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May 31, 2011

The Honorable Christine Varney
Assistant Attorney General
Antitrust Division
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

The Honorable Jon Leibowitz
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Re: Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017

Dear Assistant Attorney General Varney and Commissioner Leibowitz:

On behalf of the Illinois Hospital Association (IHA), thank you for the opportunity to provide comments to your respective agencies on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations [ACOs] Participating in the Medicare Shared Savings Program (Statement). IHA echoes comments submitted by the American Hospital Association (AHA). We urge the agencies to revise the guidance in order for the Medicare ACO program to achieve its goal of helping transform the way in which health care is paid for and delivered to benefit patients and communities.

The Medicare Shared Savings Program offers a real opportunity for the Medicare program to control costs and improve quality. However, as currently written, the proposed Statement will stifle the creation of ACOs and impede the goals of the program. The establishment of successful ACOs will be complex and expensive. The antitrust statement adds enormously to both the complexity and the cost.

We urge your agencies to provide user-friendly guidance on how the agencies will analyze, under the rule-of-reason, clinically integrated organizations that are or are like Medicare ACOs to avoid or minimize antitrust risk. Guidance from the agencies on how that analysis would be applied would assist hospitals and other providers in forming and operating clinically integrated organizations.

IHA agrees with AHA that the proposed Primary Service Area (PSA) formula should be abandoned. Among our serious concerns with this new formula are that it is untested, certain to be burdensome and costly, certain to pose great difficulties when non-Medicare

services are to be included in the ACO, and could raise issues for hospitals that undertake the PSA analysis on behalf of physicians under the fraud and abuse laws.

In addition, mandatory review of prospective Medicare ACO applicants should not be required. Instead, the agencies should continue to respond to concerns as they arise in the marketplace. Under the proposed Statement, a prospective applicant with even a single PSA above 50% would need to: (1) submit a large number of documents not required by other agencies; and (2) obtain a time-consuming and expensive antitrust analysis from an antitrust practitioner in order to be prepared to defend its ACO application before one of the agencies.

Mandatory review inappropriately delegates to the antitrust agencies the authority to determine which prospective ACO will be permitted to apply for the Medicare ACO program based on concerns about whether the ACO *could* impact price competition in the private sector. This concern seems particularly misplaced because the application at issue would be to participate in the Medicare ACO program, a program in which there is no price competition, as the terms, conditions and reimbursement provided are dictated solely by a federal agency.

The antitrust agencies could make a positive contribution by developing a truly streamlined process (90 days or less) that *allows* prospective ACO applicants to obtain antitrust guidance at the same time CMS is reviewing the application. Such a process would also aid other clinically integrated organizations.

Other concerns about the Statement that should be addressed:

- The safety zone of 30% or less is too low and should be increased to at least 35%. In addition, qualifying for the safety zone should not require that participants contract or even be able to contract with other ACOs. Exclusivity will likely be an important tool to ensure that a Medicare ACO is able to meet the quality reporting and health information technology meaningful use requirements, among others, in the CMS rule. The promise of a safety zone is seriously compromised if it is too low and exclusivity is not permitted.
- The indicia of "clinical integration" included in the CMS rule and relied on by the antitrust agencies is overly prescriptive and unnecessary. This includes, for example, a "leadership and management structure" that anticipates a formal governing body where "ACO participants hold at least 75% control." The antitrust agencies should specify which criteria are related to antitrust issues and applicable to clinically integrated health care organizations.
- The rural exception is too narrow. Having a larger share of providers where necessary should be allowed under the exception if the providers are nonexclusive (available to work with others).

We appreciate the work and collaboration among the agencies that went into the Statement; however, in its current form, it will itself be an unnecessary and unfortunate

barrier to Medicare ACO formation and operation. We hope the antitrust agencies will take this opportunity to substitute meaningful guidance instead of the Statement and a streamlined and voluntary process to obtain advice from the agencies.

Sincerely,

Maryjane A. Wurth
President