May 27, 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 Tennessee Hospital Association, we are providing 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). ACOs are designed to closely connect groups of providers who are willing and able to take responsibility for improving the overall quality, efficiency, costs and patient experience of care for a defined population. In theory, ACOs given the proper leeway, can flourish and overcome certain fee-for-service consequences that plague the delivery of healthcare. We appreciate the antitrust agencies' recognition of the importance of integrated health organizations, like ACOs, and the historic effort to work cooperatively with other federal agencies to craft a legal and regulatory framework for the Medicare ACO program.

COMMENTS RELATIVE TO THE STATEMENT

1. THE STATEMENT SHOULD BE CHANGED

The primary question posed by the agencies to prospective ACO applicants in the Statement is: "[w]hether and, if so, why, the guidance in the proposed policy statement should be changed." The simple answer is "yes;" it should be fundamentally changed in order for the Medicare ACO program to achieve its ambitious goal of helping to transform the way in which healthcare is provided and paid for to benefit patients and communities. In its current form, the Statement will serve as a significant and unnecessary barrier to participation in the Medicare ACO program and does not provide the guidance needed to spur adoption of and continued innovation in clinical integration beyond the Medicare program.

We urge your agencies to shift the focus of the Statement, to a more 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 should not be a prerequisite for participation in the Medicare ACO program, instead the agencies should continue to respond to concerns as they arise in the marketplace. The agencies should also provide for a streamlined process for clinically integrated organizations to receive more specific advice that works in sync with the Centers for Medicare & Medicaid Services' (CMS) application process.

2. THE STATEMENT LACKS USABLE GUIDANCE

One of the most useful features of the Statement was assurance that Medicare ACOs would be reviewed by the antitrust agencies under the rule-of-reason, which balances pro-competitive potential against anti-competitive risk. Guidance from the agencies on how that analysis will be applied would assist hospitals and other providers in forming and operating such clinically integrated organizations.

The hospital field has long sought guidance from the antitrust agencies on clinical integration, similar to that in the Statements of Antitrust Enforcement in Health Care. It was the 1996 Statements that first broadened the concept of legitimate provider integration to include clinical integration. Since then, the agencies have repeatedly declined to provide guidance in a similar manner, despite repeated calls by members of Congress, the hospital field and others. The Medicare ACO program provides an opportunity for the antitrust agencies to issue such guidance focused on how the agencies will analyze ACOs, and similarly clinically integrated organizations, under the rule-of-reason.

3. THE RULE OF REASON SHOULD BE EXTENDED.

The Statement provides that the antitrust agencies will apply the Rule of Reason to an ACO only for the duration of its participation in the Medicare Shared Savings Program. Therefore, an ACO that ceases to participate in the Medicare Shared Savings Program, but continues to operate essentially the same program in the commercial market will no longer have the certainty of Rule of Reason treatment. Similarly, an ACO that operates a program only in the commercial marketplace that is in all other respects similar to one that qualifies for participation in the Medicare Shared Savings Program or an ACO formed before March 23, 2010 will not have the certainty of Rule of Reason treatment. Such different treatment hardly seems appropriate. The agencies should extend the Rule of Reason to any ACO that would meet all of the CMS criteria for participation in the Medicare Shared Savings Program – irrespective of when it was formed or terminated and irrespective of whether it participates in the Medicare Shared Savings Program, if by all other measures of the program it could.

4. THE PROPOSED FORMULAS SHOULD BE ABANDONED

The Statement proposes a new, untested formula to determine the shares of each prospective ACO participants in its "Primary Service Area" (PSA). Shares must be calculated for *each* common service to be provided by *each* participating hospital and doctor (or group of doctors) within *each* provider's PSA. PSA is defined as the lowest number of contiguous zip codes from which the provider draws at least 75 percent of its patients. Among the 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 if no waiver is provided:

- Calculating PSA shares on the basis of Medicare fee-for-service data is likely to be unreliable and will be practically unavailable for any service or medical specialty that does not routinely provide

services to Medicare patients, such as obstetrics, pediatrics, burn units, and HIV services, for example. The data will also overstate the shares of providers who care for large numbers of Medicare patients and understate the shares of those who restrict their practices to commercially-insured patients. Even where Medicare fee-for-service data might be available, it will be extremely difficult for physicians to pull zip code data and match it with billing records to obtain the services provided.

- Calculating PSA shares on the basis of contiguous zip codes likely will be burdensome and costly and require substantial judgment calls.
- For purposes of calculating the PSA, it is not clear whether all patients are to be included – irrespective of payor – or only Medicare patients since the applicant's respective share is calculated based on data for services rendered to Medicare beneficiaries only.
- The "Stark" law requires that compensation for health care providers be fixed in advance and paid only for hours worked. The Stark law could be implicated if a hospital compensates physicians by organizing and paying for the costly analysis required to determine physician PSA shares. There is no indication in the notice issued by CMS and the Office of Inspector General on waivers in connection with the Medicare ACO program that a waiver for such activities and expenses is being considered.

5. MANDATORY REVIEW SHOULD NOT BE REQUIRED

Under the proposed Statement, any prospective Medicare ACO applicant that received a PSA score of 50 percent or above for any service or specialty is subject to *mandatory* review by one of the antitrust agencies due to the perceived potential for competitive harm. This is true, even if the score is for a non-Medicare service, such as pediatrics, and even if the ACO applicant's PSA share is well below 50 percent for the vast majority of services provided.

Mandatory review is not confined to the specific service(s) over 50 percent, but will subject the entire Medicare ACO applicant to antitrust scrutiny. Practically, this means that a prospective applicant with even a single PSA above 50 percent would need to: (1) submit a large number of documents (that do not overlap with those required by other agencies); and (2) obtain a time-consuming and expensive antitrust analysis from an antitrust practitioner, to be prepared to defend its ACO application before one of the agencies.

Moreover, the Statement fails to provide any guidance relative to the types of additional information or alternative data the agencies might consider beyond the PSA. The agencies should necessarily consider any substantial precompetitive information and data that justify the ACO's share relative to providing high-quality, cost-effective care to Medicare beneficiaries.

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.

6. CHALLENGE LETTERS SHOULD BE SUBJECT TO DUE PROCESS

The Statement provides that the reviewing agency may provide the applicant with a letter stating that if is likely to challenge or recommend challenge if the ACO proceeds. The reviewing agency is not required to state the basis of such a conclusion, which means ACO's receiving such letters would likely be prevented from participating in the Medicare Shared Savings Program and would have no relevant information upon which to restructure or otherwise take appropriate ameliorative action. Additionally, the

Statement is silent regarding any appeal rights or administrative process to seek redress or review of such a letter.

The Statement should require both an explanation of the basis for the reviewing agency's conclusion and should specify the applicant's appeal rights.

7. OTHER CONCERNS THAT SHOULD BE ADDRESSED

There are number of other concerns about the Statements that should be addressed:

- The safety zone of 30 percent or less is too low and should be increased to at least 35 percent. And, 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 percent 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 for the Statement meaningful guidance and a streamlined and voluntary process to obtain advice from the agencies. We look forward to working with the agencies to make the Medicare ACO program a success and to lay a stronger foundation for other clinically integrated arrangements to flourish.

Sincerely,

Craig A. Becker, FACHE

President

Tennessee Hospital Association