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Report to Congressional Requesters

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MEDICARE

Application of the False Claims Act to Hospital Billing Practices

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The Honorable Bill Archer
Chairman, Committee on Ways and Means
House of Representatives

The Honorable Henry J. Hyde
Chairman, Committee on the Judiciary
House of Representatives

The Honorable Bill Thomas
Chairman, Subcommittee on Health
Committee on Ways and Means
House of Representatives

The Honorable Lamar S. Smith
Chairman, Subcommittee on Immigration and Claims
Committee on the Judiciary
House of Representatives

Improper billings to Medicare—the federal health care program with nearly 39 million beneficiaries—are a serious threat to the fiscal integrity of the program and may also create a financial burden for Medicare patients who pay deductibles and copayments. 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 $20.3 billion in fiscal year 1997—about 11 percent of all Medicare fee-for-service payments that year.

HHS and the Department of Justice have stepped up their efforts to identify and recover overpayments, assisted by additional resources and enforcement tools provided by the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and the False Claims Act (31 U.S.C. sec. 3729(a) to 3733), which was strengthened by the Congress in 1986. HHS and Justice reported that their efforts combating health care fraud returned almost $1 billion to the Medicare Trust Fund in fiscal year 1997. Two nationwide initiatives—the 72-Hour Window Project and the Lab Unbundling Project—have raised concerns on the part of hospitals that they have been unfairly targeted by Justice and that the use of the False Claims Act to pursue penalties and damages under these initiatives

is inappropriate.[1] The 72-Hour Window Project targets separate payments for outpatient services that were included in the Medicare inpatient payment to hospitals, and the Lab Unbundling Project targets excess payments for lab tests that were performed concurrently on automated equipment.

Because of concerns about these projects, you asked us to provide you with (1) an overview of the False Claims Act and its application to claims involving health care programs; (2) information on the data sources, analysis, and procedures used to bring False Claims Act cases against hospitals under the 72-Hour Window Project; and (3) similar information on the Lab Unbundling Project. This report also includes information on two recent developments related to the issues in your request: recent changes by the Department of Justice in its management of national initiatives involving the use of the False Claims Act and the release of model compliance guidance by HHS-OIG.

To address these issues, we reviewed pertinent federal laws and regulations and obtained information from the Health Care Financing Administration (HCFA), which administers the Medicare program. We also met with HHS-OIG headquarters and Boston regional office staff to discuss their audits of Medicare payments to hospitals, the data they provided to the Department of Justice, and their work with Justice staff on the national initiatives. We met with Department of Justice headquarters officials and with U.S. Attorneys' Offices in the Middle District of Pennsylvania, the Northern District of Ohio, the Southern District of Texas, and the Massachusetts District. We also met with fiscal intermediaries (HCFA contractors that pay claims filed by hospitals) in Massachusetts, Ohio, and Texas. In addition, we met with the American Hospital Association (AHA); the Massachusetts, Ohio, and Texas hospital associations; and representatives of several hospitals that were involved in the national initiatives pursued by the Department of Justice. We obtained the perspectives of these representatives on the Department of Justice's actions regarding the national initiatives.

To be able to issue the report on the date requested, we did not independently verify the accuracy of the data used by HHS-OIG and the Department of Justice or the analyses used in their application of the False Claims Act against hospitals. However, we did determine how the data were generated and used by these agencies in their investigations and

[1]We will address another multistate initiative involving hospital billings to Medicare for physicians at teaching hospitals (PATH) in a separate report.

discussed the reliability of these data with representatives of the hospital associations and fiscal intermediaries. Also, at one U.S. Attorney's Office, Justice officials provided information only on typical procedures used to investigate possible health care fraud cases; they declined to provide detailed information on the procedures used to investigate potential lab unbundling cases because they believed public disclosure of that information could compromise unresolved matters. With these exceptions, we performed our work between March and June 1998 in accordance with generally accepted government auditing standards.

Results in Brief

The False Claims Act was originally created to help combat widespread fraud in government contracts during the Civil War. Amendments to the False Claims Act in 1986 strengthened the government's ability to identify and recover improper payments to federal programs, such as defense procurement and Medicare. The number of civil health care fraud matters pending at the Justice Department at the end of the year increased from 270 in fiscal year 1992 to over 4,000 in fiscal year 1997. By comparison, in fiscal year 1997 all civil fraud matters pending at the end of the year totaled about 6,500. Because the Medicare program involves millions of claims submitted by thousands of providers, the cumulative effect of even small overpayments can involve billions of dollars in Medicare losses. The False Claims Act allows for penalties of between $5,000 and $10,000 for each false claim plus damages of up to three times the amount of the erroneous payment. These penalties can result in potential liability of millions of dollars to high-volume health care providers, even though many individual Medicare claims total less than $100 each. The Justice Department's use of the False Claims Act currently includes two major multistate initiatives involving hospitals—the 72-Hour Window Project and the Lab Unbundling Project.

The 72-Hour Window Project investigates whether hospitals have separately billed Medicare for outpatient services covered by the Medicare inpatient payment, such as preadmission tests provided within 72 hours of admission. Hospitals that do so are, in effect, double-billing Medicare. The Department of Justice and HHS-OIG have been working together to analyze hospitals' Medicare billings and to develop the information needed for False Claims Act cases. In most states, the U.S. Attorney for the Middle District of Pennsylvania is implementing the project for all federal judicial districts in the state. Hospital and Justice representatives have negotiated a nationwide approach for reaching False Claims Act settlements for the 72-Hour Window Project. As of April 1998, about 3,000 hospitals had

received demand letters seeking recovery of overpayments, and about $58 million has been recovered. Of the 2,400 hospitals that have settled with the Department of Justice, about 1,700—those that had only a few erroneous billings—were required only to return the overpayments with interest, and not to pay damages.

The Lab Unbundling Project investigates whether hospitals have billed Medicare separately for each blood test performed concurrently on automated equipment or billed Medicare for medically unnecessary tests. The project began as a joint state-federal effort in Ohio but has since been pursued independently by individual U.S. Attorneys' Offices. Although hospitals and their associations have been critical of both national initiatives, they are particularly concerned that the Lab Unbundling Project involves cases in which, they contend, U.S. Attorneys have issued demand letters that threaten prosecution without valid supporting data analysis. They also contend that billing problems have resulted from unclear or conflicting Medicare guidance rather than false billing by hospitals. Justice has responded to these concerns by changing how it manages national initiatives, creating a working group to increase coordination among the U.S. Attorneys' Offices, and issuing guidance for all Justice Department attorneys handling civil health care fraud matters.

The widespread application of the False Claims Act to improper Medicare billing is a change in approach to resolving this issue and has heightened the importance of hospital compliance with program requirements. Most of the settlements under the 72-Hour Window Project have involved a focused compliance strategy to improve billing practices that have resulted in the specific types of billing errors that prompted Justice's demand letters. In addition, in February 1998, HHS-OIG released program compliance guidance for hospitals covering every aspect of Medicare billing. This guidance was developed with the cooperation of the American Medical Association and the AHA and has been well received. Both HHS-OIG and Justice officials have stated that the presence of an effective compliance program would indicate a hospital's intent to comply with Medicare policies. In such a situation, Justice officials have said, billing errors would be likely to be viewed as inadvertent mistakes rather than as deliberate or reckless overbilling subject to the False Claims Act.

Use of the False Claims Act in Federal Health Care Programs Has Increased

The False Claims Act is the federal government's primary civil remedy for improper or fraudulent claims. It applies to all federal programs, from military procurement contracts to welfare benefits to health care benefits. People who "knowingly" submit false claims may be found liable under the act for penalties of between $5,000 and $10,000 for each false claim plus up to three times the amount of the damages caused to the federal program. Specific intent to defraud the government is not required: the government need only establish that the claim submitted is false and that it was submitted knowingly, as defined in the statute. Thus, the False Claims Act covers activity that would not be included under the traditional definition of fraud, which requires actual knowledge and the intent to defraud. As with most other civil actions, the government must establish its case by presenting a preponderance of the evidence rather than by meeting the higher burden of proof that applies in criminal cases.

Enacted in 1863 in response to allegations of widespread fraud in connection with Union Army procurement contracts, the False Claims Act underwent major amendments in 1986 when, among other things, the Congress both defined the knowledge requirement and specified the burden of proof at the level of a preponderance of the evidence.[2] To prove that a defendant has submitted a false claim knowingly, the government must establish that the person submitted the claim with actual knowledge, in deliberate ignorance, or with reckless disregard for the claim's truth or falsity. Statements in the Senate report on the 1986 amendments clarify that the statute is not intended to apply to honest mistakes and negligence. However, as another statement indicates, one of the goals of the amendments was to establish that "those doing business with the Government have an obligation to make a limited inquiry to ensure the claims they submit are accurate."

Most of the False Claims Act cases brought in the aftermath of the 1986 amendments involved defense contractors. However, as spending on federal health programs and interest in combating health care fraud have grown, the act has been applied more frequently to health care providers than in the past. The number of civil health care fraud matters pending at the Justice Department at the end of the year rose from 270 in fiscal year 1992 to more than 4,000 in fiscal year 1997, as compared with all civil fraud matters pending at the end of fiscal year 1997, which totaled about 6,500. Each U.S. Attorney's Office now has a health care fraud coordinator, and there is increasingly close coordination among Justice, HHS-OIG, the Federal

[2]The amendments also strengthened the False Claims Act's provisions that enable private parties to bring actions on behalf of the government through qui tam, or whistleblower, cases.

Bureau of Investigation, state Medicaid fraud units, and a number of other federal agencies. The False Claims Act has been applied to cases of improper billing practices; claims for services not rendered; provision of medically unnecessary services; misrepresenting eligibility or credentials; and, most recently, substandard quality of care.

The Medicare program involves claims for services submitted by thousands of providers on behalf of 39 million beneficiaries. The cumulative effect of even small overpayments can translate to significant program losses because of the number of claims and providers involved. Justice's recent multistate initiatives reflect the particular nature of the Medicare program—vulnerable to major losses from a large number of relatively small overpayments.

The increased attention to health care does not mean that participants in other federal programs are not subject to potential liability under the False Claims Act, which continues to be widely used in defense-related matters but also covers activities related to all federal programs. Examples of False Claims Act activity in other federal programs include pursuit of false certifications of eligibility for student financial aid, the Food Stamp program, and disability and retirement benefits.

The 72-Hour Window Project Involves Coordinated Nationwide Efforts

The 72-Hour Window Project focuses on Medicare billings by hospitals for certain outpatient services already covered by a Medicare inpatient payment to the hospital. Medicare pays hospitals for inpatient services using a prospective payment system with a fixed fee based on the patient's diagnosis. Outpatient diagnostic services and most nonphysician services provided within 72 hours of the date of admission or during an inpatient stay are included in Medicare's fixed fee for inpatient services.[3] In a series of audits over several years, HHS-OIG determined that numerous hospitals were violating these rules by billing Medicare separately for services already covered by Medicare inpatient payments. Responding to HHS-OIG's referral of these violations, the Department of Justice established the 72-Hour Window Project and notified hospitals of their potential liability under the False Claims Act. Justice started the project in Pennsylvania and then expanded it nationwide. As of April 1998, about 3,000 hospitals had received demand letters from the Department of Justice, and settlements totaled about $58 million. Although some settlements involved damages, most required only that the hospitals return the overpayment plus interest.

[3]For hospitals not included in the prospective payment system, this only applies to services furnished within 24 hours before the date of admission.

Improper Billing Was Widespread

In 1988, HHS-OIG reported that between October 1983 and January 1986 Medicare paid over 5,500 hospitals about $28 million in claims that violated the rule against billing separately for services covered by the inpatient payment.[4] Overpayments were identified from a computer match of HCFA's file of prospective payment system hospital claims with its file of all claims paid by the fiscal intermediaries, including payments for nonphysician outpatient services. HHS-OIG recommended that HCFA (1) instruct the intermediaries to install computerized claims processing edits to deny payments for claims that violated the 72-hour window rule and (2) put the hospitals on notice that they would be subject to sanctions if they did not correct their billing procedures; HCFA agreed to implement these recommendations. In 1990, 1992, and 1994, HHS-OIG issued additional audit reports with similar findings.[5]

HHS-OIG officials told us that frustration over continued violations of the 72-Hour Window rule caused them to bring this matter to the attention of the Department of Justice. It should be noted, however, that the timing of HHS-OIG's audit reports limited the ability of the hospitals to react to the audit findings. For example, the third audit report covered December 1987 through October 1990; since the second audit report was not released until August 1990, there was little time for any corrective action taken by the hospitals in response to the second audit report to be detected in the third audit. Indeed, while little improvement was detected by the first three audits, the fourth audit did detect a substantial decrease in the level of claims improperly paid by the fiscal intermediaries. According to an HHS-OIG official, this decrease could be attributed to many factors, including improved edits installed by the fiscal intermediaries and improved hospital billing performance.

HHS-OIG and the U.S. Attorney's Office for the Middle District of Pennsylvania established a project team that initially focused on 145 hospitals in Pennsylvania served by one fiscal intermediary. Using data developed during HHS-OIG's fourth audit, Justice, after consultation with HHS-OIG, decided to employ the False Claims Act against these hospitals rather than have the fiscal intermediary seek repayment of the amounts

[4]HHS, OIG, Millions in Improper Payments to Hospitals for Nonphysician Services Under the Prospective Payment System, A-01-86-62024 (Washington, D.C.: HHS, July 1988).

[5]HHS, OIG, Improper Medicare Payments for Nonphysician Outpatient Services Under the Prospective Payment System February 1986 through November 1987, A-01-90-00516 (Washington, D.C.: HHS, Aug. 1990); HHS, OIG, Nationwide Review of Improper Medicare Payments for Nonphysician Outpatient Services Under the Prospective Payment System, A-01-91-00511 (Washington, D.C.: HHS, Dec. 1992); and HHS, OIG, Expansion of the Diagnosis Related Group Payment Window, A-01-92-00521 (Washington, D.C.: HHS, July 1994).

improperly billed, as had been done in the past. The project team used letters to notify the hospitals of their total potential financial exposure through civil prosecution under the False Claims Act. This exposure consisted of recoupment of unrecovered overpayments, assessment of damages, and a mandatory minimum penalty of $5,000 per false claim. The demand letters offered the hospitals the opportunity to settle the matter before litigation.

In response to these letters, the Hospital Council of Western Pennsylvania, the Pennsylvania Hospital Association, and the AHA worked closely with the U.S. Attorney's Office and HHS-OIG to develop a model settlement agreement among the Pennsylvania hospitals, the HHS-OIG, and Justice that reflected the relative volume of each hospital's inappropriate billing. Hospitals were divided into three tiers primarily on the basis of the number of errors per hospital bed. The first tier contained hospitals with a total of 10 or fewer erroneous claims and hospitals with relatively few erroneous claims per hospital bed, compared with other hospitals in the state. The second tier contained hospitals with a higher number of errors per bed, and the third-tier hospitals had the most errors per bed. In defining the tiers, the U.S. Attorney's Office looked for clusters of hospitals with comparable volumes of inappropriate claims per bed. Therefore, the number of hospitals in each tier can vary significantly. The Justice Department and HHS-OIG subsequently expanded this initiative nationwide to all 4,660 hospitals identified in HHS-OIG's fourth audit as receiving overpayments. After the project expanded to other states, a "tier 0" was established to include all hospitals with overpayments of less than $1,000 regardless of the number of errors per bed. The criteria for the different tiers in two states are illustrated in table 1.

Table 1: Criteria for Assigning Hospitals to Tiers in New Jersey and Nebraska

	New Jersey		Nebraska	
Tier	Hospitals	Criteria	Hospitals	Criteria
0	1	Less than $1,000 in overpayments	[a]	Less than $1,000 in overpayments
1	31	Less than 0.0676 errors/bed or 10 or fewer errors	[a]	10 or fewer errors
2	29	Between 0.0725 and 0.1385 errors/bed	3	Between 0.0438 and 0.0769 errors/bed
3	28	Between 0.1429 and 0.4592 errors/bed	4	Between 0.1189 and 0.5467 errors/bed

[a]Nebraska's hospitals in tiers 0 and 1 total 55; break-down data were not available.

Source: U.S. Department of Justice.

Hospitals were given the opportunity to justify the claims in question on the basis of their analysis and interpretation of the claims data, and some were able to convince the Assistant U.S. Attorney to put them in a lower tier. The damages assessed against hospitals in each tier were negotiated between the U.S. Attorney's Office and hospital representatives and are depicted in table 2. Hospitals, except those in tier 0, agreed to institute a compliance strategy to correct billing problems associated with outpatient services rendered in connection with an inpatient stay. In addition, all hospitals agreed to reimburse Medicare beneficiaries for their copayments and deductibles paid.

Table 2: Settlement Terms by Tier Level

Tier	Repayment	Damages assessed
0	Overpayments plus interest	None
1	Overpayments plus interest	None
2	Overpayments plus interest	75% of actual overpayments detected in third HHS-OIG audit and recovered by the fiscal intermediary.
3	Overpayments plus interest	200% of potential overpayments detected in fourth HHS-OIG audit; 100% of actual overpayments detected in third HHS-OIG audit and recovered by the fiscal intermediary.

The project team in Pennsylvania asked every fiscal intermediary for information on the 4,660 hospitals nationwide identified as having received overpayments and, together with other U.S. Attorneys' Offices, is steadily reaching agreements with hospitals on the basis of the model settlement used in Pennsylvania.[6] Of the approximately 3,000 hospitals that had received demand letters from the Department of Justice by April 1998, 2,400 have settled with the Justice Department. Of these, 1,700 were in either tier 1 or tier 0.[7] Thus, most of the hospitals have not been required to pay any damages. Altogether, settlements totaled about $58 million as of April 1998.

Hospital associations contend that their members attempt to bill Medicare correctly but that their efforts are stymied by the complexity of the regulations or by conflicting instructions from HCFA and the fiscal intermediaries. Further, they point out that Medicare is just one of the

[6]Hospitals are divided into tiers within service areas of each intermediary—which usually, but not always, correspond to individual states—so that the data underlying the tier placement within each fiscal intermediary's service district are consistent.

[7]Some hospitals had such a low error rate that they were not included at all in the initiative.

many medical insurance programs that they deal with. While it is incumbent upon HCFA and its fiscal intermediaries to issue clear, consistent instructions regarding billing procedures and other Medicare requirements, Justice and HHS-OIG officials stress that the restrictions on outpatient billings prior to an inpatient stay have been part of the Medicare statute since 1984 and should be clear to everyone. Further, Justice officials note that they deal only with straightforward billing, involving the same provider number, to avoid the more complex situations involving multiple affiliated providers.

Hospital groups also state that it is inappropriate to handle billing errors as potential False Claims Act cases rather than routine overpayments. They believe that this could result in the negative impression that hospitals have committed fraud against the government when, in fact, only inadvertent billing mistakes have occurred. These groups stress that, in the past, routine overpayments were corrected through the review of the annual cost reports submitted to the fiscal intermediaries. However, this is not entirely accurate, because the annual cost report review does not examine the appropriateness of specific claims. Instead, it involves a reconciliation of the cost report with interim payments that have been made to the hospital.

Hospital groups also contend that the False Claims Act's enormous penalties make its use in this area inherently coercive. They have stated that the only reason that hospitals settle with the Justice Department and HHS-OIG is that they would face huge liability if they lost in court. Justice officials state that they are not out to coerce or punish hospitals for inadvertent billing errors and point to the fact that 1,700 of the 2,400 hospitals that have settled to date have not paid any damages, and no hospital has been assessed a per-claim penalty of between $5,000 and $10,000.

The Lab Unbundling Project Lacks Centralized Control

The Lab Unbundling Project is an investigation of improper billing of outpatient clinical lab tests by hospitals.[8] Unlike the 72-Hour Window Project, the Lab Unbundling Project was not centrally coordinated by one U.S. Attorney's Office. Originally known as the Ohio Hospital Project, it began as a joint effort between the two U.S. Attorneys' Offices in Ohio and the Ohio State Auditor. Following training on data sources and techniques by the Ohio U.S. Attorneys' Offices and HHS-OIG, U.S. Attorneys' Offices in

[8]Most cases involve how tests for the chemical and cellular composition of blood should be coded and billed, concerns about whether a physician ordered the tests, and the medical necessity of certain tests.

other states have begun to independently pursue lab cases. Hospitals are highly critical of this initiative and claim that no legal basis exists for requiring them to bill automated tests as one claim. Further, they contend that the demand letters issued by U.S. Attorneys' Offices are overly aggressive and in some cases do not reflect the necessary research and data analysis needed to support them. On the other hand, Justice officials have said that hospitals' claims to Medicare must accurately indicate the services performed for automated tests and that changes are being made in the letters sent to hospitals.

Codes to Indicate Automated Lab Tests Are Not Always Used

Developments in technology have made it possible to perform multiple clinical tests on a single blood sample simultaneously, greatly decreasing labs' labor costs as well as costs associated with occupational hazards due to contact with blood and medical waste. To reflect these lower costs, the coding system used for billing these tests—referred to as "automated multichannel tests"—includes generic codes to indicate that the tests were done as part of an automated series, or "profile," rather than individually. Each profile code specifies the number of tests performed. A profile is generally reimbursed at a lower rate than the same combination of tests submitted separately, or "unbundled," using the specific code for each test. An overpayment may occur when tests are submitted and paid for separately if they were in fact performed as a profile.

The Medicare Hospital Manual, section 437j, instructs hospitals to follow the Physicians' Current Procedural Terminology, Fourth Edition—commonly referred to as the CPT-4—in the absence of instructions from their fiscal intermediary.[9] The section in the CPT-4 entitled "Automated, Multichannel Tests" states:

> The following list contains those tests that can be and are frequently done as groups and combinations ('profiles') on automated multichannel equipment. For any combination of tests among those listed immediately below, use the appropriate [code] number 80002-80019. Groups of the tests listed here are distinguished from multiple tests performed individually for immediate or 'stat' reporting.

A list of 19 tests follows this statement.[10]

[9]The Physicians' Current Procedural Terminology, Fourth Edition (Chicago: American Medical Association, 1993), is a compilation of codes and descriptive terms used as a standard system for reporting medical, surgical, and diagnostic services.

[10]Three additional tests, also frequently done on automated multichannel equipment, are the subject of controversy about whether they are required to be bundled with other automated tests in a profile or may be billed separately.

As the Medicare Hospital Manual indicates, if the fiscal intermediary has issued other instructions, hospitals should follow those. Some intermediaries issued instructions regarding lab bundling at various times in the early 1990s. In 1994, HCFA required its intermediaries to implement comprehensive edits to detect and bundle separate codes for lab tests on the same claim following an HHS-OIG audit report citing significant overpayments due to inadequate edits.[11] Most fiscal intermediaries established edits and notified hospitals in the summer of 1994.

Hospital representatives dispute that they have an obligation to bill multichannel tests as a profile. They assert that it is the responsibility of the fiscal intermediary to determine the correct payment amount. They also contend that billing instructions from HCFA and the fiscal intermediaries are misleading, contradictory, and an insufficient basis for a legal obligation for hospitals to bundle their services for billing purposes. Justice officials and the U.S. Attorneys we met with stated that a hospital's obligation is very simple: claims to Medicare must accurately indicate the services performed; therefore, tests done on automated multichannel equipment must be billed using the profile codes established in the CPT-4.

Ohio U.S. Attorneys' Offices Conducted Initial Reviews

The Lab Unbundling Project involved the U.S. Attorneys' Offices in the Northern and Southern Districts of Ohio as well as the State Auditor's office, the fiscal intermediary, and HHS-OIG. In 1994, one of the Assistant U.S. Attorneys in the Northern District investigated allegations of duplicate billings for venipuncture at a hospital outpatient lab. While reviewing the hospital's lab claims, he noticed unusually high numbers of blood chemistry tests. Then, in December 1994, he was informed by an Assistant U.S. Attorney for the Eastern District of Pennsylvania that some Ohio hospitals had been clients of a billing consultant who had recommended strategies to maximize reimbursement that the Justice Department considered suspect. To follow up on the possibility of improper billing for clinical lab tests, the Assistant U.S. Attorney in Ohio requested that the Ohio fiscal intermediary process data from these client hospitals as well as the hospitals with the highest outpatient lab billings—about 40 in all—for a 29-month period beginning in 1992. The fiscal intermediary had already begun to analyze hospital outpatient lab claims in 1993 following audit findings by HHS-OIG showing systematic overpayments for automated blood chemistry tests in another state.

[11]HHS, OIG, Reimbursement by Massachusetts Blue Cross for Laboratory Services Performed by Hospitals as an Outpatient Service, A-01-92-00523 (Washington, D.C.: HHS, Aug. 1993).

The computer program developed to identify duplicate, or unbundled, claims was tested and refined several times before hospitals were contacted about potential liability under the False Claims Act. To determine the accuracy of the program and underlying claims data, the U.S Attorney's Office sampled medical records for 50 beneficiaries from 15 hospitals to review the physician's order, the itemized bill, and the test results. The review and interviews with hospital personnel established that the blood chemistry tests that can be performed on automated test equipment are always done that way.

Both U.S. Attorneys for Ohio began to issue demand letters for hospitals on the basis of the first round of claims data analysis in 1995. These letters covered Medicare and Medicaid clinical lab claims over a 6-year period.[12] In contrast with the 72-Hour Window Project, these letters did not list a specific amount of damages; instead, they indicated the codes that showed up as potential problems on the basis of the claims data analysis for each hospital. The demand letters sent in the Northern District of Ohio presented hospitals with a settlement option: conduct an independent self-audit based on a work plan approved by the Assistant U.S. Attorney and pay two times the amount of overpayments identified. Most Ohio hospitals chose to conduct self-audits.

Settlement agreements began to be announced in the summer of 1996. Repayments and damages are being negotiated individually for each hospital rather than according to a tier arrangement as in the 72-Hour Window Project. According to hospital representatives, most settlements in the Northern District were negotiated for between 1.6 and 1.8 times the overpayments identified in the self-audit for claims before July 1, 1994. As of May 5, 1998, settlements of over $22 million from 80 hospitals had been announced. In October 1996, the Ohio Hospital Association, along with the AHA, had filed suit in federal district court against the Secretary of HHS seeking injunctive relief from application of the False Claims Act to hospitals' outpatient lab claims. This case was dismissed on jurisdictional grounds.

Data Sources and Techniques Were Shared With Other U.S. Attorneys

Although the project had not been conceived as a potential nationwide initiative, Assistant U.S. Attorneys from both Ohio districts and HHS-OIG representatives provided a briefing on the Ohio Hospital Project for Department of Justice officials in March 1997. These Assistant U.S.

[12]As part of HHS-OIG's Partnership Plan to conduct joint reviews with state auditors, the Ohio State Auditor's Office had already conducted audits involving similar Medicaid billing requirements for several hospitals.

Attorneys shared sample documents and discussed lab billing requirements and data sources with their counterparts in other districts.

The U.S. Attorney's Office in Boston requested that data on outpatient lab claims compiled by HHS-OIG be made available to other U.S. Attorneys' Offices around the country.[13] The Boston U.S. Attorney's Office notified other U.S. Attorneys' Offices that these data were available for them to use as a first step in identifying hospitals with potentially improper billing patterns. Any U.S. Attorney's Office interested in pursuing lab bundling cases could use HHS-OIG data or request data from the fiscal intermediary within its district and proceed independently.

In Texas, lab unbundling cases are being pursued in a coordinated effort by all four U.S. Attorneys' Offices using claims data to which the fiscal intermediary applied the program developed in Ohio for identifying improper claims. The demand letters were sent on the basis of summary data for each hospital that had been checked against HHS-OIG's audit data. A follow-up letter was sent later, along with disks with detailed claims data for the hospital's review. Hospitals were also provided the option of conducting an independent self-audit. Hospitals with overpayments of less than $2,000 have not been subject to False Claims Act damages, and those with very few errors were simply instructed to repay the fiscal intermediary without participating in a formal settlement.

Concerns Have Been Raised About the Implementation of the Lab Unbundling Project

Hospital representatives have criticized the wording and tone of the demand letters themselves as well as the intimidating nature of False Claims Act liability. This issue is particularly acute in Texas, where the demand letters were not accompanied by supporting claims data and hospitals' individual circumstances had not been closely analyzed before the hospitals were contacted. Justice officials and the U.S. Attorney in Texas we met with acknowledged that some letters were overly aggressive and that the situation should have been handled differently, with more advance research and individual attention. However, they also indicated that the harsher aspects of the demand letters do not reflect the reality of the process. For example, they stated that hospitals in Texas have always been granted additional time to analyze their situation if they requested it, and the threat of legal action if hospitals failed to respond within 14 days has never been carried out.

[13]These data consisted of national claims information from 1992, 1994, and 1995 to which HHS-OIG had applied its own audit protocols to identify potential duplicate or otherwise improperly billed lab claims.

Hospitals have also raised concerns about the cost of conducting the self-audit. One hospital representative in Ohio that we met with estimated the hospital's audits and attorney fees cost at least $40,000—in addition to the hospital's own staff time. One hospital spent over $25,000 defending claims of $15,425 in alleged overpayments. Hospital representatives in Texas told us they believe the cost of the audits is prohibitive, particularly for large-volume providers. They were also concerned that the audit option proposed by the U.S. Attorneys' Offices included more types of lab claims than did Justice's estimate of overpayments, thereby putting hospitals who chose the audit option at risk of even greater liability. The one Texas U.S. Attorney we met with stated that, at the time of our visit, no hospitals in his district had opted to conduct audits or tried to negotiate the scope of the audit that would be required. However, in cases in which hospitals have brought concerns about the data to the attention of Assistant U.S. Attorneys in Texas, adjustments have been made. For example, separate claims for the three tests that are not included in the CPT-4 list of automated multichannel tests were removed from the estimates of overpayments by the U.S. Attorneys' Offices in all four districts.

Ohio hospital representatives also stated that there were errors in the data used by the U.S. Attorneys' Offices, particularly regarding the dates of service. Dates of service were not available for many older claims, so some tests that in fact were performed on different days may have been identified as duplicates. While this does raise concerns, in Ohio the settlements were almost always based on overpayments identified in the self-audits, not the U.S. Attorneys' Offices' analyses. Furthermore, the fiscal intermediary in Ohio estimated that, at the most, only about 15 percent of lab claims contained services that occurred on more than 1 day. Texas hospitals have also raised concerns about the date of service issue. Because few if any hospitals in Texas have conducted audits at this time, the scope of this problem has not been identified. The U.S. Attorney we met with was aware of the situation and indicated an intent to take appropriate action.

Justice Has Announced Changes to Its Management of Multistate Initiatives

Responding to hospital concerns, Justice has announced a new approach to how it manages national initiatives such as the Lab Unbundling Project. In June 1998, Justice issued detailed guidance on the use of the False Claims Act in national health care initiatives. The guidance instructs all Justice Department attorneys handling civil health care fraud matters to first research the relevant provisions in both statutes and regulations and

to verify the data being used to support the investigation. Further, the guidance directs the use of "contact letters" instead of "demand letters" in most circumstances. According to the Justice officials, a contact letter will notify hospitals that claims data indicate possible concerns and invite hospitals to evaluate and discuss the situation with the U.S. Attorney's Office. Justice officials believe that this guidance will ensure more thoroughness and consistency in national initiatives.

Justice officials have stated that they believe it is important that multistate initiatives also preserve the flexibility of U.S. Attorneys to respond to local circumstances. Guidance issued by the Department of Justice now requires the Lab Unbundling Project and future multistate initiatives involving health care issues to establish working groups. The goal of these working groups is to promote coordination among Assistant U.S. Attorneys involved in similar cases across the country by consolidating contacts with other government agencies, developing data sources, gathering documents needed for background research, and preparing sample documents. Once an initiative is under way, the working group will continue to operate as an information clearinghouse and track how cases are being resolved in different districts.

Representatives of the AHA stated that the guidance was a step in the right direction. However, they were concerned about several aspects of the implementation of the guidance by the U.S. Attorneys' Offices: AHA representatives believe individual U.S. Attorneys' Offices may not fully implement the guidance; moreover, AHA is concerned because the guidance did not specify how the Department of Justice would monitor its implementation. AHA felt that U.S. Attorneys' Offices would not be held accountable for the manner in which they implemented national initiatives in their districts without Justice Department monitoring. Further, AHA representatives believed that the working groups for national initiatives involving health care matters should include representatives from HCFA and HHS-OIG to promote understanding and agreement on technical aspects of Medicare billing issues.

HHS-OIG Has Issued Compliance Guidance

HHS-OIG and Justice officials acknowledged that some billing errors are inevitable. They believe, however, that providers need to take steps to minimize such errors. These officials told us they believe that the presence of an effective compliance program would indicate a hospital's intent to comply with all Medicare rules and regulations. Theoretically, billing errors would be caught by the hospital itself, and those not caught would

more likely be viewed as inadvertent mistakes rather than a billing pattern subject to the False Claims Act. Representatives of hospital associations and individual hospitals told us that they are hopeful HHS-OIG and Justice will follow through with this approach.

While hospitals had to implement compliance strategies as part of the settlement agreement for the 72-Hour Window Project, those strategies addressed only billing issues associated with outpatient services rendered in connection with an inpatient stay. Compliance programs foster a culture within hospitals that encourages compliance with applicable rules and regulations and establishes systems to prevent, detect, and resolve conduct that does not conform to them. In order to encourage institutionwide compliance programs for all aspects of Medicare billing, HHS-OIG released guidance for developing hospital compliance programs in February 1998. This guidance was developed with the active involvement of the American Medical Association and the AHA.

Hospital representatives told us that HHS-OIG's February 1998 guidance is both reasonable and flexible and that the 72-Hour Window and Lab Unbundling Projects have encouraged increased attention to compliance by hospitals and their representatives. For example, the Ohio Hospital Association has sought written clarification from HCFA on some complex billing questions on behalf of the Association's members. Moreover, hospital accounts managers told us that historically their offices have received low priority for computer and staff resources and that the new attention to compliance has already been helpful in their effort to design billing systems that will better ensure accuracy. We plan to assess the effectiveness of compliance programs in future work.

Conclusions

Health care providers participating in the Medicare program must bill the program in accordance with its requirements and retain only those payments they are entitled to receive. Given its volume of claims, the Medicare program can suffer significant cumulative losses even with small overpayments on individual claims. Such losses could compromise the solvency of the program and its ability to sustain the current level of benefits available to Medicare beneficiaries. At the same time, HCFA and its fiscal intermediaries also have a responsibility to clearly and consistently delineate Medicare billing policies in a timely manner and install proper edits to ensure that Medicare pays only what it is supposed to. However, because so few claims are audited, the voluntary compliance of hospitals is crucial for maintaining the integrity of the Medicare program.

The False Claims Act is a powerful tool available to the federal government to ensure compliance with government program requirements. Its widespread application to the health care field is a relatively recent phenomenon that surprised many health care providers—particularly its use in multistate initiatives. Hospital groups have raised legitimate concerns about how the Justice Department used computer data from various sources as the sole basis for alleging liability under the False Claims Act. It is important that Justice officials test and refine the computer data to ensure their accuracy before hospitals are notified of potential False Claims Act liability. Such notification may seem threatening because the penalties and damages that can result are so extensive. Further, it is important that providers be given a realistic opportunity to review and analyze the data in question and provide an explanation for why they may not be accurate before legal action against providers is either threatened or undertaken. The Department of Justice has recognized the legitimacy of these concerns and has both developed guidance for using the False Claims Act in multistate initiatives and established working groups to improve coordination and development of cases.

Agency and Other Comments and Our Evaluation

We provided a draft of this report for comment to HCFA, the Department of Justice, HHS-OIG, and the AHA. The following summarizes their comments and our responses.

HCFA officials reviewed the draft and had no comments. Department of Justice officials generally agreed with the report but suggested some technical and editing changes. In some cases, we agreed to make changes along the lines Justice suggested. In other cases, Justice agreed that a change it suggested was not needed or that alternative wording we suggested was acceptable.

HHS-OIG officials said the draft report fairly characterized the factual basis for the nationwide initiatives. We discussed technical and editing changes they suggested, and we reached agreement on most points. However, regarding the timing of the series of audit reports on the 72-Hour Window rule, HHS-OIG officials believe that hospitals had enough time between the issuance of the first and third audits to improve their billing practices, although no improvement was detected by the third audit. We agree, but, as noted in our report, this is not consistent with HHS-OIG and Justice statements that the 72-Hour Window Project was undertaken because all four audits detected little improvement in hospitals' billing practices.

HHS-OIG officials agreed that there was significant improvement detected in the fourth audit. However, they believe this improvement was a result of edits installed by the fiscal intermediary rather than an improvement in hospitals' billing practices. The fourth audit did not determine the exact cause of this improvement. Recognizing the uncertainty over the source of improvements found in the fourth audit, we clarified our report's presentation on this issue.

Representatives of the AHA clarified their views on a number of issues raised in the report. In particular, they stressed that hospitals do not object to returning overpayments, but they oppose the use of the False Claims Act to address what they believe are billing errors due to many factors, including the complexity of the Medicare program, rather than fraudulent behavior by hospitals. AHA representatives acknowledged, however, that using the False Claims Act got the attention of hospitals and led them to focus on improving their billing practices.

AHA officials took issue with our conclusion that, because so few claims are audited, the voluntary compliance of hospitals is crucial for maintaining the integrity of the Medicare program. AHA representatives said that virtually all claims are audited because they are processed through automated claims processing edits. They added that all hospitals undergo annual cost report reviews and hospitals also employ other methods to identify and correct billing errors. We disagree that all claims are audited. Even if fiscal intermediaries do implement effective prepayment edits, those edits are not equivalent to audits because the edits cannot determine if the information on a claim is accurate.

AHA representatives also stressed that the Medicare program is highly complex and expressed the view that the billing policies governing the 72-Hour Window rule and the bundling of lab claims are not as clear-cut as the report implies. They expressed doubts that over 4,600 hospitals would have purposely misbilled Medicare under the 72-Hour Window rule as alleged by the Department of Justice and HHS-OIG. They stated that HCFA should take major responsibility for the billing errors that have occurred because of its failure to promulgate Medicare billing policies in a clear and timely manner. We note in our report that HCFA and its fiscal intermediaries have a responsibility to clearly and consistently delineate Medicare billing policies in a timely manner.

AHA representatives acknowledged that the newly issued guidance from the Justice Department governing the management of national health care

initiatives was a step in the right direction but were skeptical that U.S. Attorneys would implement the guidance consistently. They provided examples of actions taken by U.S. Attorneys' Offices since the issuance of the guidance on June 3, 1998, that they believe demonstrate this inconsistency. While examination of these situations is beyond the scope of this review, we did include AHA's concerns in the section of the report dealing with the newly issued Department of Justice guidance.

Finally, AHA representatives said that any time a hospital receives a letter from the Justice Department, it is an intimidating event whether it is a contact letter or a demand letter. Our report acknowledges that notification of potential False Claims Act liability can be perceived as threatening, and we stress that providers be given a realistic opportunity to respond before legal action against them is either threatened or undertaken.

As agreed with your offices, unless you release its contents earlier, we plan no further distribution of this letter for 30 days. At that time, we will make copies available to other congressional committees and Members of the Congress with an interest in these matters, the Secretary of Health and Human Services, the HHS Inspector General, the Administrator of HCFA, and the U.S. Attorney General.

This report was prepared by Frank Putallaz and Suzanne Rubins under the direction of William Reis, Assistant Director. Please call me at (202) 512-7114 or Leslie G. Aronovitz, Associate Director, at (312) 220-7600 if you or your staff have any questions about the information in this letter.

William J. Scanlon
Director, Health Financing and
Systems Issues

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