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

SUBJECT: 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:

The California Hospital Association (CHA) is pleased to submit comments on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Statement). CHA is a nonprofit organization representing more than 400 hospitals and health systems in California. CHA acknowledges the unprecedented coordination of the Department of Justice and the Federal Trade Commission (Antitrust Agencies) with other federal agencies to encourage the development of ACOs.

CHA, however, is concerned that the Statement does not sufficiently protect hospitals and other providers that may wish to participate in an ACO. Elements of the Statement may actually serve as a barrier to organizations that wish to form ACOs within the Medicare program, as well as for commercially insured patients.

Encourage Additional Guidance

CHA supports the Antitrust Agencies' determination that they will apply the "rule-of-reason," which balances procompetitive potential against anticompetitive risk. However, the Statement lacks meaningful guidance on how the rule would be applied to ACOs. Additional guidance on how the rule-of-reason analysis would be applied would assist hospitals and other providers in forming and operating such clinically integrated organizations.

Abandon PSA Formula

The Statement proposes a new, untested and highly problematic formula to determine the shares of each prospective ACO participant 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

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codes from which the provider draws at least 75 percent of its patients. Serious concerns with this new formula include that it is untested; is certain to be burdensome and costly; is certain to pose great difficulties when non-Medicare services are 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 that care for large numbers of Medicare patients, and understate the shares of providers that 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.
- 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. The notice issued by CMS and the Office of Inspector General on waivers in connection with the Medicare ACO program has no indication that a waiver for such activities and expenses is being considered.

Role of Antitrust Agencies
The Statement establishes a regulatory framework in which an ACO applicant that received a PSA score of 50 percent or more for *any single* service line is subject to mandatory review by the Antitrust Agencies. This requirement is burdensome because it creates uncertainty, as well as significant document preparation and antitrust analysis for the entire organization, not just the service line in question.

More fundamentally, the mandatory review framework inappropriately places the Antitrust Agencies into a role in which they determine who will, and will not, be an ACO. ACO applicants should not be placed in the position of requesting approval from the Antitrust Agencies prior to forming an ACO. The goal of encouraging innovation in the development of ACOs can be accomplished if the Statement is revised to provide more meaningful guidance on how the "rule-of-reason" analysis will be applied, and then monitoring marketplace conduct and taking enforcement action as necessary.

The antitrust agencies could also 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.

Additional Adjustments to Antitrust Review Framework
In addition to CHA's concerns regarding the mandatory review requirement for ACOs that exceed the 50 percent PSA share threshold, we have additional concerns regarding the threshold estab-

lished for the 30 percent or less safety zone. The safety zone of 30 percent or less is too low and should be increased. 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 "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).

Review of ACOs Outside the Safety Zone

CHA appreciates that the Antitrust Agencies acknowledge that ACOs outside the safety zone and below the 50 percent mandatory review threshold frequently may be procompetitive, and may proceed without additional scrutiny. Still, the Statement indicates that the Antitrust Agencies may review conduct that may be anticompetitive and describes five indicia that may trigger additional review. It would be helpful if the Statement more clearly stated that the conduct, if appropriately applied, could be procompetitive.

For example, a strict interpretation of these provisions could interfere with hospitals' ability to provide a broad range of health care services in their communities, thus forcing patients to travel long distances for some care. In addition, these provisions could also increase costs because they will reduce the efficiencies obtained when hospitals coordinate the provision of health care services. The negative impact could be most severe in lower income or underserved communities.

CHA believes that patients deserve to have meaningful, accurate and reliable information regarding both the cost and quality of hospital care for them to make informed decisions. The Statement should be amended to ensure that hospitals are not subject to additional scrutiny simply because they require that consumers be provided with information that is meaningful, accurate and reliable, and that any formula developed to display this information is itself transparent and based on a legitimate methodology.

Thank you for the opportunity to provide these comments. For more information, please contact Dietmar Grellmann, CHA senior vice president, managed care and professional services, at (916) 552-7572 or dgrellmann@calhospital.org.

Sincerely,

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