



**American Hospital
Association**

Richard J. Umbdenstock
President and
Chief Executive Officer

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 626-2363 Phone
www.aha.org

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The Honorable Eric Holder, Jr.
Attorney General
Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20001

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Attorney General Holder and Secretary Sebelius:

On behalf of the American Hospital Association's (AHA) more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, I am writing to respectfully request that the cabinet-level Health Care Fraud Prevention and Enforcement Action Team (HEAT) undertake a policy review of ongoing enforcement initiatives proceeding under the auspices of the *False Claims Act* (FCA).

As the Department of Justice (DOJ) explained to Congress in connection with recent amendments to the FCA granting it wider authority to investigate and aggressively pursue alleged violations of the statute, the FCA does not apply to billing errors, mistakes or even non-culpable over-utilization. The AHA is concerned that aggressive FCA investigations are being initiated upon the discovery of evidence of a mistake or overutilization, making FCA enforcement through negotiated "settlement" a self-fulfilling prophecy. For example, we believe that the "kyphoplasty" initiative being advanced by United States Attorney for the Western District of New York is a prime candidate for such a policy review.

Specifically, notwithstanding the fact that kyphoplasty claims have long been subject to changing and ambiguous regulations and guidelines, the kyphoplasty initiative appears to observers to rely on data mining to establish a presumption that hospitals are liable for "knowing" violations of the civil FCA and subject to treble damages and penalties. Targets of the initiative have received letters disconcertingly similar to letters written prior to the issuance of the original "Holder Memo" in 1998 (*Guidance on the Use of False Claims Act in Civil Health Care Matters*).



The kyphoplasty initiative emanates from the settlement of an FCA investigation of the business practices of a manufacturer of medical devices used in a particular surgical procedure involving the artificial restoration of collapsed vertebrae. In the underlying investigation, DOJ alleged that the manufacturer misled physicians and hospitals about the medical necessity of an inpatient hospital stay following a kyphoplasty, and the applicability of certain billing codes to the procedure and the inpatient stay.

Form letters received in recent months by hospitals across the country indicate that DOJ has established a data-driven presumption that a hospital billing for an inpatient stay following a kyphoplasty “knowingly” violated the FCA and will be liable for treble damages and penalties. The letter offers to compromise any such liability if the hospital “cooperates.” It strongly suggests that the prerequisite to a “double damages” compromise is for the hospital to undertake a prescribed onerous, burdensome and very costly self audit and to provide the United States Attorney’s Office with the results of that audit in a prescribed form.

Our concern is that DOJ’s initial “contact” letter strongly suggests that the Western District has seized upon data analysis that flags billing errors and/or over-utilization and converted it into a presumption of FCA liability, and that DOJ is using the threat of FCA liability as an audit tool. The letter does not suggest that DOJ has reviewed the medical necessity of any admission. Instead, the letter presents an argument that appears to overstate the meaning of certain regulatory provisions, understates and ignores other relevant provisions and relevant agency guidance, and asserts that there is virtually no justification for admitting a kyphoplasty patient for an inpatient stay. The letter’s argument thus presumes that: (a) the physician judgment on which hospitals must depend was compromised in every case; and (b) hospitals knowingly or recklessly acceded to that judgment.

However, guidance published by the Centers for Medicare & Medicaid Services (CMS) and its quality assessment contractor calls the propriety of that presumption into question. CMS’ guidance recognizes that inpatient hospitalization may well be appropriate under certain circumstances – many of which likely apply to the Medicare-covered population.

While it is possible that the FCA could be the appropriate remedy in some cases, and that some hospitals may have acquiesced in or even encouraged medically unnecessary admissions, the AHA is concerned that commencing a medical necessity review with an FCA “contact letter” of this nature requires hospitals to treat each case as an FCA case, regardless of merit. As you know, FCA cases pose great risk in terms of monetary and administrative sanctions. Consequently, the threat of FCA liability leads hospitals to incur expenses related to retaining specialized counsel and outside forensic accountants and, in the event an overpayment is discovered, to negotiate a formal FCA settlement where a simple cost report adjustment is all that is really necessary.

Understandably, some hospitals have elected to settle FCA claims rather than to force DOJ to prove its allegations. Without greater oversight from your offices, we are concerned that such settlements will be taken as vindication of a theory, and of tactics. In many of these cases,

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absent evidence of hospital culpability, the hospital could be as much a “victim” of improper physician admission decisions as the program, especially where CMS-sanctioned guidance deprived hospitals of the means to challenge an admission order because the guidance actually supported inpatient care for some cases at the time of the admission.

Under these circumstances, we seek your review of the kyphoplasty initiative and any other similar initiative now underway. We believe your Departments can restore confidence in the working relationship between hospitals and the departments by offering providers a clear assurance that such oversight authority will be exercised. I respectfully request a meeting with you to discuss how best to address this and similar issues.

Thank you for your attention to this matter.

Sincerely,

Rich Umbdenstock
President and CEO