May 20, 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 Texas Hospital Association and its more than 400 member hospitals, we are providing comments to your respective agencies on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program. We appreciate the effort by your agencies to work together and with the Centers for Medicare & Medicaid Services in the development of antitrust enforcement policy relative to ACOs, and your willingness to accept public comment on the proposed Policy Statement.

In the proposed Policy Statement, the agencies have sought comment on: (1) whether the proposed statement should be changed in any respect; (2) whether other sources of data exist to determine relevant primary service areas; and (3) whether providing the documents and information required to obtain expedited antitrust review will present an undue burden on ACO applicants. The following THA comments will respond to each of these questions.

Whether the proposed Policy Statement should be changed?

A. Rule of Reason Analysis

The Policy Statement is important because it provides guidance on how the agencies will review clinically integrated organizations that seek approval as a Medicare ACO and that may enter into similar arrangements with private payers in the commercial market. The Proposed Statement provides that the agencies have determined that CMS's proposed eligibility criteria for ACOs are

broadly consistent with the indicia of clinical integration that the agencies have established in the *Health Care Policy Statements* issued to date, and the statement suggests that organizations meeting the CMS criteria for approval as an ACOs will be reviewed under a rule of reason analysis. Further, the Proposed Statement states that "[t]he Agencies will provide rule of reason treatment to an ACO if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes it use to qualify for and participate in the Shared Savings Program. This rule of reason treatment will apply to the ACO for the duration of its participation in the Shared Savings Program."

The hospital industry supports application of a rule of analysis to approved Medicare ACOs. This type of antitrust review is reasonable and appropriate for organizations that can meet the requirements of the Medicare ACO rules. However, the Policy Statement should be expanded to address those organizations that would meet the requirements of the ACO rules, but may not seek approval as an ACO or may choose to terminate its contract under the Shared Savings Program. As the agencies are aware, the proposed reimbursement mechanisms and other regulatory requirements for ACOs are still under consideration by CMS and unless modified there may be a limited number of organizations that will participation in the program. While the Policy Statement suggests that the agencies will use a rule of reason analysis to an ACO entering into contracts with commercial payers if the ACO uses the same governance and leadership structure and same clinical and administrative processes, it is not clear whether and to what extent the agencies would apply rule of reason analysis to those organizations that are not participating in the program.

B. Use of Primary Service Area Shares

For purposes of the proposed antitrust safety zone and mandatory review the Policy Statement proposes to evaluate an ACO's share of services in each ACO participant's primary service area. The PSA for each service is defined as the lowest number of contiguous zip codes from which the provider draws at least 75 percent of its patients. Thus, an ACO applicant must make multiple calculations of the geographic area from which the ACO draws 75% of its patients.

It is recognized that the agencies must establish an appropriate data base and approach to determine the market share of ACO participants; however, there are serious concerns with this proposed methodology. Calculating PSA shares on the basis of Medicare fee-for-service data is likely to be unreliable and will be unavailable for any services not provided to Medicare patients, such as obstetrics or pediatrics. The data also will overstate the shares of providers who care for large numbers of Medicare patients and understate the shares of those who focus their practices on commercially-insured patients. Further, calculating PSA shares on the basis of contiguous zip codes likely will be very costly and require substantial judgment calls.

While the agencies have noted that CMS will make PSA data available and that this sharing of data will help reduce the burden of making the PSA calculations, this approach will not address the complicated process of calculating the PSA numerator. As the American Hospital Association and other associations have suggested the agencies should reconsider this approach. THA recommends that the agencies and CMS consider the feasibility of developing the necessary data, algorithms, and process whereby ACO applicants might conduct their PSA share analysis. This approach would ensure the use of reliable and consistent data and could facilitate

the review process. The agencies also should consider use of geographically-defined areas, such as metropolitan statistical areas or counties, as a basis for calculating market shares. Use of geographically-defined areas could substantially reduce the complexity of the required calculations and reduce the associated costs.

C. Mandatory Antitrust Review

Under the proposed Policy Statement, an applicant for participation in the Medicare Shared Savings Program that received a PSA score of 50 percent or above for any service or specialty is subject to mandatory antitrust review. This review is not confined to the specific service(s) over 50 percent, but will subject the entire Medicare ACO applicant to antitrust scrutiny. The review process will require the submission of a large number of documents and an antitrust analysis of the proposed business plans and operations of the ACO applicant.

As the agencies are aware, the establishment of mandatory review process represents a significant change in enforcement of the antitrust laws by the agencies and will effectively give the agencies the authority to prevent an organization from participating in this Medicare program. Depending upon the number of organizations that apply for participation in the program, this review process also may substantially expand the agencies involvement in health care. Further, the proposed review process will be very expensive for both ACO applicants and the agencies. For these reasons, THA recommends that the agencies consider making the review voluntary. Under this approach, organizations that wish to obtain the certainty and benefits of the review are able to do so; and those organizations that prefer not to incur the costs associated with this review would be subject to the existing antitrust enforcement process.

D. Safety Zone Non-Exclusivity

The proposed Policy Statement requires that for an ACO to fall within the safety zone any hospital or ambulatory surgery center in the ACO must be non-exclusive to the ACO. The same non-exclusivity requirement applies to rural hospitals that seek to qualify under the rural provider exception. The agencies have suggested that an ACO must be "non-exclusive in fact and not just in name," and refer to the *Health Policy Statements* for indicia of non-exclusivity. Under the policy statements providers must actually participate in, or contract with, other networks or there must be other evidence of their willingness to do so. Requiring non-exclusivity may mean that a hospital that develops an ACO may need to participate in another hospital-based ACO that is formed in that service area. Clarification of this section of the Policy Statement is necessary and important to provide guidance to organizations on how the safety zone will be applied and how the agencies consider exclusivity in evaluating organizations that may not meet the safety zone.

Whether other sources of data exist to determine relevant primary service areas?

In a number of states, all payer claims data systems have been established and hospitals, ambulatory surgery centers and other providers are required to submit claims data to a state agency. For example, in the State of Texas the Texas Health Care Information Collection Center for Health Statistics collects inpatient hospital and outpatient claims data. These data reports follow national uniform billing data element specifications. These state data systems may provide a more complete source of data and should be considered by the agencies. In addition,

there are a number of proprietary sources of data that exist and could be made available to determine the primary service areas.

Whether providing the documents and information required to antitrust review will present an undue burden on ACO applicants?

Clearly, the proposed Policy Statement contemplates that ACO applicants will submit an extensive amount of data and other information relating to the size, composition and proposed business plans of the organization. Depending on how the agencies interpret the information requirements, the types of information to be submitted could be overly broad and not needed to conduct the antitrust review. For example, ACO applicants likely will have a large volume of documents created by staff or consultants relating to the planning and development of the ACO that may not be relevant to competitive issues.

To lessen the burden on data submission the agencies are encouraged to further clarify and limit the amount of data and information that is initially required to be submitted and allow the agencies to request additional information, as necessary.

Conclusion

THA appreciates the work and collaboration among the agencies that went into the development of the Policy Statement and our association appreciates the opportunity to provide comments. THA encourages the agencies to reconsider the approach and requirements of the Policy Statement so that prospective participants in the Medicare Shared Savings Program will have meaningful guidance on how the agencies will review the antitrust issues associated with ACOs and the review process will not be overly burdensome or costly for ACO applicants.

Sincerely,

Charles W. Bailey
Senior Vice President, General Counsel
Texas Hospital Association