American Hospital Association

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*Submitted electronically via e-mail*
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September 27, 2010

Donald S. Clark, Secretary
The Federal Trade Commission
600 Pennsylvania Ave., NW
Washington, DC 20580

Daniel R. Levinson, Inspector General
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Donald M. Berwick, MD, Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Ave., SW, Rm. 445-G
Washington, DC 20201

***RE: Workshop regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, Civil Monetary Penalty (CMP) Laws***

Dear Secretary Clark, Dr. Berwick and Inspector Levinson:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our nearly 40,000 individual members, the American Hospital Association (AHA) welcomes your decision to convene a workshop and to examine how your enforcement of the antitrust, physician self-referral, anti-kickback and civil monetary penalty laws will affect achievement of health care reform's goal of transforming the health care delivery system through the integrated delivery of care. As you point out in the *Federal Register* notice announcing the workshop, the *Patient Protection and Accountable Care Act* (ACA) "seeks to improve the quality of health care services and to lower health care costs by encouraging providers to create integrated health care delivery systems." While we understand your interest in the potential of accountable care organizations (ACOs), which are still undefined in regulation, we urge you to look more broadly at the impact your enforcement of these laws is having on the variety and spectrum of clinical integration activities that will be necessary to achieve the ACA's goals.

The AHA and its members have long advocated the benefits of coordinated care and sought ways to address the problems of a fragmented health care delivery system. Through its most recent initiative, *Health for Life: Better Health, Better Health Care*, the AHA offered a framework for change – a set of goals and ideas for creating better, safer, more affordable care

and a healthier America. A key component of that initiative was eliminating the legal and regulatory barriers to greater collaboration and teamwork between hospitals and other providers. We agree that how you enforce the laws on which this workshop focuses will be key to determining whether the clinical integration necessary to achieve the goals of health care reform will occur.

The AHA has done significant work examining the current impact of these laws on the ability of providers to work cooperatively to improve the quality and efficiency of the care they deliver to patients, and the serious impediments these laws create. We appreciate the opportunity to share what we have learned and look forward to working with you to achieve the necessary changes.

Since 2007, the AHA has urged the federal agencies to recognize the public policy imperatives for clinical integration and called for guidance and enforcement of the laws to enable hospitals and others to work together. The passage of health care reform makes the need for additional guidance and appropriate enforcement of these laws even more critical. Although CMS has yet to issue proposed regulations governing ACOs and bundled payments, or any of the other ACA initiatives designed to encourage clinical integration, hundreds of hospitals throughout the country have begun to consider ways that they can collaborate with physicians and other providers. A recurring concern in these planning discussions has been how to ensure that such efforts can withstand legal scrutiny.

Through the attached documents we hope to provide information about the landscape of clinical integration activity – what is being attempted or done, and what cannot be done – under the current legal regime, as well as a drill-down look at the individual laws, the impediments we have identified, and recommendations for the kind of changes that are needed.

The 2010 *Trendwatch* report, "Clinical Integration – The Key to Real Reform," examines how hospitals are working with physicians and other care providers to more closely coordinate care, and the legal and regulatory barriers to this critical element of health care reform. A chart at the end of the report summarizes which federal and state laws apply to clinical integration and the unintended consequences of their current application.

The 2010 *AHA Research Synthesis Report*, "Accountable Care Organizations," presents an overview of ACOs, including a discussion of their potential impact, key questions to consider in developing an ACO, and a review of the key competencies needed to be an effective ACO. The report is focused on the overall concept of ACO with highlights of the specifics of the ACO model proposed in health reform legislation.

The recently revised "Guidance for Clinical Integration," a working paper developed in 2007, was prepared for the AHA by a team of antitrust experts. It includes a road map for hospitals and other providers spelling out what they need to consider in establishing a clinical integration program, as well as a discussion aimed primarily at hospital counsel on some of the more difficult antitrust issues raised by such efforts. The AHA recognizes that considerable information has been provided in recent years by the FTC. What is missing, however, is user-

friendly, officially backed guidance that clearly explains to caregivers what issues they must resolve to embark on a clinical integration program without violating the antitrust laws.

The set of fact sheets, "Getting More Reform from Health Reform: Five Barriers to Clinical Integration in Hospitals (and what to do about them)," describe, in summary form, how each of the four laws that are the subject of the workshop, as well as the Internal Revenue Code, create barriers to clinical integration – the foundation for achieving the goals of the ACA. The physician self-referral law is premised on compensation arrangements for services rendered, an "hours worked" approach, that is out of sync with clinical integration, where compensation is linked to the achievement of results or use of clinical protocols or best practices. Its regulations have become a tight web of confusing and changing requirements that place hospitals at risk for serious sanctions based on inadvertent or procedural violations.

The civil monetary penalty (CMP) law is a vestige of concerns in the 1980's that Medicare patients might not receive the same level of services as other patients after the prospective payment system was implemented. In today's environment, it is impeding clinical integration programs. While health reform is about encouraging the use of best practices and clinical protocols, using incentives to reward physicians for following best practices and protocols can be penalized under current enforcement of the CMP law. The antikickback law has been stretched to cover any financial relationship between a hospital and physician. The result is that rewards for a physician following best practices or evidence-based protocols could be construed as violating the statute. The ACA is driving providers to clinically integrate to serve Medicare beneficiaries. Regulatory oversight of financial relationships between hospitals and physicians must also change to enable the clinical integration that is essential to achieve ACA's goals.

Clinical integration is important. Meaningful health care reform, and the quality and efficiency improvements it promises, is built around the teamwork clinical integration creates. The AHA looks forward to working with the agencies to assure the legal and regulatory framework is in place to enable hospitals, physicians, and other providers, to work together so the full benefits of clinical integration are realized and the goals of health care reform are achieved.

If you have any questions, feel free to contact me at (202) 626-2336 or mhatton@aha.org.

Sincerely,

Melinda Reid Hatton
Senior Vice President and General Counsel

Attachments
*Trendwatch*, "Clinical Integration – The Key to Real Reform"
*AHA Research Synthesis Report*, "Accountable Care Organizations"
"Guidance for Clinical Integration"
"Getting More Reform from Health Reform: Five Barriers to Clinical Integration in Hospitals (and what to do about them)"