

May 31, 2011

**VIA ELECTRONIC MAIL**

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, NW  
Washington, D.C. 20580

**REF: Matter V100017**

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

Dear Assistant Attorney General Varney and Commissioner Leibowitz:

Catholic Health Initiatives (CHI) appreciates the opportunity to provide comments on the Proposed Statement of Antitrust Enforcement Policy Regarding the Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Statement). CHI is a faith-based, mission-driven health system that includes 72 hospitals; 40 long-term care, assisted living and residential units; two community health service organizations; and numerous physician practices and home health services across 19 states. As a health system, CHI is committed to patient-centered, coordinated, evidence-based healthcare throughout our organization.

**Safety Zone Threshold**

The statement sets forth a process that is intended to help clinically integrated organizations avoid or minimize antitrust risk. The statement proposes a safety zone for certain ACOs that are unlikely to pose threats to competition. An ACO that falls within the safety zone would have no obligation to

seek agency approval in order to proceed with its application for ACO designation. The statement proposes a new, untested formula to determine the shares of each prospective ACO participant in its Primary Services Area (PSA). The formula is burdensome and costly for our hospitals and providers to determine whether their shares of common services fit within a safety zone. We urge the FTC and DOJ to modify the process for determining the PSA.

We have three additional comments regarding the Safety Zone. First, the threshold is too narrow, especially when applied to market share in rural areas. Many of our facilities are located in medically underserved areas where providers and suppliers are in short supply, and Medicare represents a significant part of the market. In some cases the hospital, physicians and suppliers in the area are the only providers available, causing their market share to be greater than the 30 percent threshold. We recommend that the Safety Zone for exclusive clinically integrated arrangements be set at a minimum of 35 percent of the relevant market, which is the benchmark that the agencies use for joint-purchasing arrangements. For a number of our hospitals, providers and suppliers, this threshold will help ensure a full panel of providers spanning a broad array of specialties.

Second, we object to the prohibition on exclusivity. Exclusivity is an important component of changing the delivery model and it helps ensure that the ACO meets the standards and requirements established for the program. Participants should not be required to contract with other ACOs. In a voluntary program that is expected to provide the full continuum of care in a coordinated fashion, exclusivity is important to facilitate efficiencies and minimize the risk of “free-riding.”

Third, the protection from federal antitrust enforcement will be necessary to give providers peace-of-mind before organizing an ACO; however, it is not enough. ACOs still risk liability from civil antitrust lawsuits brought by individuals under state or federal law. FTC should provide some protection from civil suits and provide for some preemption of state antitrust laws.

***Recommendations: CHI urges FTC and DOJ to make a number of changes to the safety zone threshold provisions of this enforcement policy. The agencies should reconsider the process for determining the PSA, taking into consideration the costly and burdensome analysis it places on an ACO applicant. The minimum threshold for clinically integrated arrangements should be set at 35 percent. The agencies should remove the prohibition on exclusivity to allow ACOs to ensure that its participants provide coordinated care. Finally, the agencies should provide antitrust protections from civil lawsuits and state laws.***

### **Rural Exception**

There is a rural exception that applies if the prospective ACO covers more than one rural county and the ACO's PSA share for a common service exceeds 30 percent. In that case, the ACO may include one physician per rural county for that common service so long as that physician's participation is non-exclusive. CHI is unclear how the rural exception will operate. We interpret the exception to mean that an ACO may include at least one physician per rural county for that common service. It is unclear how the exception would work if there are multi-physician practice groups and only one physician is participating in the ACO, but is not exclusive. This needs to be clarified.

If an ACO needs the vast majority of providers in an area (i.e., rural areas), PSA share may not be reflective of precompetitive efficiencies. As such, we believe that the PSA maximum share for an ACO, particularly in rural areas, should be increased. A number of our hospitals are critical access hospitals that provide acute care services over a wide service area. The physicians in the county that send patients to the hospital should not be prevented from joining an ACO because they have a PSA assessment over 50 percent.

***Recommendation: The agencies should clarify the rural exception language as it relates to multi-physician practices, particularly where only one physician is participating on a non-exclusive basis. The agencies should extend the PSA assessment limit beyond 50 percent, particularly in rural areas, where competition is naturally limited by geography.***

### **90-Day Review Process**

For prospective ACO participants whose Primary Service Area (PSA) assessment is over 50 percent, an expedited 90-day review is available if all of the required information is submitted to FTC/DOJ. The applicant is required to submit a substantial amount of information that does not overlap with the information required by the CMS application process. We question whether the 90-day review cycle is realistic and achievable. We recommend that the agencies monitor their review periods to ensure that they are meeting the targeted timeframe.

***Recommendation: The agencies should monitor their review period for PSA assessments to ensure that they are meeting the truncated 90-day timeframe.***

Thank you for the opportunity to share our comments on the statement of antitrust enforcement policy. If you would like more information, please contact Colleen Scanlon, Senior Vice President of Advocacy, at 303-383-2693.

Sincerely,

Kevin E. Lofton  
President and Chief Executive Officer