Cleveland Clinic

Oliver C. Henkel, Jr.
Chief Government Relations Officer
Office of Government Relations

May 27, 2011

Federal Trade Commission
Office of the Secretary, Room H-113 (Annex W)
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

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

Dear Madam or Sir:

Cleveland Clinic, a not-for-profit integrated healthcare system dedicated to patient care, teaching and research respectfully submits the following comments to the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.

PSA as Proxy for Geographic Market

The Policy Statement premises the Agencies' analysis upon the proposed ACO's share of a Primary Service Area ("PSA"), which is defined as "the lowest number of contiguous postal zip codes from which the [ACO participant] draws at least 75 percent of its [patients] for that service." The Policy Statement acknowledges that a PSA "does not necessarily constitute a relevant antitrust geographic market." Utilizing the PSA as a proxy for the relevant geographic market for antitrust purposes is a departure from principles accepted by courts in determining market share. Indeed, a PSA is only an approximation for an antitrust relevant geographic market, and may yield incorrect geographic market share conclusions. And, notably, courts would not be bound to follow the PSA share calculation in defining the relevant geographic market in an action brought by private litigants. We respectfully submit that the Policy Statement be modified to allow the PSA to be one factor in determining eligibility for safety zone protection; however, it should not be the threshold or determinative consideration.

Exclusivity Requirement for Hospitals

The Policy Statement provides that, "any hospital. . . participating in an ACO must be non-exclusive to the ACO to fall within the safety zone, regardless of its PSA share." The Policy Statement goes on to explain that, "[i]n a non-**exclusive** ACO, a **hospital . . .** is allowed to contract individually or affiliate with other ACOs or commercial payers." (Emphasis added.) The Policy Statement does not specify if a

The Cleveland Clinic Foundation
9500 Euclid Avenue / H18
Cleveland, Ohio 44195
Tel 216 445-7445
Fax 216 444-2436
henkelo@ccf.org

hospital may meet the non-exclusivity requirement through either contracting with multiple ACOs, or commercial payers. Stated differently, must a hospital contract with both multiple ACOs and payers to enjoy the protections of the safety zone? The inclusion of the word "or" in the emphasized sentence above seems to indicate that exclusivity is required only with respect to either payers or other ACOs, but not both. We respectfully request clarification on this point and submit that anticompetitive concerns will be eliminated by requiring hospitals to contract on a non-exclusive basis either with commercial payers or other ACOs. Allowing hospitals to meet the non-exclusivity requirement though non-exclusive contracts with payers alone (while permitting hospitals to participate in only one ACO and still enjoy safety zone protections) will also avoid the result of forcing hospitals to join ACOs that they otherwise would not, which may have competing or conflicting arrangements with the same payers served by the competing ACO.

Changes to Composition of the ACO

The Policy Statement requires clarification regarding the impact of an ACO's changed PSA share during its existence. Obviously and ACO's PSA share will change over time as providers leave and join the organization. The Policy Statement provides that, if an ACO is eligible for safety zone protection, "[t]he safety zone will remain in effect for the duration of an ACO's agreement with CMS, unless there is a significant change to the ACO's provider composition." What constitutes "significant change" is not discussed and, we respectfully submit, clarification of this concept is required.

The Policy Statement also provides that, "[I]f . . . there is a significant change to the ACO's provider composition such that the ACO exceeds the 50 percent threshold or is materially different than what was initially reviewed, the ACO must seek antitrust review as set forth above." The Policy Statement does not contain a definition or other explanation of what "materially different than what was initially reviewed" means. Clarification of this important concept likewise is warranted.

Furthermore, we submit that the Agencies should provide an explanation of the antitrust treatment an ACO will receive whose composition "significant[ly] change[s]" or becomes "materially different." Will, and at what point, will those ACO's actions be subject to per se treatment or otherwise be challenged by the Agencies? We respectfully submit that ACO's that require subsequent antitrust review due to changes in their provider composition be afforded a "safety period" for the ACO's activities until such additional review is completed, provided the ACO continues to follow the practices in place when it received its "no challenge" letter from the Agencies.

Review of Agency Determination

Finally, the Policy Statement is silent on what recourse is afforded if an Agency letter excludes an ACO from the Medicare Shared Savings Program. We respectfully submit that an ACO that does not receive antitrust approval be afforded the right to

appeal that determination through the appropriate administrative process, and ultimately to the courts for review.

We appreciate the opportunity to provide these comments, and we look forward to further guidance on these issues from the Agencies.

Sincerely

Oliver C. Henkel, Jr.
Chief Government Relations Officer

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