and the eight state hospital associations we spoke to were generally satisfied that U.S. Attorneys' Offices were adhering to DOJ's False Claims Act guidance in the national initiatives. They had no specific examples of noncompliance with the guidance either by a particular U.S. Attorney's Office or in a specific national initiative. Many of these representatives provided us with examples of DOJ's compliance with the guidance. For example, some stated that since the guidance was issued, U.S. Attorneys' Offices have shown greater willingness to communicate with hospitals. Similarly, they mentioned that these offices were now more likely to consider information that hospitals submit in their defense and otherwise treat them reasonably in resolving these matters. Some associations noted that in the more recent national initiatives—PPS Transfer and Pneumonia Upcoding—DOJ seems to have carefully identified potentially improper payments before contacting hospitals. Several hospital association representatives attributed improved working relationships between DOJ and the health care community to the development of an ongoing dialogue between some U.S. Attorneys' Offices and hospital associations regarding billing issues.

However, a few hospital association representatives we spoke to did raise some concerns regarding the appropriateness of DOJ's use of the False Claims Act. For example, a representative of one state hospital association questioned whether U.S. Attorneys' Offices were giving enough consideration to the clarity of Medicare's billing rules and the adequacy of communicating these rules to providers in its current initiatives. However, the four offices we visited appeared to be willing to consider whether hospitals misunderstood the billing rules. In the case of PPS Transfer, both of the offices we visited that were participating in this initiative exclusively targeted hospitals that had been the subject of prior PPS Transfer audits conducted by the HHS-OIG. These audits identified improper billings and the results were shared with the hospitals. In DOJ's opinion, these audits should have clarified hospitals' understanding of the PPS billing rules.

Although the AHA and state hospital association representatives we spoke to acknowledged that DOJ's guidance has resulted in less threatening communications, they reported that hospitals nonetheless feel intimidated when they are notified by DOJ that they are under investigation. One association suggested that, instead of DOJ conducting initial investigations and notifying hospitals, the contractors that process and pay Medicare claims should be permitted to initiate investigations. In our review, which included an examination of correspondence between the U.S. Attorneys' Offices and the hospitals, we did not detect an unreasonable or threatening tone. And, while Medicare contractors as well as the HHS-OIG conduct audits and perform other tasks to detect and investigate improper billings, it remains the prerogative of DOJ to pursue providers who may have violated the False Claims Act. Moreover, only DOJ can initiate a False Claims Act action against a provider.

AHA representatives also expressed concern about an ongoing False Claims Act case that is not related to the national initiatives. Their concerns involve an investigation of over 100 hospitals that allegedly billed Medicare improperly for investigational medical devices. This investigation is based on a qui tam lawsuit. As with all qui tam cases, DOJ was required to investigate the allegations and determine whether to join the lawsuit. Part of its investigation, therefore, included an assessment of whether the alleged billing improprieties merited pursuit under the False Claims Act. AHA representatives said the billing rules regarding these devices had been unclear and that the use of the act was uncalled for. However, DOJ officials explained that, while these rules changed over time, their clarity was sufficient to have permitted hospitals to bill Medicare properly. Because of this pending lawsuit's qui tam status and the fact that many cases remain under seal, we were unable to address the matter further.

Finally, some hospital associations raised an issue that was also brought to our attention in preparing last year's report. Association representatives continue to be concerned that corporate integrity agreements they regard as burdensome may be included in settlement agreements of national

<sup>&</sup>lt;sup>15</sup>Investigational medical devices are those that have not been approved for marketing by the Food and Drug Administration.

 $<sup>^{16}</sup>$ A qui tam lawsuit involves an action brought by an individual on behalf of the United States alleging that false or fraudulent claims have been submitted to the government.

initiative matters at the insistence of the HHS-OIG.<sup>17</sup> Consistent with our findings last year, the imposition of these agreements was not routine for the matters we reviewed this year. These agreements were required in 7 of the 19 closed matters we examined. Moreover, in an open letter to the medical community in November 2001, the HHS inspector general announced new criteria that would be used in determining when a corporate integrity agreement would be required. These new criteria are based on a variety of factors including the age and financial significance of the alleged impropriety and whether the provider has a viable voluntary compliance plan in place.

# Concluding Observations

DOJ's oversight of U.S. Attorneys' Offices has helped to foster compliance with its False Claims Act guidance. DOJ has instituted sufficient monitoring of U.S. Attorneys' Offices participating in the national initiatives and other civil health care fraud matters to help ensure that offices use the act in a fair and even-handed manner. The review of each office's compliance is now an integral component of the periodic evaluations conducted of all U.S. Attorneys' Offices. The annual certification of compliance with the guidance by each U.S. Attorney's Office pursuing civil health care fraud matters has also helped encourage compliance, as have the activities of the working groups that coordinate and oversee offices participating in national initiatives. Our review of open and closed PPS Transfer, Pneumonia Upcoding, and Laboratory Unbundling project files in the four offices we visited also supports that the guidance is being followed. And, although hospital association representatives still expressed some concerns with the use of the act, they did not identify specific instances of noncompliance by either a particular U.S. Attorney's Office or in a specific national initiative.

We believe that it is in the interest of both the government and the hospitals to pursue investigations thoroughly and resolve them expeditiously. DOJ is involved in a balancing act. On one hand, if offices have sufficient evidence to allege that false claims have been filed, but do not pursue them, the government loses the opportunity to use the sanctions of the act for the intended purpose of discouraging false claims

<sup>&</sup>lt;sup>17</sup>A corporate integrity agreement is an obligation imposed by the HHS-OIG on a provider as part of a settlement of a potential fraud matter. The provider agrees to take affirmative steps to improve compliance and report periodically to the HHS-OIG. The HHS-OIG, in turn, agrees not to seek further administrative penalties for the behavior in question. Corporate integrity agreements typically last for 3 years for national initiative matters.

for federal monies. On the other hand, if offices overextend themselves by opening more matters than they can reasonably be expected to resolve within the required timeframes, the hospitals are kept in a state of uncertainty about their investigations for unnecessarily prolonged periods while the government is also unable to use the act as a deterrent. One of the offices we visited had opened many Laboratory Unbundling matters in 1995, prior to the issuance of DOJ's guidance, and is still in the process of resolving some of these matters. However, offices participating in the two newer national initiatives—PPS Transfer and Pneumonia Upcoding—are now opening fewer investigations, reducing the likelihood that this situation will resurface.

#### **Agency Comments**

We provided a draft of this report to DOJ for comments. Officials from DOJ's Executive Office for U.S. Attorneys and its Civil Division provided oral comments, in which they generally concurred with our findings and concluding observations. They also provided technical comments, which we incorporated, as appropriate.

We are sending copies of this report to the attorney general of the United States, the secretary of HHS, and other interested parties. We will make copies available to others upon request.

If you or your staff have any questions about this report, please call me on (312) 220-7767, or Geraldine Redican-Bigott at (312) 220-7678. Other major contributors were Lynn Filla-Clark, Don Kittler, and Barbara Mulliken.

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Administration and Integrity Issues

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# Appendix I: GAO Reports Concerning the Use of the False Claims Act in Civil Health Care Fraud

Reports Mandated by the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (P.L. 105-277)

Medicare Fraud and Abuse: Early Status of DOJ's Compliance with False Claims Act Guidance. GAO/HEHS-99-42R. Washington, D.C.: February 1, 1999.

Medicare Fraud and Abuse: DOJ's Implementation of False Claims Act Guidance in National Initiatives Varies. GAO/HEHS-99-170. Washington, D.C.: August 6, 1999.

Reports Mandated by the Consolidated Appropriations Act of 2000 (P.L. 106-113)

Medicare Fraud and Abuse: DOJ Has Made Progress in Implementing False Claims Act Guidance. GAO/HEHS-00-73. Washington, D.C.: March 31, 2000.

Medicare Fraud and Abuse: DOJ Has Improved Oversight of False Claims Act Guidance. GAO-01-506. Washington, D.C.: March 30, 2001.

#### Other Related Products

Medicare: Application of the False Claims Act to Hospital Billing Practices. GAO/HEHS-98-195. Washington, D.C.: July 10, 1998.

Medicare: Concerns with Physicians at Teaching Hospitals (PATH) Audits. GAO/HEHS-98-174. Washington, D.C.: July 23, 1998.

Letter to the Committee on Ways and Means. B-278893. Washington, D.C.: July 22, 1998.

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