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Office of the General Counsel

Subject: Use of False Claims Act to Target Hospitals

File: B-279893

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The Honorable William M. Thomas
Chairman, Subcommittee on Health
Committee on Ways and Means
House of Representatives

The Honorable Jim McCrery
Subcommittee on Health
Committee on Ways and Means
House of Representatives

In 1995, the Department of Health and Human Services' Office of the Inspector General (HHS-OIG) and the Department of Justice (DOJ) embarked jointly on a nationwide project targeting improper Medicare claims by hospitals for outpatient services (referred to below as the Joint Project or the 72 Hour Window Project). Medicare reimbursement of hospitals for inpatient services includes compensation for related outpatient services, such as laboratory tests, provided during the 3 days preceding the day of admission. The HHS-OIG stated that, despite prior warnings, hospitals were continuing to submit claims for these preadmission services in addition to their claims for the related inpatient procedures, resulting in double payment.

The primary objectives of the ongoing DOJ/HHS-OIG Joint Project include requiring hospitals to establish internal controls to prevent submission of such improper Medicare claims, recouping amounts improperly paid to hospitals plus interest, and, in the more egregious cases, collection of penalties from the claimant. The authority for civil penalties and damages for anyone who knowingly submits a false or fraudulent claim to the United States is found in the False Claims Act, section 3729 of title 31, United States Code.

Hospitals have expressed concern about the use of the False Claims Act to support imposition of penalties for claims that they consider to be for insignificant amounts; in their view, the government should not have used the False Claims Act with respect to these "non-material" claims. The hospitals also say that their claims are not knowingly false but are simply mistaken.

You asked us in your letter of August 4, 1997, to address a number of questions concerning the use of the False Claims Act in this situation, some of which we have

combined and restated. The questions are: (1) how the HHS-OIG/DOJ Joint Project is enforcing the False Claims Act against hospitals, and whether the law is unclear; (2) whether advisory opinions would assist in clarifying the law; (3) whether the Joint Project is treating the health care industry differently from other industries; and (4) whether the Joint Project is pursuing billing errors that are not material, and whether a "materiality" standard, limiting use of the False Claims Act to disputed amounts that are material, would be appropriate, either through legislation or through administrative action by DOJ. In connection with the last question, we looked specifically at the operation of the Joint Project in Louisiana, where the state hospital association has complained that the failure of the Project to take materiality into account led to unfair treatment of hospitals.

In summary, (1) we found no evidence that errors hospitals made with respect to the 72 hour rule were the result of unclear or ambiguous statutes, regulations, or guidance. The law is reasonably clear in describing the conditions under which nonphysician outpatient services are not separately reimbursable. For this reason, (2) advisory opinions do not appear to be necessary or helpful in clarifying the 72 hour rule. In addition, since culpability under the False Claims Act depends on the state of mind of the person taking the action, advisory opinions--to the extent that they rely on assumptions concerning that person's knowledge or state or mind--might not be meaningful. Further, (3) we found no evidence that health care providers or hospitals in particular have been singled out under the False Claims Act by the Joint Project or have had a different standard applied to them. Finally, (4) the current practice of DOJ in effect takes materiality into account in settlements negotiated by the Joint Project under the False Claims Act. This has been augmented by safeguards provided in recent DOJ guidance on False Claims Act enforcement in health care matters. These existing protections seek to strike a reasonable balance between protecting the rights of the subjects of investigations and those of those of the government.[1]

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[1]Two other GAO products, soon to be available, address closely related issues. The first of these addresses the data sources, analysis and procedures used to bring False Claims Act cases against hospitals for outpatient and clinical laboratory services. That report also discusses recent changes by DOJ in its management of national initiatives involving the use of the False Claims Act and the release of model compliance guidance by HHS-OIG. Also, our report on DOJ use of the False Claims Act in cases involving hospital billings to Medicare for physicians at teaching hospitals will be issued soon.

Background

Under the Prospective Payment System for Medicare inpatient hospital services, Medicare pays predetermined amounts for specific covered services.[2] These amounts are calculated to compensate the hospital not only for the inpatient services but also for related outpatient services rendered during a window of time before the admission. Specifically, the predetermined reimbursement for an inpatient procedure includes compensation for nonphysician outpatient services related to the admission, like diagnostic tests, that are performed during the 3 days immediately preceding the date of admission. This is commonly referred to as the 72 hour rule.[3]

For example, the charge for an electrocardiogram performed by the hospital 2 days before, but related to, hospital admission cannot properly be billed separately to Medicare. Reimbursement for this test is included (or "bundled") in the predetermined amount paid to the hospital by Medicare for the beneficiary's inpatient stay. A separate, unbundled, claim to Medicare for the test would be improper; it would constitute billing twice for the same service. Such a claim could also result in an unwarranted expense to the beneficiary in the form of a copayment or deductible.

Between 1986 and 1996, the HHS-OIG performed five successive reviews of claims by hospitals covered by the prospective payment system, in order to assess compliance with the prohibition on billing Medicare for nonphysician outpatient services rendered during a specified window of time prior to admission. In each review, the HHS-OIG determined that millions of dollars of claims had been inappropriately filed and paid. In addition, Medicare beneficiaries have paid millions of dollars in deductibles and coinsurance for which they should not have been responsible, in connection with these improper claims.

In the first review, covering the period October 1983 through January 1986, the HHS-OIG identified significant improper payments made nationwide and not previously detected. In that first report, issued in 1988, the HHS-OIG recommended that fiscal intermediaries, the contractors that manage Medicare billing and

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[2]The amount paid to hospitals for a service depends on the nature of the illness and its classification under a so-called diagnosis-related group or DRG.

[3]A one-day window applied from October 1, 1983 through December 31, 1990. Effective January 1, 1991, the window was expanded to 3 days. (A one-day rule still applies under limited conditions.) Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4003(a), 42 U.S.C. § 1395ww(a)(4). In this letter we refer only to the 72 hour rule, but some of the earlier reviews by the HHS-OIG of hospital compliance, discussed below, properly applied the one-day standard then in effect.

reimbursement, implement computer controls to prevent further improper payments, and that they recover overpayments from hospitals. The HHS-OIG further recommended that the Health Care Financing Administration (HCFA), the agency that administers the Medicare program, notify hospitals that they must correct billing procedures or face sanctions. The findings and recommendations were much the same for the second report issued in 1990, covering the period February 1986 through November 1987. The two reports identified $68 million in overpayments.[4]

Claims submitted during the period covered by the fourth report, November 1990 through December 1991, showed a significant decrease in overpayments.[5] However, that report, issued in 1994, showed that overpayments continued, totalling $8.6 million for the 14-month period. Concluding that more needed to be done, in 1995 the HHS-OIG and DOJ jointly initiated a national project to include the 4,660 hospitals identified in the fourth HHS-OIG report as having submitted potentially improper claims. The national project had its genesis in a pilot project begun in Pennsylvania.[6]

The Joint Project decided to adopt a new tactic to deal with hospitals found in the more recent reviews to have been submitting claims for outpatient procedures that were not allowable under the 72 hour rule. DOJ would bring civil actions under the False Claims Act against the hospitals unless they agreed to negotiated settlements. As described below, the settlement offers to hospitals took into account the penalties to which those hospitals might be subject under the Act.

The False Claims Act provides that any person who "knowingly presents, or causes to be presented" a false claim to the Government is liable to pay a civil penalty of

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[4]A third HHS-OIG report, issued December 1992, identified overpayments totalling $38.5 million for claims submitted between December 1987 through October 1990. The report cautioned that significant improper claims and payments continued, and recommended that HCFA emphasize to hospitals that they would be subject to penalties unless they adopted adequate procedures to avoid improper billing.

[5]The fourth HHS-OIG report identified potential improper payments at an annual rate of about $7 million. For the period covered by the fifth report, January 1992 through December 1994, the corresponding annual rate was about $9 million. The fifth HHS-OIG report was issued in 1996.

[6]In 1993, the HHS-OIG and the Office of the United States Attorney for the Middle District of Pennsylvania began a pilot project, initially involving two hospitals in Pennsylvania but later expanded to most Pennsylvania hospitals. The United States Attorney for the Middle District of Pennsylvania took the lead when the joint decision was made in 1995 by the HHS-OIG and DOJ to expand the effort nationally.

no less than $5,000 and no more than $10,000 per claim, plus an amount normally three times the damages which the Government sustains as a result of the false claim.[7] The current penalty levels were established in 1986; until then, the penalties had remained at the level at which they were set in the original Civil War statute--a $2000 penalty for each claim and double damages.

Under the current version of the False Claims Act, the claimant's knowledge or state of mind is an important factor in determining liability. A claimant does not have to intend specifically to defraud the government when presenting a false claim in order to have violated the Act, but something more than innocent mistake or simple negligence is necessary.[8] A claim is "knowingly" false not only when the claimant has actual knowledge that the information is false, but also when he acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

Before approaching the hospitals, the Joint Project consulted with representatives of the American Hospital Association (AHA). AHA participated in drafting a model "demand letter" to be sent to hospitals and a model settlement agreement. The demand letters notify hospitals of their potential exposure to civil liability under the False Claims Act and offer to settle the matter before litigation. Enclosed with each letter is a listing of the claims by the hospital that the Project believes to have been improper and a proposed settlement agreement, including a proposed amount.

AHA and the Hospital Council of Western Pennsylvania also worked with the U.S. Attorney's Office to develop the strategy of scaling the settlements to the relative culpability of each hospital. This was initially done by assigning hospitals in each state to one of three "tiers" (numbered as 1, 2, and 3) based on, among other things, the ratio of potentially false claims identified in the HHS-OIG's fourth report to the number of hospital beds. Subsequently, a tier zero was established, comprising hospitals with less than $1000 of overpayments regardless of the number of beds.[9]

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[7]In this report, we use the term "overpayments" to refer to the amount the government pays, in excess of what it should have paid, as a result of a false claim.. We use the term "penalties" to refer to recoveries by the government under the Act, apart from interest, in excess of the amount of overpayment. Thus, when the Act calls for treble damages, this comprises recovery of the overpayment plus a penalty equal to 200 percent of the overpayment.

[8]E.g., Wang ex rel. United States v. FMC Corp., 975 F.2d 1412, 1421 (9th Cir. 1992): "The Act is concerned with ferreting out 'wrongdoing,' not scientific errors."

[9]Hospitals are grouped and divided among the tiers within the service areas of each fiscal intermediary, which usually but not always correspond to individual states.

In the settlements, all tiers are required to repay, with interest, the potential overpayments identified in the fourth and fifth HHS-OIG audits, and estimated overpayments up to the date of settlement.[10] This is the only payment sought from tier zero hospitals, those hospitals that were overpaid less than $1000, and tier 1 hospitals, those whose overpayments exceed $1000 but that have relatively few improper claims per bed.[11] The majority of hospitals fall into tier 1 or tier zero and are not asked to pay any penalties.

Tier 2 includes institutions with a higher proportion of false claims per bed. Settlements calling for sanctions begin at this tier. In addition to reimbursing Medicare for overpayments plus interest, tier 2 hospitals are asked to pay a penalty equal to 75 percent of the overpayments identified and recovered as a result of the third HHS-OIG audit.

Hospitals with the greatest proportion of potential false claims per bed are placed in tier 3. DOJ's offers of settlement to tier 3 institutions include reimbursing Medicare for overpayments plus interest and, in addition, penalties measured as (1) 100 percent of the overpayments identified and recovered as a result of the third audit and (2) 200 percent of the potential overpayments identified in the fourth audit.

According to DOJ, the goal of its approach to these settlements has been to alter hospital conduct, not to generate revenues. Even in the highest tier, the hospitals have not been asked to pay the $5,000 to $10,000 per false claim penalty which is mandatory under the statute if the claim is determined in court to have been knowingly false or fraudulent and therefore to have violated the Act. Only tier 3 hospitals have been asked to pay what the Act refers to as treble damages, and then only on overpayments identified in the fourth audit. By the same token, the proposed settlement agreements for hospitals in tiers 1, 2, and 3 require that the hospitals develop internal management systems and controls to address the recurring Medicare overpayments. If a hospital establishes and implements controls to prevent such billing errors in the future, the government, under the express terms of the settlement, will view any subsequent incorrect claim as inadvertent.

To reinforce the collaborative nature of the settlement process, any hospital which asks for reconsideration of its tier designation has been allowed to present new

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[10]In addition, all hospitals must agree to make reasonable efforts to refund copayments and deductibles paid by Medicare beneficiaries.

[11]Tier zero hospitals are not asked to sign a settlement agreement. Settlement agreements are entered into with tier 1, tier 2, and tier 3 hospitals. Settlements with tier 1 hospitals include no damage or penalty provisions but commit hospitals to implement internal controls to prevent future false claims.

data and, based on these requests, DOJ has assigned some hospitals to lower tiers. Further, to ensure that hospitals investigated in the later stages of the Project were treated no differently from those investigated earlier, no penalties were assessed against any hospital for activities after 1991, the end of the period covered by the fourth audit. Hospitals, however, are required to reimburse Medicare for overpayments up to the date of settlement.

Clarity of Law and Guidance

You expressed concern that providers could be penalized for errors occurring as the result of unclear or ambiguous laws. We do not believe that this is an issue with respect to the 72 hour rule.

The statute and the Medicare guidance are straightforward.[12] The law defines "operating costs of hospital inpatient services" to include:

> "the costs of all services for which payment may be made under [Medicare] that are provided by the hospital (or by an entity wholly owned or operated by the hospital) to the patient during the 3 days . . . immediately preceding the date of the patient's admission if such services are diagnostic services (including clinical diagnostic laboratory tests) or are other services related to the admission (as defined by the Secretary [of Health and Human Services])."[13]

There could be questions in a given case whether a service is "related to the admission"[14] but, as required by the law, the Secretary has provided definitions to help with that determination.[15] The U.S. Attorney for the Middle District of Pennsylvania, whose office is coordinating the Joint Project, told us that hospitals

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[12]42 U.S.C. § 1395ww(a)(4); Medicare Hospital Manual §§ 415, 415.6.

[13]42 U.S.C. § 1395ww(a)(4).

[14]The Joint Project decided to limit its enforcement effort to improper billings within a single hospital, and eliminated multiple hospital issues from the settlement. In a small number of cases, the 72 hour rule applies to situations involving more than one hospital. For example, if a patient, while admitted to hospital A for a procedure, goes to hospital B for a test related to the procedure, hospital B should bill hospital A, not Medicare.

[15]Medicare Hospital Manual § 415.6.

have not complained that either the statute or guidance on the 72 hour rule is unclear or ambiguous.[16]

Advisory Opinions

We agree with the Department of Justice that the use of advisory opinions in connection with statutes like the False Claims Act in which knowledge or state of mind is a factor presents serious difficulties. We find no compelling need to require advisory opinions in connection with the False Claims Act generally or the 72 hour rule in particular.

Advisory opinions are analyses by the agency charged with enforcement of a law, indicating how the agency would interpret and apply the law or regulations in specific circumstances. The purpose of these opinions is generally to permit people engaging in a complex or unprecedented transaction to act with some confidence that their actions will not later be found to have been illegal.

These opinions are "advisory" both in the sense of providing advice and also because they are based on hypothetical situations: the agency indicates how it would apply the law if it were presented with circumstances described by the person requesting the opinion. Advisory opinions are strictly limited to the facts presented, and may be relied upon only by the requestor; others are not bound by, nor may they legally rely on advisory opinions. (Of course, to the extent a third party can establish that his situation is the same as that covered in an advisory opinion, it would be difficult for the government to justify treating the third party differently from the recipient of the advisory opinion.)

Advisory opinions play a role in the regulatory activities of some federal agencies, such as the Internal Revenue Service (private letter rulings on tax matters) and the Federal Trade Commission (application of antitrust laws). In addition, advisory opinions are provided by a number of state governments in response to questions on various issues, such as election finance, tax, or ethics. However, with the exception of a provision in the recently-enacted Health Insurance Portability and Accountability Act of 1996 (HIPAA),[17] we are not aware of any provisions for advisory opinions on statutes, like the False Claims Act, where the existence of a violation depends on a determination of someone's knowledge or state of mind.

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[16]The letters that you forwarded to us from the Louisiana Hospital Association that complain of certain aspects of the Joint Project also do not raise lack of clarity as an issue.

[17]Section 205, Public Law 104-191, 42 U.S.C. § 1320a-7d.

HIPAA directs the Secretary of Health and Human Services (HHS), in consultation with the Attorney General, to issue advisory opinions binding on HHS and the parties seeking those opinions, concerning the legality of practices under specific sections of Medicare law. However, in the preamble to its regulations governing availability of these advisory opinions, HHS points out that "it is not practical for the agency to make an independent determination of the subjective intent of the parties [to a business transaction] based only upon written materials submitted by the requestor." It therefore designed the regulations "to avoid the potential pitfalls of advisory opinions on intent-based statutes."[18]

In comments on an earlier bill with a similar provision for advisory opinions, the HHS-OIG pointed out that authorizing advisory opinions for an intent-based statute would be without precedent in U.S. law; none of the then-existing advisory opinion processes in the federal government addressed the issue of the requestor's intent. The HHS-OIG said that advisory opinions on intent-based statutes are impractical, if not impossible, due to the inherently subjective and factual nature of this inquiry, and that DOJ and the National Association of Attorneys General also strongly opposed advisory opinions for all intent-based statutes.[19]

In commenting on the provision in HIPAA, this Office expressed similar concern. We said, as did the HHS-OIG and DOJ, that the government cannot advise meaningfully on the legality of a proposed action when that determination depends on the state of mind of the person taking the action.[20]

Advisory opinions may not be necessary to provide some protection against the threat of False Claims Act liability. Hospitals or other providers in doubt about the propriety of a particular claim are free to ask the fiscal intermediary or HCFA whether, for example, particular procedures are covered by Medicare or, in the case of the 72 hour rule, whether a specific pre-admission outpatient procedure will be regarded as "related to the admission."[21] While the answers would not have the

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[18]62 Fed. Reg. 7350 (February 19, 1997). The regulations provide that advisory opinions will not be available when "[a]n informed opinion cannot be made, or could be made only after extensive investigation . . . or collateral inquiry." 42 C.F.R. § 1008.15(c)(3). Since February 21, 1997, the effective date of the regulations, HHS has issued fourteen advisory opinions under HIPAA.

[19]H.R. Rep. No. 104-276, Pt. 1, at 500-01 (1995).

[20]Letter to Rep. Stark, B-270093, March 18, 1996.

[21]With respect to the 72 hour rule, section 415.6 of the Medicare Hospital Manual defines "related to the admission" as "furnished in connection with the principal

(continued...)

binding legal authority of advisory opinions, the government would find it difficult to argue that a provider who had been advised by HCFA or a fiscal intermediary that a claim was covered had knowingly submitted a false claim.

The False Claims Act Applies Government-Wide

Application of the False Claims Act is not limited to health care providers. It covers any claims against the United States, ranging from defense contracting to agricultural price supports.[22] Medicare and Medicaid figure prominently, since they account for a substantial number of the claims filed with the federal government, but the Act reaches many other activities. Claims of any kind that cannot be explained as mere inadvertence or innocent mistake can subject the individual or firm filing the claims with any agency of the government to penalties under the False Claims Act, even if the claims are for small amounts.

The same standard of proof--that a person "knowingly" filed a false claim with the federal government--applies to all false claims civil enforcement efforts, including health care and defense. The principal differences between the Medicare and defense procurement programs lie in the size of the individual claims and the law enforcement strategies employed. Efforts to control defense procurement fraud generally have focused on the small number of contractors that receive the vast majority of defense procurement dollars; individual defense contractors may receive overpayments exceeding $1 million for one claim. In contrast, Medicare pays

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[21](...continued)
diagnosis that necessitates the patient's admission as an inpatient (i.e., if the outpatient principal diagnosis is the same as the inpatient principal diagnosis)," thus considerably narrowing the scope of any questions a hospital might have.

[22]DOJ has been active in several national initiatives regarding the False Claims Act since the 1970's. In the late 1970's and early 1980's, at the request of the General Services Administration, several U.S. Attorneys' offices undertook large-scale procurement fraud investigations. Periodically, the Department of Housing and Urban Development asked that DOJ act on large-scale housing fraud issues.

One of the most noteworthy initiatives under the False Claims Act arose out of large-scale Department of Defense (DOD) procurement fraud investigations by the DOD Inspector General. This resulted in the creation within DOJ of the Defense Procurement Fraud Unit which focused on the 100 DOD contractors who received 70 percent of DOD procurement dollars. Between 1987 and 1994, DOJ reported $1.7 billion in settlements against DOD contractors. Between 1981 and 1992, there were 92 civil defense procurement fraud cases involving 38 of the top 100 DOD contractors or their subsidiaries. Nearly half of the cases were settled without litigation; another quarter were settled after they were brought to trial.

millions of claims every year to thousands of hospitals and other providers; while, in the aggregate, Medicare is a large program, each claim typically is relatively small. The loss to the government from false claims in both programs, however, is large and can seriously undermine the public's trust.

Consideration of the Materiality of a Claim Under the False Claims Act

In enforcing the False Claims Act, it is appropriate for DOJ to consider whether "errors that are considered to be non-material to the case at hand" should be treated differently from other errors.[23] This is in effect what DOJ now does. As discussed below, there are several possible disadvantages to a legislative materiality requirement. We believe that existing protections, when properly implemented, should serve the purpose of preventing injustices to providers, either in the form of overly harsh punishment or of treating innocent mistakes as violations. We found no evidence in the 72 Hour Window Project to suggest that either of these has occurred.

The sanctions established by the Act--treble damages and civil penalties of $5000 to $10,000 per claim--could be considered to be harsh, for example, if the dollar amount of false claims is small. A materiality requirement, some might argue, is needed to protect those who are less culpable from the penalties that would otherwise be required by the Act.[24]

There are competing policy considerations in this area. Certainly sanctions should not be imposed that are out of proportion to the offense, or that punish innocent mistakes. At the same time, vigorous pursuit of improper billing in Medicare is a

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[23]It may not be easy to define materiality. For present purposes, we use it to refer to the basis for a determination (whether set out in statute, regulation, policy, or decided on a case-by-case basis) that an action under the Act should not be pursued because the scale of the false claims does not warrant enforcement action. This may be, for example, because of small dollar value or small number of claims, taking into account the cost of enforcement among other factors. What constitutes materiality is clearly relative: an amount that may be material in one set of circumstances may not be material in another.

[24]Proposed legislation provides an example of how such protection might be implemented. H.R. 3523 would limit civil actions under the False Claims Act. An action could not be brought based on improper claims submitted to a federally funded health care program (like Medicare) unless the amount in question were "material." An amount is not material under the bill unless it exceeds a certain percentage of the total amount of claims submitted. Further, the amount to be compared against a percentage for determining whether it is material is the amount of a single claim, unless the claim is part of a pattern.

reasonable strategy for the government because of the scope of the problem. According to the HHS-OIG, overpayments due to billing errors, fraud, medically unnecessary services, lack of supporting documentation, and other problems in the Medicare fee-for-service program resulted in unwarranted payments in fiscal year 1997 of $20.3 billion. In the Medicare environment of hundreds of thousands of claimants, amounts that might not be considered material with respect to one provider could in the aggregate add up to millions of dollars.

With regard to existing protections, DOJ, as is generally the case with law enforcement agencies, can take materiality into account on a case-by-case basis. In practice, law enforcement officials exercise discretion in deciding whether to bring an enforcement action and, if so, whether to seek penalties and what penalties to seek; they have broad discretionary authority not to pursue false claims which, in their judgment, do not warrant the investment of time and effort needed[25] or where, because of mitigating circumstances, the penalties may be out of proportion to the offense.

This is done through the exercise of so-called prosecutorial discretion or declination policy. Prosecutorial discretion means that law enforcement officials decide whether to prosecute or pursue a civil enforcement action in a given case based on a variety of factors including, in addition to the amount at issue, the strength of the evidence, the availability of resources, the likely deterrent effect of prosecution, and the prior behavior of the claimant and its willingness to adopt effective corrective action. Similarly, declination policy is a determination in advance not to take certain actions in cases presenting particular fact patterns or where the amount involved does not meet a dollar threshold.[26] These exercises of discretion can amount to an effective, although, informal, materiality standard.

Existing law also offers protections against misuse of the False Claims Act. The law places the burden on the government to prove that the claimant acted "knowingly" and defines that term to exclude the possibility that a mere isolated mistake can be treated as a violation. Under the definition, a person will not be held liable for a false claim made in error, unless the government can prove, through a preponderance of the evidence, that the error was the result of deliberate ignorance or reckless disregard of the truth. The government may suspect deliberate ignorance when a claimant makes the same mistake repeatedly after having been warned, but it still must prove that suspicion in court to prevail.

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[25]Kusserow, Richard P., "Civil Money Penalties Law of 1981: A New Effort to Confront Fraud and Abuse in Federal Health Care Programs," 58 Notre Dame Law Review 985, 987-989 (1983).

[26]Of course, a decision not to proceed under the False Claims Act to seek civil penalties does not preclude collection of the disputed amounts by the agency.

The recent DOJ guidance concerning False Claims Act enforcement in the health care arena adds safeguards to those described above.[27] Under the guidance, DOJ attorneys must independently evaluate whether the provider submitted false claims with knowledge of their falsity. In doing so, they must examine the statutory and regulatory provisions and interpretive guidance, verify the accuracy of the data and other evidence, determine whether the provider had notice of the rules or policy and whether they were sufficiently clear, and take into account how pervasive and how large the false claims were.

The new guidance also addresses the providers' concern that, to avail themselves of defenses to the charge of submitting false claims, they must be willing to litigate the issue, a potentially expensive process regardless of the outcome. It does this by making explicit that Department attorneys must offer providers an adequate opportunity to discuss the matter before a demand for settlement is made, and an adequate time to respond. This represents an opportunity for providers to contest specific charges of false claims.

In settlement negotiations over alleged violations of the False Claims Act, DOJ can take materiality into account by opting to forgo or moderate the penalties that would apply in a False Claims Act suit.[28] In fact, the 72 Hour Window Project in effect does this. DOJ has offered settlements with sanctions that appear reasonably in proportion to the extent of false claims, given the fact that in the past no sanctions were imposed on these hospitals and the same errors have continued. Under the tier system used by DOJ in the 72 Hour Window Project, hospitals in the lower two tiers, which comprise most hospitals, were not subject to penalties under the False Claims Act; they only had to return the overpayments with interest. Hospitals in tier 1 were also asked to sign a settlement agreement under which they committed to establishment of internal management controls to prevent future improper claims from being submitted to Medicare.

Only those hospitals in tiers 2 and 3 were subject to penalties. These were institutions that not only had uncorrected erroneous claims at a higher level than other hospitals in the service area of the fiscal intermediary, but also were

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[27]Memorandum, "Guidance on the Use of the False Claims Act in Civil Health Care Matters," June 3, 1998, from the Deputy Attorney General to all Department attorneys handling civil health care fraud matters.

[28]Under the False Claims Act, there is no requirement that the claimant actually have received payment or that the government have sustained actual monetary harm. In fact, penalties can be recovered under the FCA even if the government cannot show that it incurred any damage. See Rex Trailer Co. v. United States, 350 U.S. 148, 153, n. 5 (1956); Hagood v. Sonoma County Water Agency, 929 F.2d 1416 (9th Cir. 1991).

continuing to make the same errors that had been detected and called to their attention in the first two audits. In some cases, the amount of their current erroneous claims may have been small. This was taken into account in DOJ's calculation of a settlement offer, but so was the fact that errors were recurring. (For more specific examples of the reasonableness of DOJ's settlements, see the discussion below of the treatment of Louisiana hospitals.)

One argument against a more formal and less flexible materiality requirement is that it could weaken the salutary effect of the False Claims Act. The sanctions in the Act were intended to deter misconduct by those submitting claims to the government. A policy that erroneous claims below a certain pre-established level will not be subject to sanctions could lend itself to the kind of behavior referred to as "gaming the system," and could reduce the deterrent effect of the Act. For example, if unscrupulous providers are aware that, below a certain threshold, the government will tolerate claims that are knowingly false or fraudulent, they could attempt to exploit this policy, possibly resulting in an increase in the number of false claims which the government is unable to recover.

Establishing a materiality requirement would necessitate deciding difficult questions, such as whether the standard should apply per provider or per specific type of claim. In the case of the 72 Hour Window Project, for instance, the outcome of a materiality threshold for false claims could be very different depending whether it was measured relative to all the hospital's Medicare claims or to only those claims governed by the 72 hour rule. Related questions that would have to be resolved are: whether the standard should be a fixed amount or a percentage of claims; what period of time should apply; and whether a materiality threshold should remain the same for all providers or whether the continued submission by a provider of incorrect claims at or just below the threshold would justify a lower threshold for that provider.

Louisiana Hospitals and the 72 Hour Window Project

The State of Louisiana has enacted a materiality requirement, applicable to claims under the state's Medicaid program.[29] The Louisiana Hospital Association has suggested that the law may be a good model for a federal materiality requirement, and has urged that the treatment of Louisiana Hospitals in the Joint Project demonstrates the need for such a law.[30] We therefore examined DOJ's use of False Claims Act sanctions in negotiating settlements in the Joint Project in Louisiana.

We selected three Louisiana hospitals from the HHS-OIG data base, one from each of tiers 1, 2, and 3, for analysis. (Tier Zero hospitals, those with overpayments of less than $1000, were not asked to sign settlement agreements.) We picked hospitals that were toward the middle of each tier in terms of numbers of claims and total dollar amounts. Although this is not a statistical sample, it is representative in the sense that the U.S. Attorney used the same formula to calculate exposure and settlement offers for all hospitals in a tier.

The settlement offers to the hospitals were not disproportionate to the amount of allegedly false claims and were fair under the circumstances. The hospitals' potential liability exposure under the False Claims Act was greatly in excess of the amounts of their overpayments, but that is a consequence of the penalties established by the Act, not of misconduct by DOJ. The potential exposure assumes that in a lawsuit the maximum penalties would be imposed with respect to every charge. However, a settlement offer would consider potential defenses, and the outcome might be less than the maximum liability. In addition, hospitals may legitimately wish to avoid being sued under the False Claims Act for reasons such as the expense of litigation or the possible damage to their reputations.

Tier 1 hospitals only had to repay, with interest, potential overpayments identified in the fourth and fifth HHS-OIG audits, and estimated overpayments up to the date of settlement. For tiers 1, 2, and 3 in Louisiana, DOJ arrived at the amount of

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[29]Louisiana's law provides that a Medicaid claim will not be considered false or fraudulent unless it is "in regard to material information" and will not be prosecuted unless it resulted in actual damages to the state of at least $1,000. 1997 La. Acts; Act No. 1373, July 15, 1997. The law uses the accounting definition of materiality, whether an omission or misstatement of a specific piece of financial information is of sufficient magnitude in relation to the entire financial health of an entity that it would reasonably influence the judgment of a person relying on it to come to a different conclusion.

[30]The Association has said that DOJ's use of sanctions under the False Claims Act for what the Association calls mere billing errors "borders on extortion."

potential overpayments for the period 1994 through the date of settlement by doubling the amount of potentially improper claims identified in the HHS-OIG's fifth report.

For example, DOJ found improper claims by a tier 1 hospital in the HHS-OIG's fourth and fifth reports totalling $2,911. This amount did not include interest or an estimate of improper payments made after 1994. DOJ calculated the hospital's potential exposure, assuming full liability in an action under the False Claims Act, as $467,909.[31] DOJ offered to settle with this hospital for $5,870.[32]

For the tier 2 hospital we looked at, DOJ offered to settle for $70,173. (The settlement offer included penalties on overpayments found in the third HHS-OIG report.[33]) The amount of potentially improper claims identified in the fourth and fifth HHS-OIG reports was $24,245, and the amount of improper payments recovered under the third HHS-OIG report had been $24,758. Potential exposure under the False Claims Act for overpayments identified in the third and fourth HHS-OIG reports would have been $1,664,418.

For the tier 3 hospital, which was in that category because of a relatively high proportion of errors per bed compared to other hospitals in the state, the potential exposure in False Claims Act litigation would have been $4,915,871. DOJ offered to settle for $124,512. The fourth and fifth audits had identified improper claims totaling $24,799, and $60,551 had been recovered for improper claims identified by

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[31]This was based on application of the maximum possible sanctions, including treble damages (repayment of overpayments plus a penalty equal to 200 percent of the overpayments) and $10,000 penalties for each false claim, applied to overpayments identified in the third and fourth HHS-OIG reports. Calculations of a hospital's potential exposure did not include potential overpayments (or penalties that could be applied to overpayments) identified in the fifth HHS-OIG report.

[32]In calculating its settlement offer, DOJ included the amount identified as improper payments in the HHS-OIG's fourth report ($606) plus interest ($170). DOJ added the amount of potentially improper claims identified in the HHS-OIG's fifth report ($2305) plus interest ($484) plus estimated overpayments up to settlement ($2305).

[33]DOJ required repayment of the potential overbillings identified in the fourth HHS-OIG report ($1,634) plus penalties calculated at 75 percent of the amounts recovered pursuant to the third HHS-OIG report ($18,569). Potential overpayments identified in the fifth HHS-OIG report ($22,611), interest on that amount ($4,748), and estimated overpayments up to settlement ($22,611) were added.

the third HHS-OIG report. Again, the settlement offer included penalties related to overpayments identified in the third and fourth audits.[34]

Conclusion

We have found no evidence that errors hospitals made with respect to the 72 hour rule were the result of unclear or ambiguous laws, regulations, or guidance. The law is reasonably clear that outpatient diagnostic procedures and other services related to admission that are provided by a hospital during the three days prior to an admission are not separately reimbursable. Payments in violation of this rule have been highlighted in successive HHS-OIG reports since 1988. Prior to initiation of the Joint Project, hospitals were required to reimburse Medicare for improper payments identified in the first three HHS-OIG reports.

Advisory opinions do not appear to be necessary or helpful in clarifying the 72 hour rule. The statute and Medicare guidance are straightforward. Moreover, because culpability under the False Claims Act depends on the state of mind of the person taking the action, advisory opinions--to the extent they are dependent on assumptions about the knowledge or state of mind of a claimant--might not be meaningful.

We found no evidence that health care providers or hospitals in particular have been singled out for enforcement action under the False Claims Act, or have had a different standard applied to them, compared to claimants in other sectors of the economy.

Finally, the current practice of DOJ in effect takes materiality into account, as do the new guidelines. The settlements sought from hospitals had a rational basis, taking into account a prior history of uncorrected errors. Also, the tier system used by the Project was in effect a materiality standard; the tiers protected most hospitals from paying any penalties, based on the small amount or frequency of their erroneous claims; where penalties were made part of the settlements, they were not disproportionate under the circumstances. It is not clear that

[34]In calculating its settlement offer, DOJ sought recovery of the potential overpayments identified in the HHS-OIG's fourth report ($11,590) plus, as penalty, 100 percent of the amount recovered under the HHS-OIG's third report ($60,551) and 200 percent of the potential overpayments identified in the HHS-OIG's fourth report ($23,180). To this amount was added the amount of potential overpayments identified in the fifth HHS-OIG report ($13,209) plus interest ($2774) plus estimated overpayments up to settlement ($23,180).

incorporating a materiality requirement in federal law would significantly improve the situation. On the other hand, there is some risk that unscrupulous providers would try to exploit such a requirement and there could be difficulties in drafting it in such a way as to provide a clear standard, while leaving sufficiently flexibility for law enforcement officials.

Officials from HHS-OIG and DOJ reviewed a draft of this letter and concurred in its findings. They suggested technical or clarifying comments which we incorporated as appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this letter until 30 days after its issue date. At that time, we will make copies available to interested parties on request.

If you or your staff have any questions, please call me at (202) 512-5400.

Robert P. Murphy
General Counsel