CALIFORNIA HOSPITAL ASSOCIATION

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Written Comments
of the
California Hospital Association
for the
Federal Trade Commission
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Workshop Regarding Accountable Care Organizations, and
Implications Regarding Antitrust, Physician Self-Referral,
Anti-Kickback, and Civil Monetary Penalty Laws
Public Workshop
October 5, 2010

The California Hospital Association (CHA) is pleased to submit these comments in response to the Notice of Meeting (Notice), published in the Federal Register on Friday, September 17, 2010. The Notice seeks comments regarding certain legal issues relating to Accountable Care Organizations (ACOs) and other innovative delivery model options authorized by the Patient Protection and Affordable Care Act (ACA).

CHA represents nearly 450 hospitals and health systems throughout California, including general acute care hospitals, children's hospitals, rural hospitals, psychiatric hospitals, academic medical centers, county hospitals, investor-owned hospitals, and multi-hospital health systems. These hospitals furnish vital health care services to millions of our states' citizens, including inpatient and outpatient hospitals services.

ACOs authorized by the ACA will bring together providers and suppliers under a shared governance structure that is integrated to maximize accountability for the quality, cost and overall care of the Medicare fee-for-service beneficiaries. CHA supports innovative care delivery models that will achieve both quality and shared savings.

Organizations eligible to form ACOs include hospitals and licensed medical professionals, groups and practice associations. As the Notice recognized, bringing together these groups into a single entity implicates many existing laws, including the anti-trust laws, the physician self-referral prohibition, the anti-kickback statute, and the civil monetary penalty laws. The structure also raises issues specific to non-profit hospitals and requirements relating to joint ventures with for-profit entities.

Additionally, most California hospitals are not permitted to employ physicians due to the existing prohibition against the corporate practice of medicine. California law only authorizes county hospitals and University of California system hospitals to employ physicians. As a result,

most California hospitals are unable to access both the state exemption to the corporate ban, and the employment exceptions or exceptions to federal fraud and abuse, and self-referral prohibitions. This complicates the ability of most California hospitals to achieve the clinical integration necessary to form an ACO and other innovative organizations. Thus, it is imperative that the federal agencies implementing the ACA provide guidance or develop regulations that provide definitive safe harbors for what would otherwise be legal hurdles presented by the antitrust, Stark, Civil Monetary Penalty and anti-kickback laws and the Internal Revenue Code.

For instance, Anti-trust laws require enterprises to have sufficient economic unity to avoid potential charges of concerted price-fixing and other market abuses the anti-trust laws are designed to prevent. The federal agencies responsible for anti-trust enforcement should consider providing detailed guidance and provide a road-map to achieve appropriate levels of clinical integration that meet the economic unity requirements in California's unique situation. Developing a "safe harbor" for providers to develop collaborative integrated healthcare delivery systems to meet the nation's health reform goals is a necessary first step to creating innovative organizations such as ACOs.

Under the existing physician self-referral prohibitions (also known as the Stark Laws), a compensation arrangement is broadly construed within the context of a financial relationship. Yet the ACO delivery model relies on aligned financial relationships that must include compensation arrangements, and shared savings. This issue cannot be resolved unless compensation arrangements are eliminated from the physician self-referral law. Alternatively, since California hospitals may not invoke the employment exception in the Stark Laws, there should be a new exception to allow those hospitals in states with a corporate practice prohibition to equally participate in the ACO partnership without having to create a complicated series of solutions to sufficiently integrate with physicians.

Similarly, the anti-kickback statute prohibits payments to induce patient referrals or over- and under-utilizing services to Medicare and Medicaid patients. As interpreted by the OIG, any incentive that may result in a reduction in care, and conceivably includes shared savings with physicians, implicates this law. The anti-kickback statute has a safe harbor for employment of physicians that is not available to California hospitals due to the corporate practice prohibition. This makes it difficult for California hospitals to structure clinical integration and shared savings programs through the ACO model. It is difficult to design a compliant organizational structure without access to existing physician employment safe harbor provisions. With this in mind, CHA requests a safe harbor that is broad enough for California hospitals to participate in clinical integration and shared savings under the ACO delivery model notwithstanding the corporate practice prohibition.

The Civil Monetary Penalty (CMP) law prohibits payments from a hospital that directly or indirectly induce physicians to reduce or limit services to Medicare or Medicaid patients. Yet to align incentives between hospitals and physicians, attain the requisite level of clinical integration, and participate in shared savings, the CMP provisions need to be amended to apply only to reductions or limits to services that are medically necessary services. This is consistent

with evidence based medicine, with protections for clinically appropriate quality of care, and with cost containment and shared savings contemplated under the ACO delivery model.

Tax-exempt requirements for use of charitable assets and for joint ventures have specific requirements that may place at risk the entity's exemption if not properly structured. IRS rules prevent a tax-exempt institution's assets from being used to benefit any private individual, including physicians. This of course affects the ability to form clinical integration arrangements such as ACOs that include not-for-profit hospitals, physicians and various physician organizations. The IRS should recognize that clinical integration programs such as ACOs that reward improving quality and efficiency do not violate IRS rules.

Thank you for the opportunity to present these written comments.