

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

The transformation of the healthcare system of the United States, including the creation of Accountable Care Organizations, is no small task. Clearly, significant governmental agency thought, discussion, and coordination went into the development of the draft regulations. From the tone of the draft regulations and the request by the agencies for comments, health reform is meant to be an iterative, as well as a collaborative process, with all parties in healthcare striving to achieve the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures.

Before release of its draft regulations, CMS communicated that ACOs would require both size and financial strength. The need for these prerequisites is clear throughout the proposed rule. Not only will organizations need to be sophisticated, and already have much of the work underway, but they must also accept that a positive financial return on this investment is unlikely under the current design. In addition, Cedars-Sinai is concerned that the Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program does not sufficiently protect hospitals and other providers that may wish to participate in an ACO.

At Cedars-Sinai we recognize that ACOs have the potential to do the right thing for the patient and the larger community, and as a result are evaluating participation considering longer term implications to the healthcare delivery system. We want to work in partnership with CMS and other governmental agencies to make this program a success; however, we believe that without regulatory modifications it is unlikely that accountable care organizations will touch enough beneficiaries and/or providers to make clinical transformation a sustainable reality.

With the intent of improving the regulations, and remaining focused on achieving the triple aim, we appreciate the opportunity to provide comments on the draft regulations. Our comments are reflective not only of being an academic medical center, but also as a community medical center residing in a highly urban area.

- The Primary Service Area Formula:

Recommendation:

- 1) Abandon the Primary Service Area formula. This formula is untested, burdensome, and likely to be costly. In addition, this could raise issues of fraud and abuse laws if no waiver is provided to the ACO for this work in advance of the distribution of shared payments.

- The Safety Zone:

Recommendation:

- 1) Increase the “safety zone” threshold of 30 percent.
- 2) Change the framework that any ACO applicant who 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 and significant document preparation and antitrust analysis for the entire organization, not just the service line in question. Instead create a mandatory review when the majority of service lines are above the 50 percent threshold.
- 3) Do not make these “safety zone” contingent on exclusivity or non-exclusivity.

- Role of Antitrust Agencies:

Recommendations:

- 1) The mandatory review framework places the Antitrust Agencies into a role of determining who will, and will not, be an ACO. We would prefer for the Antitrust Agencies roles be one of providing guidance instead of mandatory review, which we believe would encourage greater innovation. We would appreciate more clarity on how the “rule-of-reason” analysis will be applied.
- 2) Have a defined streamlined process for prospective ACO applicants to obtain antitrust guidance pre CMS application or during the application process. This would provide useful feedback throughout the prospective ACO development process.

Sincerely,

Thomas M. Priselac  
President and Chief Executive Officer  
Cedars-Sinai Health System