Testimony of the American Hospital Association

Mr. Chairman, I am Joseph diGenova, special counsel to the American Hospital Association (AHA). The AHA represents nearly 5,000 hospitals, health systems, networks, and other providers of care. We appreciate this opportunity to testify on an issue of great concern to the health care community and the general public: enforcement activities related to the Medicare program. Our comments will focus on the enforcement activities of HHS Office of Inspector General (OIG) and the need to provide hospitals with direct access to the courts.

BACKGROUND

America's hospitals and health systems are rooted in a tradition of ethics and caring. We're committed to preventing, uncovering, and eliminating health care fraud and abuse. Hospitals across the nation have voluntarily established programs to ensure compliance with Medicare's requirements - laws and regulations that are generally agreed to be complex and confusing. Each year, hospitals and health systems submit, on average, nearly 200,000 Medicare claims a day. To ensure the accuracy of those claims, the Mayo Foundation estimates that hospitals must comply with 132,720 pages of rules that govern the Medicare and Medicaid programs - that's three times the size of the IRS Code and its federal tax regulations.

The AHA has a strong commitment to ensuring that hospitals have the information and tools they need to comply with the vast array of federal and state laws and regulations. As part of a compliance service offered by the AHA, we provide updates on guidance issued by the Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration. We have also instituted a formal process with CMS to obtain additional guidance on the "gray areas" that regularly arise when attempting to translate guidance into compliance.

Our experience with the compliance service and with assisting hospitals caught up in the web of government billing investigations reinforces our view that billing issues are usually billing mistakes. Fraud is the exception. That's why we continue to urge that the starting point for any questions about a claim submitted by a hospital should be the administrative process. That process is capable of dealing with any discrepancies in billings and should be the standard means of examining any questionable billings. If, and only if there is sufficient indication of potential fraud, should a referral be made to law enforcement authorities.

Recent experiences with several national law enforcement investigations demonstrate the importance of beginning with the administrative process. The AHA has commissioned reports on two of the major investigations undertaken by the government for the submission of allegedly fraudulent billings. The first was a response to the government's initial national billing investigation for outpatient laboratory billings. The second was a more recent investigation that examined pneumonia billings. In both instances, we found that the state of guidance on what was required of hospitals was not as clear as the government asserted. In the lab matter, there was no legal duty for hospitals to bill as the government asserted there was. In fact, in many instances there were contrary instructions. As a result, the government significantly curtailed its national recovery efforts, withdrew its investigations in several states (and in one state actually refunded fines collected from hospitals); terminated compliance agreements that were imposed as part of settlements; and agreed to refer matters to the fiscal intermediary. In the pneumonia matter, guidance was ambiguous at best. These experiences with broad-based investigations demonstrate that treating billing issues as potential fraud is an unwarranted starting point.

ENFORCEMENT ACTIVITIES OF THE OIG

Hospitals are concerned with two ways the OIG is exercising its enforcement authority. We are seeing an insistence on hospital acceptance of an unnecessarily burdensome and costly corporate integrity agreement (CIA) as a condition for resolving billing issues, without regard to a hospital's own compliance program and the lack of any evidence of fraud. We have also seen disturbing evidence of the OIG using its enforcement authority to launch separate and duplicate investigations of matters previously investigated by the Department of Justice (DOJ) and resolved completely in favor of a hospital.

Corporate Integrity Agreements

A corporate integrity agreement (CIA) is the OIG's version of a compliance program that was designed for use in settling investigations, and in return for the OIG's agreement not to exclude a provider from the Medicare program. It was intended and is still viewed as a corrective action and its imposition a penalty. The AHA's members repeatedly tell us the OIG's insistence on a CIA impedes voluntary disclosures and the resolution of billing disputes. A CIA should only be used in the case of fraud. If a hospital's own compliance program is insufficient to prevent future billing irregularities, it should be improved and requirements targeted to those specific areas. In the case of billing errors and honest billing mistakes, a CIA should not be required.

The imposition of a CIA imposes significant burdens and costs on hospitals. The biggest cost factor is the requirement that a hospital contract with an independent review organization to perform reviews of the hospital's billings and implementation of the CIA. Typically, CIA's require three types of review: a systems review, a billing review and a compliance review, each to be done by an outside organization. Instead of tying a systems review to a specific, identified systems problem, it has now become boilerplate. While the systems review is usually a one-time event, it is extremely costly and the benefits are not evident. The problem with the billing review is that the OIG's audit methodology requires that there be large samples, which has a direct bearing on the cost of the review. There is little flexibility on sampling issues, notwithstanding the impact on costs. Finally, the compliance review seems unnecessary in the absence of evidence that there is a specific problem with performance under the CIA. To the extent that these reviews are necessary, providers should be allowed to conduct them using internal resources unless there is some demonstrated reason to consider such review inadequate.

CIAs' training requirements are another cost issue. The agreements usually impose a mandatory minimum number of training hours per employee that creates a burden for conscientious providers because they may have to spend time and effort tracking down a handful of employees to ensure that there has been 100 percent participation. And the emphasis on hours does not ensure that the training is productive or meaningful. Hospitals should have the discretion to conduct training in ways that they consider optimal, which might include a Web-based tool as opposed to a two-hour lecture. Also, CIAs require that the first wave of training take place within a fixed amount of time (usually 120 days) following entry into the agreement. This requirement is imposed even when the provider has had a compliance plan in operation and the underlying conduct occurred years before.

In addition to the compliance program issues, there are legal issues related to the heightened reporting accountability. For a provider that hasn't violated the law itself to learn that a later violation of the CIA may be grounds for termination from Medicare is extraordinary. As a result of their compliance efforts, providers are increasingly interested in disclosing billing errors. However, their effort to come forward over billing mistake issues that are not fraud then makes them subject to an investigation and a captive of the CIA.

Duplicate Investigations

DOJ and the OIG have concurrent jurisdiction over fraudulent claims: DOJ under the False Claims Act (FCA), and the OIG under the Civil Money Penalty (CMP) statute. Civil powers to pursue false or fraudulent claims are the same under the civil FCA for Justice as for the OIG under the CMP statute. Concurrent jurisdiction should provide flexibility to the agencies for allocating resources in an investigation. Instead, it has permitted the OIG to second-guess decisions of the DOJ. Attempts by the OIG to place a hospital under investigation for the very same issues examined and found to be without merit by DOJ, should not be permitted, and the OIG should be restrained from doing so.

We are aware of a situation in which the OIG is pursuing a hospital and demanding hundreds of thousands of dollars and a hospital-wide corporate integrity agreement under its authority to impose CMPs. The OIG is doing this despite an extensive and thorough investigation by DOJ of the very same issues, DOJ's dismissal of the case without taking any action whatever, and in spite of the OIG's active participation in the DOJ investigation.

DIRECT ACCESS TO COURT

Direct access to court is essential to provide fundamental fairness for hospitals participating in the Medicare program. In Shalala v. Illinois Council on Long Term Care, the Supreme Court held that under section 205(h) of the Social Security Act, incorporated into the Medicare Act by section 1872, claims related to the Medicare statute must go through an administrative process before being brought to court. As a result of that decision and the government's expansive application of the holding, providers are being denied the ability to challenge the legality of actions by HHS that under other statutes would be immediately subject to review. In situations where no administrative process is available, the result could be no review of HHS's actions. The restrictions being placed on Medicare providers do not apply to many other regulated entities.

Unfortunately for hospitals, that interpretation effectively insulates HHS from legal accountability for many of its actions, and places hospitals in the position of having to violate a regulation in order to challenge the legality of HHS' decisions and policies. That means the price of admission to the court for hospitals is termination from the Medicare program - a price that no hospital or its community can risk.

The Medicare statute needs to be clarified so that when a dispute (unrelated to the specific situation of a provider or beneficiary) challenges the legality of HHS' actions, or any of the other grounds for court review that currently exist under the Administrative Procedures Act, a hospital or other provider is entitled to bring an action in court. This clarification would not change the requirements that apply to anyone seeking relief in court, e.g., demonstration of standing and of a case or controversy. It would simply make clear that the HHS policy decisions are subject to the same level of judicial review as other federal regulatory agencies, such as the Food and Drug Administration and the Environmental Protection Agency.

In addition to needing access to court to challenge questionable HHS policy decisions without first being terminated from the Medicare program, hospitals need access to judicial review when there is no process for resolving a dispute. The laboratory billing investigation is a good example. Hospitals across the country were receiving demand letters from U.S. Attorneys effectively accusing them of fraud, demanding exorbitant amounts in repayment and penalties, and threatening law enforcement proceedings. As a special report commissioned by the AHA demonstrated, the foundation for the investigations was legally flawed. Hospitals were being accused of fraud for failing to follow alleged billing requirements that were never established through rulemaking, never issued as guidance by the

agency, and actually contradicted in billing instructions from fiscal intermediaries.

Hospitals sought the court's protection. They were immediately confronted with the government's attempt to dismiss them out of court, arguing that the hospitals had failed to go through an administrative process. The 6th Circuit Court of Appeals sided with the hospitals and held that the administrative process provided no review at all for hospitals. However, the Supreme Court's decision in the Illinois Council case puts at risk the 6th Circuit's view that hospitals have recourse to court when no administrative review is available. Congressional action is needed to ensure fundamental fairness for hospitalss.

CONCLUSION

Mr. Chairman, Medicare billing errors often result from confusing and conflicting regulations and instructions that are part of the Medicare reimbursement system. These are not intentional acts. Providers who make billing mistakes after attempting to comply with the complicated and frequently changing rules of Medicare payment should be treated in a fair, equitable and civil manner and granted appropriate due process rights -- rights that are guaranteed to all Americans.

To help hospitals achieve these rights, the AHA recommends the following improvements to the current administrative resolution and enforcement system:

Provide oversight of the OIG enforcement activities. The OIG plays a vital role in the government's anti-fraud efforts; however, its recent activities clearly indicate that the agency has overstepped its authority. First, Congress should limit the OIG's use of CIAs to instances of intentional fraud. If a hospital's compliance program has deficiencies, those should be remedied, but the OIG should not be allowed to impose an overly burdensome and costly CIA. Second, the OIG should be prohibited from second-guessing decisions made by DOJ and conducting duplicative investigations. The OIG's duplicative investigations are a waste of government and hospital resources.

Enable providers to challenge questionable policy action in court. Health care providers are required to exhaust all administrative processes and remedies before they can file suit against HHS. However, when the issue is whether the department has exceeded its authority or failed in its duty, that is a matter for the courts. Congress should enact legislation to give hospitals and other providers a specific opportunity to challenge Medicare policy decisions made by HHS that are legally questionable.

The AHA is ready and willing to continue our work with HHS, CMS, DOJ and other agencies to ensure the integrity of the Medicare program. I thank the Committee again for the opportunity to describe the compliance difficulties hospitals face, and welcome any questions you may have.