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MEDICARE FRAUD AND ABUSE

DOJ's Implementation of False Claims Act Guidance in National Initiatives Varies



**Health, Education, and
Human Services Division**

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The Honorable Ted Stevens
Chairman
The Honorable Robert C. Byrd
Ranking Minority Member
Committee on Appropriations
United States Senate

The Honorable Orrin G. Hatch
Chairman
The Honorable Patrick J. Leahy
Ranking Minority Member
Committee on the Judiciary
United States Senate

The Honorable C. W. Bill Young
Chairman
The Honorable David R. Obey
Ranking Minority Member
Committee on Appropriations
House of Representatives

The Honorable Henry J. Hyde
Chairman
The Honorable John Conyers, Jr.
Ranking Minority Member
Committee on the Judiciary
House of Representatives

Improper billings to Medicare have been a longstanding threat to the fiscal integrity of the program. The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) estimates that overpayments due to billing errors, fraud, medically unnecessary services, and other problems totaled \$12.6 billion in fiscal year 1998.

With the increased attention to health care fraud and abuse in recent years, the Department of Justice (DOJ) has been using the False Claims Act (31 U.S.C. sec. 3729(a)-3733) for practices that in the past might have been dealt with by seeking repayment. The act's damages and penalties make it a powerful enforcement tool.

DOJ's efforts have included a series of nationwide investigations of hospitals. These national initiatives—as they are termed by DOJ—have been widely criticized by the hospital community.¹ Hospitals have alleged that they have been unfairly targeted and that DOJ has been overzealous in its application of the act. Responding to hospital and congressional concerns, DOJ issued guidance in June 1998 on the appropriate use of the act in civil health care matters, including national health care initiatives.

Concerns about DOJ's implementation of the guidance 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 DOJ's and the U.S. Attorneys'² compliance with the guidance, including any revisions. We are required to issue two reports on the results of our work.

Our first report, issued in February 1999, focused on DOJ's early implementation of the guidance.³ We reported that DOJ had designated four national initiatives involving hospitals—Laboratory Unbundling, 72-Hour Window, Prospective Payment System (PPS) Transfer, and Pneumonia Upcoding—and had established work groups for each. We also noted that DOJ had begun taking steps intended to ensure that the 93 U.S. Attorneys comply with the guidance.⁴ For example, we reported that DOJ had 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 U.S. Attorneys' Offices. We also reported that the work groups—consisting of representatives from DOJ and selected U.S. Attorneys' Offices—had been established to support the four ongoing national initiatives. These work groups were then in various stages of preparing documentation, such as legal analyses and investigative plans, required by the guidance to assist the U.S. Attorneys' Offices participating in the initiatives. Our survey of all 93 U.S. Attorneys found that the majority were participating in at least one national initiative. Our survey

¹DOJ 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.

²U.S. Attorneys are supervised by the Attorney General but exercise a large degree of independence and discretion in the handling of their cases.

³See Medicare Fraud and Abuse: Early Status of DOJ's Compliance With False Claims Act Guidance (GAO/HEHS-99-42R, Feb. 1, 1999).

⁴These 93 U.S. Attorneys serve the nation's 94 federal judicial districts. One U.S. Attorney serves both the District of Guam and the District of the Northern Mariana Islands.

also found that several offices had closed a large number of investigations related to one initiative without taking actions against the providers.

This report summarizes the results of our monitoring of DOJ's and selected U.S. Attorneys' Offices' compliance with the guidance. Specifically, we (1) determined the status of the work groups' efforts and reviewed the initiative-specific guidance they prepared, (2) evaluated DOJ's efforts to assess U.S. Attorneys' compliance with the guidance, (3) examined implementation of the guidance at selected U.S. Attorneys' Offices, and (4) identified state hospital associations' concerns regarding DOJ's use of the False Claims Act.

In preparing this report, we conducted work at DOJ's Civil Division and its Executive Office of U.S. Attorneys and visited 10 U.S. Attorneys' Offices. Eight of the 10 offices were participating in at least one national initiative. Four of the 10 had been involved in large numbers of Laboratory Unbundling investigations but had closed them after DOJ's guidance was issued; we visited these offices to determine the reasons they had closed the investigations. The results of our visits to these four offices are described in appendix I. Finally, we surveyed state hospital associations regarding their views on DOJ's guidance and its implementation.

DOJ officials restricted our access to certain types of information at U.S. Attorneys' Offices because they believed public disclosure of this information could adversely affect pending law enforcement matters. For example, DOJ preselected materials from pending investigations, limiting these materials to those they considered relevant to our review. Furthermore, because investigations were pending, we could not obtain complete information about how the offices were planning and conducting their initiatives. We conducted our work between February and July 1999; except for the access limitations noted above, our work was performed in accordance with generally accepted government auditing standards. These limitations, however, did not have a material effect on the conclusions we reached in this report. For a complete discussion of our scope and methodology, including the limitations on our access to information needed to conduct our review, see appendix II.

Results in Brief

DOJ's national initiative work groups have made further progress in implementing the Department's False Claims Act guidance since we issued our February 1, 1999, report. All four work groups have completed their examination of the legal and factual basis for their initiatives and have

prepared initiative-specific guidance for the U.S. Attorneys' Offices participating in the initiatives. The guidance prepared by these work groups is consistent with the requirements in DOJ's guidance. For example, the guidance addresses the legal basis underlying each initiative and includes suggestions for conducting investigations of individual hospitals.

While DOJ officials told us compliance with its False Claims Act guidance is an ongoing priority for the Department, we believe DOJ's process for assessing the U.S. Attorneys' Offices' compliance may be superficial. In February 1999, DOJ began to include in its periodic reviews of U.S. Attorneys' Offices assessments of compliance with the guidance. These assessments, however, appear to involve little more than reviewers asking supervisors what they have done to ensure compliance with the guidance. Such limited efforts will not provide the information needed to adequately assess actual compliance. While we were not given access to the review results, DOJ officials told us that, as of June 25, only 2 of the 15 assessments that had been done contained any information about these offices' compliance with the guidance. DOJ's plans for strengthening the assessment process, such as adding more questions, may not be enough to effectively assess compliance. In our view, these additional questions will not provide more substantive information than the original question and are only a starting point for an effective assessment. Accordingly, we are recommending that DOJ take additional steps to improve its oversight of national health care initiatives.

We also found that the implementation of DOJ's False Claims Act guidance varied among the eight U.S. Attorneys' Offices we visited that were participating in the national initiatives. Five of these offices were participating in the Laboratory Unbundling initiative and had begun their involvement before DOJ's guidance was issued. We found that their actions were, to varying degrees, inconsistent with the guidance. Our limited review also raised questions about whether four of these offices were promptly incorporating the guidance into their ongoing investigations. While the 72-Hour Window initiative also started before DOJ's guidance was issued, our work at the one office that was conducting this initiative indicated that the office's actions were consistent with the subsequent guidance. We could not fully assess compliance at the offices we visited that were participating in DOJ's two newest national initiatives—PPS Transfer and Pneumonia Upcoding—because few investigations had started for either initiative nationwide. Nevertheless, based on our discussions with representatives from the two work groups and the offices, it appears that the initiatives are being developed in accordance

with the guidance. Restrictions on our access at all offices prevented us from conducting a complete and independent review.

Our survey of state hospital associations indicated that the issuance of DOJ's False Claims Act guidance has lessened their concerns about national initiative investigations. Half of the associations expressing concerns with DOJ's use of the False Claims Act prior to the issuance of the guidance said that the guidance had fully addressed their concerns.

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 \$5,000 and \$10,000 for each false claim submitted. 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. In the health care setting, where providers submit thousands of claims each year, the potential damages and penalties provided under the False Claims Act can quickly add up.

DOJ's use of the False Claims Act currently includes four national initiatives involving hospitals. The 72-Hour Window initiative, which began in 1995, centers on separate payments for outpatient services received within 72 hours of a hospital admission, which are paid as part of Medicare's inpatient reimbursement to hospitals. The Laboratory Unbundling initiative, which began in 1994 by U.S. Attorneys' Offices in Ohio, identifies excess payments for laboratory tests that were performed concurrently on automated equipment but improperly billed or “unbundled” as separate tests. In January 1999, DOJ announced two new national initiatives. The PPS Transfer initiative focuses on overpayments to hospitals that incorrectly report transfers to other hospitals as discharges in order to receive higher Medicare payments.⁵ The Pneumonia Upcoding initiative targets inappropriate coding of inpatient hospital billings for a form of the disease that is more costly to treat and paid at a higher rate than was supported by a patient's medical records.

⁵Under Medicare PPS, payment rates are established in advance and hospitals treating Medicare beneficiaries must generally accept the rate as full payment, regardless of the patient's length of stay.

In 1998, we reported that hospital groups had criticized DOJ's use of the False Claims Act in the two older national initiatives.⁶ They alleged that in both the 72-Hour Window and the Laboratory Unbundling initiatives, DOJ subjected many of the nation's hospitals to unwarranted investigations, resulting in large penalties for unintentional errors. In particular, the Laboratory Unbundling initiative provoked considerable controversy. The hospital groups complained that the initiative lacked a sufficient legal basis and relied on flawed data. They also charged that some U.S. Attorneys' Offices had issued demand letters threatening prosecution without sufficient evidence that the hospitals had submitted false claims.

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 health care initiatives. It also instructs all DOJ attorneys to determine, before they allege violations of the act, that the facts and the law sufficiently establish that a claimant knowingly submitted false claims. The guidance requires them to take a number of steps, including reviewing relevant statutes and regulations and verifying the accuracy of the data relied on, to ensure that they support the allegations.

The guidance also contains new requirements specifically applicable to national initiatives. The guidance generally requires the U.S. Attorneys to use "contact letters" to notify providers of their potential exposure under the False Claims Act and to offer providers an opportunity to discuss the matter before a specific demand for payment is made. The new requirements also specify that a work group must be established for each current and future initiative. Work groups of Civil Division attorneys and Assistant U.S. Attorneys with expertise in health care fraud are expected to coordinate the development and implementation of the initiatives. The work groups are also 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 U.S. Attorneys' Offices participating in the initiatives.

DOJ's False Claims Act guidance provided that it would be subject to review within a 6-month period. This review, completed in February 1999, clarified a number of issues in the guidance and also described how providers under investigation could elevate their concerns within the

⁶See Medicare: Application of the False Claims Act to Hospital Billing Practices (GAO/HEHS-98-195, July 10, 1998) and Use of False Claims Act to Target Hospitals (B-279893, July 22, 1998).

Department if they believed the guidance was not being followed. It also announced that national initiative work groups would be required to solicit and consider the views of HHS' OIG and other relevant agencies in conducting the initiatives. The review concluded that no major revisions to the guidance were necessary.

Work Groups Have Completed Initiative-Specific Guidance

At the time we issued our first report, only the Laboratory Unbundling and PPS Transfer work groups had completed preparing the required initiative-specific guidance. Since that time, the 72-Hour Window and Pneumonia Upcoding work groups have also finished their guidance. We examined the initiative-specific guidance prepared by the work groups and found that this guidance was consistent with the requirements outlined by DOJ for False Claims Act investigations. The confidential nature of these work group documents precludes us from discussing them in detail. However, we can make some general observations about each work group's initiative-specific guidance.

All the work groups have developed model contact letters for notifying providers that they were the subjects of False Claims Act investigations. We noted that these letters were carefully worded to avoid any inference that the providers had violated the False Claims Act. Unlike the demand letters previously used by some U.S. Attorneys' Offices, the new contact letters did not include a specific demand for payment nor, in our opinion, did they contain the type of language that many hospitals had found to be intimidating and coercive.

We found similarities between the documentation prepared by the Laboratory Unbundling, PPS Transfer, and Pneumonia Upcoding work groups. All three sets of documents elaborated on DOJ's general guidance and provided detailed steps for planning and conducting the initiatives. The documentation included an analysis of the legal basis underlying each initiative; however, we did not evaluate these analyses. All three sets of documentation included investigative plans containing specific suggestions for conducting investigations of individual hospitals. These plans also outlined procedures for determining whether claims submitted by these hospitals were false and, if so, whether the hospitals knowingly submitted them. In addition, the work group materials addressed the source, limitations, and reliability of the claims data to be used in the investigations. In our opinion, the documentation prepared by these three work groups was consistent with the requirements in DOJ's guidance.

The 72-Hour Window work group prepared a report that assessed the initiative's activities in light of DOJ's guidance, rather than the detailed guidance prepared by the Laboratory Unbundling, PPS Transfer, and Pneumonia Upcoding work groups. Unlike the other three national initiatives, which are being conducted by multiple U.S. Attorneys' Offices, a single U.S. Attorney's Office is conducting the 72-Hour Window initiative. For this reason, and because the initiative was more than two-thirds complete at the time DOJ's guidance was issued, this work group did not develop the same step-by-step instructions that were developed by the other three work groups. Nevertheless, we believe the report showed that the work group, as directed, had considered whether the initiative met the requirements established by DOJ's guidance. Among other things, it evaluated the accuracy of the data used in the initiative, the clarity of the relevant billing rules, and the appropriateness of the office's approach for completing the initiative. In our view, this report satisfies the requirement that work groups prepare initiative-specific guidance.

DOJ's Assessments of U.S. Attorneys' Offices' Compliance With the Guidance May Be Superficial

According to DOJ officials, the U.S. Attorneys' Offices' compliance with the guidance is an ongoing priority for the Department. However, DOJ's process for assessing compliance may be superficial. As we described in our first report, DOJ said that beginning February 1, 1999, it would include assessments of the offices' compliance with the guidance as part of the reviews it conducts at each office every 3 years. DOJ's assessments of compliance with the guidance during these periodic reviews of offices consists of a single interview question in which supervisors are asked to identify the steps being taken to ensure compliance. We believe these assessments provide little assurance that offices comply with the guidance.

According to DOJ officials, as of June 25, 1999, reviews incorporating this assessment were completed at 15 U.S. Attorneys' Offices. DOJ officials told us the reports on these offices were not yet complete; thus, they were unwilling to share them with us. They said that they had reviewed the draft reports or, if no draft report had yet been prepared, the reviewers' submissions. DOJ officials said that reviewers typically only report negative information. They also told us that the 15 draft reports or reviewer submissions contained no negative information about the offices' compliance with the guidance; in two cases, positive comments were made. For example, according to DOJ, one reviewer's report consisted of the following:

This [office] is in compliance with the requirements of the Deputy Attorney General's guidance on the use of the False Claims Act in health care fraud cases and matters. Training on the requirements has been provided to all ACE unit personnel.⁷

In response to our concerns about these reviews, officials told us that they would require reviewers to comment both negatively and positively on offices' compliance with the guidance in all future reviews. We do not believe that the two "positive responses," however, provided much insight about either of the offices' efforts to comply or their actual compliance because the comments were not specific. In our view, if the new requirement results in the reporting of similar information on all the offices assessed, these reports would not be meaningful.

In addition, the officials told us that, due to the importance of ensuring compliance, they had instructed reviewers to ask additional questions in future reviews. These questions ask whether an office has participated in any national initiatives since the office's last review and whether the office has complied with the guidance and the work groups' recommendations for conducting investigations. While these additional questions are relevant, we believe that they are only a starting point for an effective assessment and will not provide a more meaningful assessment of compliance than the original question.

DOJ officials told us that they were taking other steps, such as the following, to ensure that the guidance is followed.

- The Deputy Attorney General has emphasized the necessity of compliance both orally and in writing on a number of occasions and has encouraged U.S. Attorneys' Offices to document their compliance in investigative case files. We noted that three of the offices we visited had developed forms to document their compliance.
- Compliance with the guidance is a top priority of the Subcommittee on Health Care Fraud of the Attorney General's Advisory Committee. In this regard, the national initiative work groups are required to update the subcommittee on the status of each initiative on a regular basis.
- Work groups are expected to maintain regular contact with U.S. Attorneys' Offices participating in an initiative, monitor their progress, and provide guidance throughout the investigative and litigative processes.
- DOJ has assigned an experienced Civil Division attorney to each work group. DOJ officials believe that because these representatives specialize in

⁷Most U.S. Attorneys' Offices have ACE (Affirmative Civil Enforcement) units, which pursue civil actions to recover money lost due to fraud and other misconduct.

False Claims Act matters, their presence on the work groups helps ensure consistent adherence to Department policies concerning False Claims Act matters.

Implementation of Guidance by U.S. Attorneys' Offices Varies Among National Initiatives

DOJ's False Claims Act guidance applies to all national initiative health care investigations—including those ongoing at the time the guidance was issued. Our limited review showed that the offices' implementation of the guidance varied among national initiatives. Eight of the offices that we visited were participating in at least one of the national initiatives. Five of these offices began participating in the Laboratory Unbundling initiative before DOJ's guidance was issued. Our review raised questions about how promptly four of them were incorporating the guidance into ongoing investigations. While the 72-Hour Window initiative also started before DOJ issued its guidance, the one office conducting this initiative did not appear to be having difficulty implementing the guidance, and we were more convinced that this office was conducting the initiative in compliance with the guidance. We could not fully assess compliance at the offices participating in DOJ's two newest national initiatives—PPS Transfer and Pneumonia Upcoding—because few U.S. Attorneys' Offices, including those we visited, had started investigations for either initiative nationwide.

Table 1 shows the participation in the national initiatives for the eight U.S. Attorneys' Offices at the time of our visits. We are not identifying these offices or the exact number of their investigations because DOJ is concerned that doing so could compromise open investigations.

Table 1: U.S. Attorneys' Offices Visited Participating in National Initiatives

National initiative	Number of offices
Laboratory Unbundling	5
72-Hour Window	1
PPS Transfer	3
Pneumonia Upcoding	5

Two of the eight offices had terminated their involvement in the Laboratory Unbundling initiative by the time of our visits. We also visited two other offices that decided to discontinue their participation in this project. These two additional offices were not involved in any other national initiative at the time of our visit. (For a discussion of the four offices' participation in the Laboratory Unbundling initiative and their decisions to terminate their involvement, see app. I.)

Implementation of Guidance Slow at U.S. Attorneys' Offices Participating in Laboratory Unbundling

The five offices participating in the Laboratory Unbundling initiative had taken actions in their investigations prior to the issuance of DOJ's False Claims Act guidance that, to varying degrees, were inconsistent with the subsequent guidance. Generally, the five U.S. Attorneys' Offices we visited sent demand letters to large numbers of hospitals that alleged or implied violations of the False Claims Act. 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. The letters also presented the hospitals with an alternative: volunteer to conduct an independent self-audit and pay two times the amount of overpayments identified. However, contrary to the subsequent guidance, at the time these allegations were made, most of the offices had not sufficiently analyzed the claims data to determine if the pervasiveness and magnitude of the apparent errors were sufficient to warrant alleging a False Claims Act violation. Moreover, they also lacked evidence that each of the hospitals had knowingly submitted the alleged false claims.

Because DOJ's guidance applies to all health care investigations, including those ongoing at the time it was issued, these offices were faced with the task of determining what needed to be done to bring their investigations into compliance. We found that, more than 1 year after the guidance was issued, four of these offices had not completed actions to address the shortcomings in their ongoing Laboratory Unbundling investigations. Allegations that over 100 hospitals violated the False Claims Act remain unresolved at these four offices. The following provides more details related to our observations at these offices.

- In late 1997, one U.S. Attorney's Office notified about two dozen hospitals that they were under investigation because the office had identified certain claims that may have been submitted in violation of the False Claims Act. However, officials told us in March 1999 that these hospitals had actually been selected primarily because they were the largest billers of Medicare in the state, not because the office had evidence that they were unbundling laboratory claims. They acknowledged that their selection methodology was inconsistent with DOJ's guidance but told us that they had subsequently obtained data showing that all of these hospitals had submitted significant numbers of unbundled laboratory claims to Medicare. We could not verify their statement because, citing the pending nature of the investigations, officials declined to share the data with us. In June 1999, more than a year and a half after beginning their investigations and 1 year after DOJ's guidance was issued, these officials told us that they had recently begun a detailed analysis of billing data on

each of the hospitals. The analysis, while not completed, indicated that at least one of the hospitals should not be pursued for violating the False Claims Act. Other hospitals could be dropped from the investigation once their analysis is completed, they said. In addition, DOJ officials told us in July that the office, which had never before provided the hospitals with any of the evidence it had compiled against them, planned to share excerpts of the data indicating they had improperly billed Medicare.

- Officials at another U.S. Attorney's Office acknowledged making False Claims Act allegations against 75 hospitals in 1997 before obtaining sufficient evidence to support the allegations, as the guidance now requires. Officials told us that they did not know if these hospitals had knowingly submitted false claims at the time they made the allegations. Investigations against some of the hospitals were dropped after further analysis by the office indicated that the estimated overpayments to them were small. In addition, responding to the hospitals' concerns about the cost of the proposed self-audits, most hospitals were later given the opportunity to accept the office's estimate of the false claims plus damages in lieu of an audit. At the time of our visit in April 1999, however, over 60 of the investigations remained unresolved. Because the investigations were pending, officials would not discuss them. They did indicate, however, that opening so many investigations at the same time had strained their resources and, as a result, establishing whether all of these hospitals had knowingly submitted false claims—a step now required before alleging False Claims Act violations—would be time-consuming and difficult. In July 1999, officials told us that all of the investigations were still pending and they did not know how long it might take to resolve them.
- In 1997, another U.S. Attorney's Office alleged that about 10 hospitals had violated the False Claims Act, but the office lacked evidence that the claims were false—let alone that the hospitals were knowingly submitting false claims. The allegations were based on a computer analysis of claims data that indicated these hospitals had received the largest overpayments from unbundling laboratory services. At the time of our May 1999 visit, all these investigations were pending. The majority of the hospitals had completed self-audits, but self-audits of the remaining hospitals had not yet started. According to the officials, all of the completed audits found insignificant billing errors that could not, in their view, support a False Claims Act case. Officials conceded that investigations against some, maybe all, of these hospitals might not have been started had they done a better analysis of the claims data, as now required by DOJ's guidance. Nevertheless, a DOJ official told us in July 1999 that investigations of the remaining hospitals will continue.

- In 1997, another U.S. Attorney's Office sent letters to about three dozen hospitals in the state alleging that the hospitals might have submitted false claims and asking them to volunteer to conduct self-audits of their laboratory billings. At this time, however, the officials had not verified the accuracy of the data they were relying on to support this allegation, nor did they have information showing that false claims were knowingly submitted. The office did not initially respond to hospital requests that it provide the data supporting its allegations of false claims. When some hospitals did not promptly decide whether to volunteer for self-audits, they were warned that the government would seek the full penalties of the False Claims Act if the office did the audits itself. The office continued to assert that hospitals had submitted false claims. For example, in a late 1997 letter to an attorney representing one of the hospitals, the office said it did not consider the matter to be a mere overpayment case. Rather, the letter said that the office would agree to settle the case for an amount equal to twice the overpayment, absent extenuating circumstances. Ultimately, the office obtained additional data that revealed that the original data used to select the hospitals for investigations had apparently overstated the hospitals' billing errors. In late 1998, more than a year after the investigations had begun, the office concluded that about one-fourth of the hospitals should not be pursued for False Claims Act violations. At the time of our May 1999 visit, officials told us that they were developing overpayment estimates for the remaining hospitals. In July 1999, a DOJ official told us that a few additional investigations had been resolved but the office was attempting to collect evidence from the remaining hospitals in order to prove the "knowing" element necessary to establish that the claims were false.

The fifth U.S. Attorney's Office sent letters to about 75 hospitals—virtually all the acute care hospitals in the office's jurisdiction—alleging that they had submitted false claims. Based on our review, this office appeared to have stronger evidence than the other offices that some of these hospitals had knowingly submitted false claims because they had been repeatedly identified in Medicaid audits and investigations as having unbundled laboratory services. At the time of our visit, the majority of the office's investigations had been settled and over \$5 million had been recovered. However, over 40 percent of these settlements involved only the recovery of the overpayments without False Claims Act damages or penalties being assessed.

Implementation of Guidance at the U.S. Attorney's Office Leading the 72-Hour Window Initiative Appears Appropriate

The 72-Hour Window initiative, like Laboratory Unbundling, began before DOJ issued its False Claims Act guidance. Officials at the one office conducting the 72-Hour Window initiative told us that they believed that actions taken in their investigations were consistent with the guidance. Our review of selected closed case files found no compelling evidence to dispute the officials' assertions. Consequently, despite limitations on our access, we were more convinced that this office was conducting the initiative in compliance with the guidance than we were at offices involved in the Laboratory Unbundling initiative.

Our review of closed files showed that the office had sent letters to the hospitals alleging that they had violated the False Claims Act and providing an estimate of their total financial exposure under the act. The hospitals were offered an opportunity to settle these matters before litigation by paying lesser amounts. The case files contained overpayment data that the officials told us had been developed from an audit conducted by HHS' OIG. These data formed the basis for the office's allegations that the hospitals had submitted false claims. Moreover, this audit was the fourth in a series of audits going back to 1983 that showed that thousands of hospitals had repeatedly violated the 72-Hour Window. In addition, they told us that the three prior audits along with the recovery of overpayments identified in those audits clearly put the hospitals on notice of the billing rule. The officials believed that the hospitals' continued submission of improper claims after these audits was a strong indicator that the hospitals were "knowingly" submitting false claims.

We did note, however, that some investigations that were pursued as False Claims Act violations before DOJ's False Claims Act guidance was issued involved small dollar amounts. The guidance requires offices to consider the pervasiveness and magnitude of the improper billings in assessing whether the false claims were knowingly submitted rather than mere mistakes. Officials told us that the pervasiveness and magnitude of improper billings would be taken into account in future investigations.

Implementation of Guidance Cannot Be Fully Assessed at U.S. Attorneys' Offices Participating in the PPS Transfer and Pneumonia Upcoding Initiatives

We could not fully assess compliance with DOJ's False Claims Act guidance at the U.S. Attorneys' Offices we visited that were participating in the two newest national initiatives—PPS Transfer and Pneumonia Upcoding. Most investigations related to these initiatives were pending at the time of our visits and, consequently, our access to information related to both initiatives was restricted. Moreover, only a few PPS Transfer investigations had been started and none of them had progressed very far. Further, many of the pending Pneumonia Upcoding investigations were related to a qui tam lawsuit,⁸ which we agreed to exclude from the scope of our review. While we could not fully assess compliance with the guidance, based on our work, it appears that these two initiatives are being developed in accordance with DOJ's guidance.

While DOJ's PPS Transfer national initiative has been under development since late 1997, only a few U.S. Attorneys' Offices are currently participating in the initiative, and investigations of individual hospitals by these offices are just beginning. We visited three of these offices. Shortly before our visits, two of the offices had sent several hospitals contact letters notifying them that they were under investigation. Officials at the third office told us they had recently completed analyzing data on one hospital, had concluded an investigation was warranted, and planned to send the hospital a contact letter soon. Other than showing us redacted copies of the contact letters and, in one instance, a redacted copy of the hospital's response, officials at the three offices told us they could not provide any other information about these pending investigations.

DOJ's Pneumonia Upcoding initiative was established to determine whether certain hospitals referred by HHS' OIG had violated the False Claims Act by upcoding pneumonia claims. But investigations of hospitals referred by the OIG had not started at the offices we visited. Five of the offices, however, were involved in investigations of pneumonia upcoding at 19 other hospitals. All but two of these investigations were pending at the time of our visits; therefore, our access to information about these cases was restricted. Moreover, many of the pending investigations were related to a qui tam lawsuit and thus, as discussed further in appendix II, these were outside the scope of our review. At two offices, we were provided some documents related to several pending investigations that did not involve qui tam lawsuits. At a third office we examined materials associated with one of the closed investigations—not enough information,

⁸A 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.

in our opinion, to be able to reach conclusions regarding these offices' implementation of the DOJ guidance.

DOJ's Guidance Appears to Have Lessened State Hospital Associations' Concerns

Of the 39 state hospital associations responding to our survey, 34 indicated they were concerned with DOJ's use of the False Claims Act prior to the issuance of the guidance. Seventeen of the 34 reported that the guidance fully addressed these concerns, and 2 said they were not sure. The remaining 15 reported concerns reflecting a range of issues. But no single concern was shared by a majority of these associations. For example, six associations told us that they believed that the guidance should have established a minimum threshold of alleged overpayments before a False Claims Act investigation would be initiated. One association charged that the guidance is vague enough to allow DOJ to characterize intimidating and unfair use of the act as compliance with the guidance.

Eight state hospital associations reported that they did not believe the guidance was being followed in an ongoing 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.⁹ These eight state hospital associations also mentioned a variety of other concerns related to the Laboratory Unbundling initiative. For example, they criticized U.S. Attorneys' Offices for using questionable data, alleging False Claims Act violations based on these data, and requesting the hospitals to assist in the investigations by conducting self-audits.

Conclusions

One of DOJ's most important weapons in the fight against health care fraud is the False Claims Act. As with all enforcement tools, it is important that the law be fairly applied. Questions about the appropriateness of DOJ's use of the act in national initiatives led to the issuance of DOJ's False Claims Act guidance. DOJ has made progress in implementing the guidance since it was issued last year. The materials the work groups have prepared to guide U.S. Attorneys' Offices provide detailed steps for planning and conducting the initiatives. In our view, these materials are consistent with the guidance and are designed to avoid actions that offices previously took that would not have met the guidance's requirements. DOJ also appears to be developing the two newest national initiatives—PPS Transfer and Pneumonia Upcoding—in a manner that is consistent with the guidance. In

⁹As previously stated, we did not evaluate the legal merits of any of DOJ's national initiatives, but we did verify that DOJ has performed a legal analysis for the Laboratory Unbundling initiative.

addition, our limited review at the one office conducting the 72-Hour Window initiative suggested that little would need to be changed to incorporate the guidance into the initiative. However, four of the five U.S. Attorneys' Offices we visited that were participating in the Laboratory Unbundling initiative had not completely incorporated the guidance into investigations they had started before the guidance was issued.

DOJ's assessments of the U.S. Attorneys' Offices' compliance with the guidance, as now performed, appear superficial. Although DOJ intends to enhance these reviews, we do not believe that the proposed enhancements will provide more useful information about the offices' compliance. Given the importance DOJ says it places on the guidance, we believe that its monitoring of U.S. Attorneys' Offices should provide DOJ management with specific information on the offices' compliance efforts and the results of these efforts. Such assessments should involve more than asking questions about an office's compliance; it should also include verification of this compliance.

Recommendation

We recommend that DOJ improve its oversight of U.S. Attorneys' Offices participating in national health care initiatives. Specifically, DOJ should

- develop guidance for reviewers that includes specific steps for determining whether offices appropriately follow the guidance and
- require reviewers to independently determine whether the offices are complying with the guidance.

Agency Comments

We provided DOJ a draft of this report. In written comments, the Department generally agreed with our findings and said it would implement our recommendations. In addition, DOJ said it would give special attention to U.S. Attorneys' Offices where the Laboratory Unbundling initiative was ongoing at the time its False Claims Act guidance was issued. As an initial step, DOJ plans to require these offices to document their compliance with the guidance.

DOJ also offered comments in response to our concerns about the Laboratory Unbundling initiative. These comments revolved around two issues: (1) the timeliness of incorporating the guidance into ongoing investigations and (2) the adequacy of the evidence used as a basis for alleging False Claims Act violations.

Concerning the first issue, DOJ said that a number of factors have affected the speedy resolution of Laboratory Unbundling investigations. In particular, it said that investigations have proceeded with caution to ensure that errors made in the past are not repeated. DOJ also explained that, in many cases, hospitals have requested extensions to allow for further review of claims data and that these requests have been granted. While we agree that offices should proceed cautiously and that it is reasonable to grant time extensions, we are uncertain about the extent to which the slow progress in these investigations is attributable to these factors. For example, as we described in the report, more than 1 year after the guidance was issued, one office had only recently begun a detailed analysis of hospital billing data. Also, as mentioned in the report, officials at another office attributed their slow progress to having opened too many investigations at the same time. According to these officials, the volume of pending investigations had strained their resources, making it difficult and time-consuming to bring these investigations in compliance with the guidance.

Concerning the second issue, DOJ questioned our contention that some of the offices we visited had alleged violations of the False Claims Act before obtaining sufficient evidence. DOJ acknowledged that one office had sent letters to hospitals discussing possible False Claims Act violations prior to obtaining evidence that false claims had been submitted by these hospitals. However, DOJ said that the other offices contacted hospitals only after examining several years of claims data that had suggested claims were improperly submitted. We agree these offices had some data that suggested that unbundling of laboratory services could be occurring. However, the offices used these data as a basis for alleging that numerous hospitals had violated the False Claims Act. As discussed in the report, at the time these allegations were made, most offices had not adequately analyzed the data to determine if the apparent errors were sufficient to warrant a false claims violation, as DOJ guidance now requires. We also found that these offices lacked evidence that each of the hospitals had knowingly submitted false claims.

Finally, DOJ said that self-audits have always been, and remain, a voluntary option for hospitals. DOJ expressed concern with a statement in our draft report that one office was requiring hospitals to conduct self-audits. We recognize that the self-audit approach is a voluntary option and we revised the report accordingly. We have included the Department's comment letter as appendix III.

We are sending copies of this report to the Honorable Janet Reno, Attorney General of the United States, officials from the organizations we visited, 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. Other major contributors to this report include Paul D. Alcocer, Barry R. Bedrick, Stefanie G. Weldon, Robert T. Ferschl, and Geraldine Redican-Bigott.

A handwritten signature in black ink, reading "William J. Scanlon". The signature is written in a cursive, flowing style.

William J. Scanlon
Director, Health Financing and
Public Health Issues

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Abbreviations	
ACE	Affirmative Civil Enforcement
DOJ	Department of Justice
EOUSA	Executive Office for U.S. Attorneys
HHS	Department of Health and Human Services
OIG	Office of Inspector General
PPS	prospective payment system

Data Problems Led to Termination of Laboratory Unbundling in Illinois and Texas

In our February 1999 report, we discussed the results of our survey of all the U.S. Attorneys' Offices. We reported that some offices closed large numbers of Laboratory Unbundling investigations after DOJ's False Claims Act guidance was issued, without taking adverse actions against providers. We also said we planned to determine the reasons for the seemingly large number of Laboratory Unbundling declinations in preparation for this report. The majority of these declinations—more than 85 percent—involved U.S. Attorneys' Offices in Illinois and Texas. These offices had also reported they were no longer involved in Laboratory Unbundling.

The three U.S. Attorneys' Offices in Illinois and the four U.S. Attorneys' Offices in Texas pursued Laboratory Unbundling investigations on a coordinated basis in their respective states. The investigations began in 1996 in Illinois and in 1997 in Texas. At their peak, more than 100 investigations were under way against Illinois hospitals, while about 300 hospitals were under investigation in Texas. We visited two offices in each of these states.

We observed that these four offices—like the other offices we visited that were continuing with their Laboratory Unbundling investigations as discussed in our letter—had taken actions during their investigations that would no longer be permitted by DOJ's guidance. For example, the offices sent demand letters to the hospitals alleging that the hospitals had unbundled laboratory claims in violation of the False Claims Act. However, the offices had not adequately verified or analyzed the data they were relying on as a basis for their allegations and they also lacked evidence that any false claims had been “knowingly” submitted by the hospitals. The key difference between the Illinois and Texas offices and the offices that are continuing with Laboratory Unbundling appeared to be related to the accuracy and reliability of the data supporting the False Claims Act allegations. In Illinois and Texas, these data were seriously flawed. The other offices did not appear to have such serious data problems, but we could not be sure in all instances because of limitations on our access to this information.

The allegations against Illinois and Texas hospitals were based on claims data obtained from the local fiscal intermediaries,¹⁰ and the hospitals were provided with either computer disks or printouts listing claims the offices believed had been unbundled. These claims data, however, had not been adequately analyzed and verified before the offices made their allegations.

¹⁰Fiscal intermediaries are private insurance companies that contract with the government to pay Medicare claims for services from hospitals and certain other health care providers.

When hospitals reviewed the data, they found what they believed to be a variety of errors. Follow-up by the U.S. Attorneys' Offices confirmed that the data were indeed flawed. Offices in both states made adjustments to their overpayment estimates on the basis of partially corrected fiscal intermediary data, but not all of the errors could be readily corrected. Primarily because of the unreliability of the data, both the Illinois and Texas offices ultimately concluded they had no alternative but to withdraw their allegations of False Claims Act liability against the hospitals and terminate their involvement in the initiative.¹¹

¹¹Three of the offices told the hospitals they were referring the matters to the local fiscal intermediary for possible collection of some of the amounts. The other office reached an agreement with the hospitals it was investigating whereby the hospitals agreed to repay an adjusted amount to the fiscal intermediary without damages or penalties. At the four offices we visited, hospitals that had previously settled—5 in Illinois and 19 in Texas—were refunded the amounts they had paid as part of their settlement agreements. In addition, one Texas hospital opted not to rescind its settlement agreement. A refund to another Texas hospital, which was involved in bankruptcy proceedings, had not been made at the time of our visit.

Scope and Methodology

To monitor DOJ's compliance with its False Claims Act guidance, we met with officials from the Civil Division and the Executive Office for U.S. Attorneys (EOUSA). In addition, we met with representatives from the work groups that have been established to support the four national health care initiatives. We also visited 10 U.S. Attorneys' Offices to discuss the offices' participation in the national initiatives; their implementation of the guidance; and, in four cases, their decisions to terminate their involvement in the Laboratory Unbundling initiative.

We used the results of our survey of all U.S. Attorneys' Offices, discussed in our first report, to judgmentally select the 10 locations. Six of the 10 offices were chosen because they had significant numbers of pending investigations related to at least one of the national initiatives. In addition, four offices were selected primarily because they reported closing large numbers of Laboratory Unbundling investigations without adverse action against the providers. These four offices were no longer participating in the Laboratory Unbundling, but two of them were participating in other national initiatives at the time of our visit. Thus, in total, we visited eight offices that were actively involved in at least one of the national initiatives.

We stated in our first report that DOJ was unwilling to give us access to information relating to its use of the False Claims Act that we needed to assess compliance with the guidance. At that time, DOJ would not give us access to certain work group documents and deleted or "redacted" portions of other documents. In addition, DOJ would not allow us access to documents related to ongoing investigations. DOJ deemed this information confidential and feared that public disclosure could potentially compromise these investigations.

For this review, DOJ officials agreed to expand our access, provided that we not disclose the contents of these documents. We agreed and, consequently, were permitted to examine unredacted versions of the work group documents. We were also allowed access to some documents related to pending national initiative investigations at U.S. Attorneys' Offices. However, DOJ officials preselected these documents and limited them to those that they considered relevant to our review. In addition, while we routinely obtain copies of documents in our reviews, DOJ would not permit us to have copies of any of these materials. In most cases, we were allowed to take handwritten notes, but this was a time-consuming process that may have interfered with our ability to monitor the offices while we were there. Moreover, while we normally have independent access to officials outside of an agency's headquarters, DOJ would not

permit us to interview or contact officials from U.S. Attorneys' Offices unless a representative from EOUSA was present. Likewise, we were not permitted to meet with work group representatives without an EOUSA official in attendance. For these reasons, we cannot say with certainty that we have all of the information necessary to conduct a complete and independent review of U.S. Attorneys' compliance with the guidance.

Our access was also limited by the existence of qui tam or "whistleblower" lawsuits, which, DOJ officials told us, involved the majority of pending investigations related to one of the national initiatives—Pneumonia Upcoding. Such lawsuits are typically filed under seal allowing DOJ to investigate without the defendant's knowledge. DOJ officials told us the seal prohibits them from disclosing information about such cases. Consequently, we excluded pending qui tam investigations from the scope of our review. By doing so, however, our ability to monitor U.S. Attorneys' Offices' compliance with the Pneumonia Upcoding initiative was limited.

In performing our work, we did not attempt to assess DOJ's legal basis for alleging that hospitals had violated the False Claims Act, nor did we attempt to verify the accuracy of the data used by DOJ in making these allegations. In addition, while DOJ's False Claims Act guidance applies to all civil health care fraud and abuse investigations, we limited our review to those investigations that were related to the four designated national initiatives.

We surveyed hospital associations from all 50 states as well as the District of Columbia and Puerto Rico to obtain their views on DOJ's False Claims Act guidance and its implementation in national initiatives. We also met with representatives from a state association and from the American Hospital Association.

We performed our work between February and July 1999. Except for the access restrictions discussed above, our work was performed in accordance with generally accepted government auditing standards. These limitations, however, did not have a material effect on the conclusions we reached in this report.

Comments From the Department of Justice



U.S. Department of Justice

Office of the Deputy Attorney General

Special Counsel for Health Care Fraud

Washington, D.C. 20530

July 30, 1999

Mr. Paul Alcocer
Assistant Director
Health Financing and Public Health Issues
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Alcocer:

Thank you for sharing with the Department of Justice (DOJ) the draft report prepared by your office entitled Medicare: Variations in DOJ's Implementation of Its False Claims Act Guidance in National Health Care Initiatives (GAO/HEHS-99-170). We appreciate the opportunity to provide comments.

Generally, we agree with many of the findings outlined in your report. In particular, as you indicate, since the General Accounting Office (GAO) issued its initial report on February 1, 1999, DOJ's national initiative working groups have made substantial progress in implementing the Department's June 3, 1998, False Claims Act guidance (June 3rd guidance). All four working groups have conducted a comprehensive analysis of the legal and factual basis for its national initiative and prepared initiative-specific guidance for use by participating United States Attorneys' offices (USAOs). We concur with GAO's finding that the working group materials for each of the four national initiatives are consistent with the requirements in the June 3rd guidance.

As noted in your report, the Department has taken a number of affirmative steps to ensure that USAOs are complying with the June 3rd guidance. The Deputy Attorney General has emphasized the importance of following the guidance on a number of occasions and remains committed to ensuring that the False Claims Act is applied in a fair and responsible fashion. In supplemental guidance issued December 4, 1998, and February 3, 1999, the Deputy Attorney General emphasized again that all Departmental attorneys are expected to comply with the June 3rd guidance. Moreover, the Attorney General's Advisory Committee, through its Subcommittee on Health Care Fraud, actively monitors the progress of each initiative and regularly meets with national initiative working groups for status updates. Working groups comprised of Assistant United States Attorneys (AUSAs) and Civil Division Trial Attorneys are working closely with USAOs participating in national initiatives and are providing guidance throughout the investigative and litigative process.

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Additional steps have also been taken by the Department to ensure that the June 3rd guidance is followed. For example, the Department has provided substantial assistance to its attorneys on the application of the June 3rd guidance in more than twelve formal training courses or seminars. Both the Civil Division and the Executive Office for United States Attorneys (EOUSA) have incorporated the June 3rd guidance into their training curriculum. Additionally, experienced Health Care Fraud Coordinators in the Civil Division and in EOUSA are available to respond to questions regarding application of the guidance. Further, members of the working groups speak regularly with USAOs that work on national initiative investigations, obtain updates on the progress of those investigations, and provide advice and guidance on subjects such as data analysis, investigative process and settlement issues.

The report contains several constructive suggestions for strengthening our efforts to ensure that all matters and cases are handled in accordance with the June 3rd guidance. Specifically, the report recommends that DOJ improve its oversight of USAOs by (1) developing guidance for reviewers that includes specific steps for determining whether offices appropriately follow the guidance, and (2) requiring reviewers to independently determine whether the offices are complying with the guidance. The Department will take steps to implement both of these recommendations. Moreover, we recognize that the transition districts discussed in the report, i.e., the districts where the laboratory unbundling national initiative was ongoing at the time of the June 3rd guidance, require special attention. We will be taking additional steps above and beyond those recommended by GAO to ensure that these transition districts are in full compliance with the June 3rd guidance. As an initial step, these districts will be required to document their compliance with that guidance, as suggested in the Deputy Attorney General's memorandum on compliance with the June 3rd guidance, issued December 4, 1998.

With regard to the districts participating in the laboratory unbundling project discussed on pages 10 - 12 of the draft report, we appreciate the opportunity to address the primary concerns outlined in your report. Your report indicates that some offices have not completed actions to address shortcomings in laboratory unbundling investigations.

Districts have diligently worked to allow hospitals every opportunity to analyze data and present mitigating evidence and/or defenses for consideration. With respect to GAO's perception that some offices have not moved expeditiously to conclude ongoing investigations and reach settlements, a number of factors have impacted the speedy resolution of laboratory unbundling investigations. In part, the progress of these investigations resulted from a change in the direction that the initiative has taken since the creation of the unbundling working group and implementation of the June 3rd guidance. In particular, Department attorneys and USAOs have proceeded with caution in unbundling investigations in order to ensure that errors made in the past are not repeated and do not mar ongoing investigations. Additionally, in many cases, hospitals have requested extensions of time to further review claims data or obtain additional information for analysis. Districts have readily agreed to requests for additional time by hospitals.

Now on pp. 11-14.

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In four of the five districts discussed, you indicate that hospitals were alleged to have violated the False Claims Act before knowledge of actual violations was obtained. It is true that one district sent contact letters discussing possible False Claims Act violations to certain hospitals prior to obtaining detailed claims data for those hospitals. However, these letters were sent before the June 3rd guidance, and this oversight has since been corrected. For all of the other districts cited, the districts invariably contacted hospitals only after having examined several years of claims data suggesting the submission of improper claims. Upon receiving letters from USAOs, hospitals were informed that certain claims had been identified that might constitute false claims and were given information regarding the areas of identified concern. Districts are still in the investigative stage of the laboratory unbundling initiative and the investigations are proceeding cooperatively. This cooperative approach to these investigations is consistent with the careful analysis of potential False Claims Act cases required by the June 3rd guidance.

Districts investigating unbundling cases have obtained varying degrees of evidence that false claims were submitted knowingly by hospitals. In a few instances, evidence of knowing unlawful conduct has been acquired through conventional means such as subpoenas or interviews. Other indicia of knowledge may have been obtained through detailed analysis of claims data. Generally, districts have taken a measured, cooperative approach to conducting unbundling investigations. The districts have attempted to work with hospitals to minimize the use of discovery tools -- such as subpoenas -- that are traditionally employed to determine the extent to which improper billings are knowingly submitted.

With respect to claims data audits being undertaken by the hospitals in the transition districts you visited, self-audits have always been, and remain, a voluntary option for hospitals. One district that is continuing to work with hospitals on voluntary self audits is mentioned in the report as lacking evidence that the hospitals' claims were false or that the False Claims Act was violated. In fact, however, the district raised the self-audit option only after acquiring evidence suggesting that improper claims were submitted. In the absence of evidence that the hospitals knew these claims to be false, this district followed the June 3rd guidance and chose not to pursue these matters under the False Claims Act. Rather, the district entered into settlement discussions with hospitals simply to enable the United States to be made whole from the improper payments that the hospitals received. The pending investigations are being examined on an individualized basis and, while the hospitals are pursuing self-audits, they are not being required to do so.

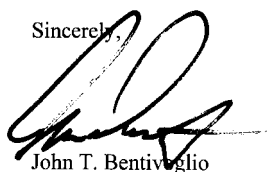
Finally, the Department recognizes the difficulties GAO encountered in conducting this review in light of the Department's longstanding policy of protecting the confidentiality and integrity of pending investigations. We greatly appreciate GAO's agreement to protect the confidential nature of documents reviewed by GAO auditors. As you know, the Department made every possible attempt to facilitate the GAO review. For example, we provided access to information sought by GAO regarding closed cases. We also facilitated discussions with supervisory USAO personnel in the districts GAO visited. In some instances, we were able to provide GAO access to redacted materials in pending cases because they already had been

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provided to the hospitals. Unfortunately, pursuant to the Department's longstanding policy regarding pending matters – which is designed to protect the integrity of our law enforcement efforts – we could not provide complete access to some information sought by GAO.

Thank you very much for the opportunity to comment on this draft report. The Department remains committed to the fair and responsible use of the False Claims Act in civil health care matters.

Sincerely,

A handwritten signature in black ink, appearing to read "John T. Bentivoglio", is written over a horizontal line.

John T. Bentivoglio

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