American Hospital Association

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December 7, 2010

Edward N. Siskel
Associate Deputy Attorney General
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20001

Michael F. Hertz
Deputy Assistant Attorney General
Civil Division
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20001

Dear Messrs. Siskel and Hertz:

I want to thank you again for taking the time to meet with us on November 22, 2010 to discuss the kyphoplasty initiative and the Department's commitment to the principles underlying the original "Holder Memo" (*Guidance on the Use of False Claims Act in Civil Health Care Matters; 1998*). Our members, my colleagues and I greatly appreciate the time and resources that you, U.S. Attorney Hochul and each of the attorneys in attendance expended to participate. We also appreciate the serious manner in which you approached the meeting and listened to our concerns.

As we discussed, False Claims Act (FCA) investigations can have a substantial and even devastating impact on our members. They can also have unintended consequences for the delivery of health care services to patients, including Medicare and Medicaid beneficiaries. As a result, we feel an obligation to monitor enforcement developments and maintain a dialogue with the Department to ensure that the consequences and tactics of FCA investigations continue to serve our mutual interest in the effective, fair and just administration of the statute and the federal health care programs.

Toward that end, in addition to expressing our gratitude for the attention you already afforded us, I would like to reiterate the requests we made at the meeting for greater oversight of the kyphoplasty initiative, for a public reaffirmation of the principles underlying the Holder Memo,

and for the issuance of an updated version of the Memo. For your convenience, I have enclosed an additional copy of the page we provided outlining our proposed updates to the Memo. I would also like to reiterate our request to meet again to discuss your response.

As I explained in my September 7, 2010 letter to Attorney General Holder and Secretary Sebelius, we believe steps like those outlined above can restore confidence in the working relationship between hospitals and the Department by offering providers a clear assurance that such oversight authority will be exercised properly and judiciously. If 60 days is sufficient time for you to prepare a response, we would be happy to meet again the week of January 24, 2011. Please contact Melinda Hatton, AHA's general counsel, at (202) 626-2336 or mhatton@aha.org, regarding arrangements for a meeting.

Thank you again for your attention to this matter.

Sincerely,

Rich Umbdenstock
President and CEO

Enclosure

cc: The Honorable William J. Hochul, Jr., United States Attorney, W.D.N.Y.
Daniel R. Anderson, Deputy Director, Civil Fraud Section, U.S.D.O.J.

Suggested Updates to the DAG's June 3, 1998 Memorandum:
"Guidance on the Use of the False Claims Act in Civil Health Care Matters"

1. DOJ coordination requirements should apply not only to designated "National Initiatives," but to any investigation that involves claims submitted by more than one provider and originates from:

    a. allegations raised by a relator or other whistleblower;
    b. referral from a CMS contractor; or
    c. "data mining" by any DOJ or HHS component or contractor.

2. Technical advice and confirmation of any restatement, summary or application of agency rules, regulations or manuals should be obtained from responsible agency personnel before a DOJ attorney:

    a. relies on any interpretation of the meaning or significance of same to commence an investigation; or
    b. asserts such an interpretation in an email, letter or other document released outside of DOJ.

3. Requests for information and records, whether informal or formal, should take into account the cost and burden of ediscovery and be based on an individualized assessment of provider circumstances. Relevant factors include:

    a. The extent to which provider databases, EHR and accounting records are searchable and reasonably accessible;
    b. The scope, cost and burden attendant to litigation hold notices, including data storage and retrieval costs; and
    c. The impact of delayed review of provider submissions and delayed resolution on provider accounting and debt ratios.

4. The manner of cooperation expected from or proposed to a provider should be based on an individualized assessment of the provider's circumstances – the expense and burden of retaining a third-party auditor should not be required in every case, or of every provider that is subject to investigation in a particular case.

5. While government attorneys have an interest in confirming the qualifications of third-party auditors and the soundness of their methodology, any review of auditor qualifications and methodology should be conducted so as to minimize actual, apparent or potential interference in the deliberations or conclusions of the auditor.