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Committee on Appropriations
United States Senate

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

The Honorable C. W. Bill Young
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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

Subject: Medicare Fraud and Abuse: Early Status of DOJ's Compliance With False Claims Act Guidance

Last year, legislation was introduced in the House and the Senate that would have restricted the Department of Justice's (DOJ) ability to use the False

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Claims Act to prosecute civil health care fraud. This legislation responded to concern that DOJ, through a series of national antifraud projects, was misusing the act. The American Hospital Association (AHA) charged that DOJ was subjecting many of the nation's hospitals to unwarranted investigations, resulting in large penalties for unintentional errors. Although the legislation did not pass, DOJ issued detailed internal guidance in June 1998 on the appropriate use of the False Claims Act. This guidance applies to all civil health care matters and specifically addresses the use of the act in national health care initiatives. DOJ defines these initiatives as nationwide investigations of "a common wrongful action accomplished in a like manner by multiple, similarly situated health care providers."

The Congress remains concerned about how DOJ and its U.S. Attorneys' Offices are implementing the guidance. As a result, it added a provision to the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (P.L. 105-277) requiring us to monitor DOJ's and all U.S. Attorneys' compliance with the guidance, including any revisions. The act also requires us to report on this compliance not later than February 1, 1999, and again by August 2, 1999, to the Committees on the Judiciary and the Committees on Appropriations of the Senate and the House of Representatives.

This is the first of the two required reports and addresses DOJ's early implementation of its False Claims Act guidance. In addition, it provides information on U.S. Attorneys' involvement in DOJ's national health care initiatives, as well as our plans for conducting our remaining work. To prepare this report, we discussed the guidance and its implementation with appropriate officials from the Civil Division and the Executive Office of the U.S. Attorneys. We also met with representatives of several of the DOJ working groups that have been established to support national health care initiatives. To obtain information regarding the extent of U.S. Attorneys' participation in these initiatives, we surveyed all 93 U.S. Attorneys.[1] Finally, we met with representatives of AHA and a state hospital group to identify their concerns about the guidance and its implementation. We began our work in October 1998, and this work is being conducted in accordance with generally accepted government auditing standards.

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[1]These 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.

In summary, DOJ has begun taking steps to implement its False Claims Act guidance and has designated four national antifraud projects as "national initiatives." However, it is too early for us to reach a conclusion regarding DOJ's compliance with the guidance, in part, because its working groups are in various stages of preparing documentation to guide participating U.S. Attorneys' Offices. In addition, while we surveyed all U.S. Attorneys' Offices concerning their involvement in national initiatives, we still need to visit selected offices to evaluate their compliance with the guidance. Our survey indicates that while most offices have matters pending related to at least one of these national initiatives, such matters represent a small part of their overall civil caseload. The survey also indicates that since the guidance was issued, almost seven times as many national initiative matters were closed as were opened. About one-half of these closed matters involved settlements, while the remainder did not involve any adverse actions against providers.

BACKGROUND

Improper billings to Medicare have been a longstanding threat to the fiscal integrity of the program. In recent years, the government has stepped up its efforts to identify and recover overpayments, using the False Claims Act as its primary enforcement tool. The act provides that anyone who knowingly submits false claims to the government is liable for three times the amount of the erroneous payment plus mandatory penalties between $5,000 and $10,000 for each false claim submitted. Because high-volume providers may submit thousands of claims each year, the potential damages and penalties can add up quickly, even if relatively few claims are found to be in violation of the False Claims Act.

DOJ's efforts to combat this threat have included nationwide investigations of multiple providers. These projects have included

- Physicians at Teaching Hospitals (PATH)–focuses on inappropriate payments to teaching physicians for services that were actually performed by residents.
- Laboratory Unbundling–identifies excess payments for laboratory tests that were billed separately although performed concurrently on automated equipment.
- 72-Hour Window Rule–centers on payments for outpatient services received within 72 hours of a hospital admission already paid for as part of Medicare's inpatient reimbursement to hospitals.

- PPS[2] Transfer–identifies overpayments to hospitals that incorrectly report transfers to other hospitals as discharges in order to receive higher Medicare reimbursements.

- DRG[3] Pneumonia Upcoding–targets inappropriate coding of inpatient hospital billings for a form of the disease more costly to treat than was supported by patients' medical records.

DOJ issued "Guidance on the Use of the False Claims Act in Civil Health Care Matters" on June 3, 1998, to its attorneys, including U.S. Attorneys. The guidance emphasizes the fair and responsible use of the act. It also instructs all DOJ attorneys handling civil health care fraud matters 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 in making their determination, including reviewing relevant statutes and regulations and verifying the accuracy of the data relied on to ensure that they support the allegations. It further requires that they consider whether the rule or policy violated had been clearly communicated to the provider and whether the provider had made efforts to comply with the rule or policy. The guidance provides other safeguards that DOJ attorneys should consider, such as alternative remedies to civil action; a provider's ability to pay; the effect on the community served by the provider, particularly for rural and community hospitals; and the extent to which the provider cooperated in the investigation or audit.

The guidance also contains new requirements specifically applicable to national initiatives. The new requirements specify that a working group must be established for each current and future initiative. Working 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 their initiatives. The working groups are also expected to prepare documentation, 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. The guidance also generally requires the U.S. Attorneys to use so

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[2]Under the Medicare Prospective Payment System (PPS), payment rates are established in advance, and hospitals treating Medicare beneficiaries must generally accept the rate as full payment for a patient's entire stay.

[3]PPS payments are based on diagnosis related groups (DRG), which are classifications of the reasons for a patient's hospital admission in terms of diagnosis and treatment.

called contact letters to notify providers of their potential exposure under the False Claims Act and to offer the providers an opportunity to discuss the matter before a specific demand for payment is made. The use of this approach was directed to avoid the problems associated with issuing demand letters before offering to conduct a dialogue with hospitals. Such demand letters were previously used by some U.S. Attorneys and were alleged by many hospitals to be intimidating and coercive.

DOJ'S EARLY IMPLEMENTATION OF ITS FALSE CLAIMS ACT GUIDANCE

DOJ has begun taking steps intended to ensure that U.S. Attorneys' Offices comply with the June 1998 False Claims Act guidance. For example, DOJ has incorporated the guidance into its training programs on health care fraud issues, thereby providing instruction to its attorneys throughout the country on the appropriate use of the act in civil health care matters. DOJ also has an evaluation program under which a broad review of the operations of each U.S. Attorneys' Office is conducted every several years. DOJ officials have told us that they plan to include an assessment of compliance with the guidance in these reviews beginning February 1, 1999.

DOJ also told us that it does not expect that the June 1998 guidance will necessarily require significant changes by all the U.S. Attorneys' Offices. According to DOJ, much of the guidance reemphasizes DOJ's existing policies. Only procedures pertaining to the national initiatives--namely, the requirements to establish working groups and use contact rather than demand letters--are actually new.

DOJ has designated four projects as national initiatives thus far--Laboratory Unbundling, the 72-Hour Window Rule, PPS Transfer projects, and DRG Pneumonia Upcoding. Although working groups for all four initiatives have been formed, only the Laboratory Unbundling and the PPS Transfer working groups have finalized documentation to guide offices participating in these initiatives.

Besides the four designated national initiatives, DOJ has other antifraud projects involving multiple judicial districts under way. However, DOJ considers only the multidistrict projects that rely on national claims data to be subject to the new requirements of the guidance that pertain specifically to national initiatives. For example, the nationwide PATH project, which is based on Department of Health and Human Services-Office of Inspector General (HHS-OIG) audits, has not been designated a national initiative by DOJ. Consequently, multidistrict projects that are not formally designated as national initiatives may be subject

to a different type of oversight than those that have been so designated. While 34 U.S. Attorneys' Offices reported participating in such multidistrict projects, we do not know how many projects are under way or how similar they are to projects that are covered by the new requirements that pertain specifically to national initiatives.

INVOLVEMENT OF U.S. ATTORNEYS IN NATIONAL INITIATIVES

The results of our survey of U.S. Attorneys' Offices indicate that matters related to national health care initiatives represent a relatively small portion of their civil caseload.[4] All 93 U.S. Attorneys responded to our survey.[5] They reported that of the 117,433 civil matters pending in their offices, 4,722 involved affirmative civil health care matters–that is, matters in which the government makes a claim against private parties. Of these, 2,101 matters related to national initiatives. Another 155 matters involved multidistrict investigations that had not been designated national initiatives.

Sixty-nine, or about 74 percent, of the 93 U.S. Attorneys reported that they were participating in at least one national initiative.[6] Table 1 shows a breakdown of the number of offices participating in these initiatives.

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[4]When a U.S. Attorney's Office opens a civil investigation against a health care provider, the investigation is referred to as a pending matter. A pending matter becomes a case when the government files a civil complaint in a federal district court. A pending matter also becomes a case when DOJ intervenes in a qui tam lawsuit–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 this report, we use the term "matter" to refer to both matters and cases.

[5]We asked the offices to provide data as of November 30, 1998. Not all were able to do so. Instead, some offices provided this information as of the date they completed our survey–late December 1998 or early January 1999.

[6]We define "participating" as having initiated one or more investigations against specific providers.

Table 1: U.S. Attorneys' Offices Participating in Civil Health Care National Initiatives

National initiative	Number of offices participating
Laboratory Unbundling	50
72-Hour Window Rule	15
PPS Transfer	30
DRG Pneumonia Upcoding	38

The survey results also indicate that of the 2,101 matters reported as pending by the U.S. Attorneys' Offices, at most 110 matters, or about 5 percent, were opened after June 3, 1998. (We say "at most" because our survey dealt with aggregate numbers, and we could not readily tell from the responses whether any of these 110 pending matters have since been closed.) According to DOJ officials, they have limited the number of new matters related to national initiatives while working groups finalized the documentation they are required to prepare to guide U.S. Attorneys participating in the initiatives. One official speculated that some of the matters opened since June 3, 1998, may involve qui tam cases, which the Attorney General is required by law to investigate.[7]

U.S. Attorneys' Offices reported closing 752 matters since the guidance was issued, almost seven times the number opened during this period. As table 2 shows, these closed matters were almost evenly divided between settlements and declinations. The majority of settlements related to the 72-Hour Window Rule national initiative, while virtually all the matters closed without adverse action against providers involved the Laboratory Unbundling initiative. This initiative has been the subject of considerable criticism by the medical community. For example, hospitals have claimed that the legal basis for this initiative is unsound. Further, they have contended that the demand letters issued by U.S. Attorneys' Offices were overly aggressive and, in some cases, were not supported by accurate claims data. We plan to determine the reasons for the seemingly large number of Laboratory Unbundling declinations as we continue our monitoring efforts.

[7]Once a qui tam complaint is filed, the Attorney General is required to investigate the allegations and determine whether to join the lawsuit.

Table 2: National Initiative Matters Closed Since June 3, 1998, by Type of Disposition

National initiative	Settled[a]	Declined[b]	Total
Laboratory Unbundling	50	351	401
72-Hour Window Rule	346	2	348
PPS Transfer	0	0	0
DRG Pneumonia Upcoding	3	0	3
Total	**399**	**353**	**752**
Percent	**53.1**	**46.9**	**100.0**

[a]An agreement reached between the government and the provider to resolve the matter in order to avoid litigation.

[b]A matter closed without adverse action.

OUR PLANS FOR CONDUCTING THE REMAINING WORK

To prepare for our required August 1999 report, we will continue to monitor DOJ's compliance with the guidance. In this connection, we plan to meet with representatives from all the DOJ working groups. We will also verify that the working groups have prepared the documentation to guide U.S. Attorneys participating in the national initiatives, as required by the guidance.

We plan to use the results of the survey responses from the U.S. Attorneys' Offices to assist us in focusing our work. We will concentrate our continuing monitoring efforts on offices that are most actively involved in national initiatives and in pursuing other civil health care matters. At these offices, we plan to review compliance, in part, by examining matters subject to the guidance.

On the basis of our experience to date, we face one major challenge in conducting our continuing work. In order to assess DOJ's compliance with the guidance, we need access to information related to its use of the False Claims Act that it deems confidential. DOJ's policy is to restrict access to information

related to national initiatives that it considers nonpublic. DOJ is concerned that broader access could result in public disclosure of confidential information, which could potentially compromise open investigations. We are required by law, however, to maintain the same level of confidentiality for information as is required of the agency from which it is obtained.

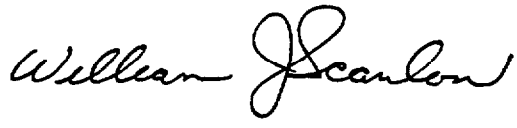
DOJ officials said they are committed to facilitating our review and providing us access to information in a manner that they believe is consistent with the confidential nature of pending law enforcement investigations. Restrictions on our access could limit our ability to reach conclusions about DOJ's or its U.S. Attorneys' compliance with the guidance.

Finally, we expect to continue a dialogue with AHA and other provider groups as our work continues. In this regard, we plan to survey all the state hospital associations to identify their concerns with DOJ's implementation of the guidance.

AGENCY COMMENTS

Officials from DOJ reviewed a draft of this report and generally concurred with its contents. They suggested technical or clarifying comments that we incorporated as appropriate.

We are sending copies of this report to the Attorney General, officials from the organizations we visited, and others who are interested. We also will 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.



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