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May 31, 2011

ELECTRONIC SUBMISSION

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

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

Dear Sir or Madam:

First and foremost, we thank the Federal Trade Commission ("FTC"), Department of Justice ("DOJ") and the other applicable regulatory agencies, in developing a coordinated and comprehensive multiagency plan to implement the Medicare Shared Savings Program. In response to the request for comments, we are writing to express a specific concern and present certain recommendations with respect to the Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program ("Policy Statement") issued by the FTC and DOJ.

Specifically, we would like to discuss the requirement that hospitals be non-exclusive to ACOs, in fact, in order to fall within the antitrust safety zone. In the relevant section, the Policy Statement provides that:

> Any hospital or ambulatory surgery center ("ASC") participating in an ACO must be non-exclusive to the ACO to fall within the safety zone, regardless of its [Primary Service Area] share. In a non-exclusive ACO, a hospital or ASC is allowed to contract individually or affiliate with other ACOs or commercial payers.

The attributed footnote explains that "[t]he ACO must be non-exclusive in fact and not just in name" and references the "indicia of non-exclusivity" from the FTC/DOJ *Statements of Antitrust Enforcement Policy in Health Care* ("Health Care Statements") as relevant criteria to such an evaluation. Specifically, in the context of assessing exclusivity of physician participation in physician network joint ventures, the relevant portion of the Health Care Statements lists the following "indicia of non-exclusivity:"

(For ease of analysis in the current context, "ACO" has been substituted in these "indicia of non-exclusivity" where physician networks or managed care plans are referenced, and "hospital" has been substituted where individual physicians are referenced.)

1. Viable competing ACOs with adequate hospital participation currently exist in the market;

2. Individual ACO hospitals actually participate in or contract with other ACOs, or there is other evidence of willingness and incentive to do so;

3. ACO hospitals earn substantial revenue from other ACOs;

4. There is an absence of any indications of significant hospital de-participation from other ACOs in the market; and

5. There is an absence of any indications of coordination among the ACO hospitals regarding price or other competitively significant terms of participation in other ACOs.

As a general matter, the Health Care Statements explain that the FTC and DOJ assess exclusivity by looking at activities, not simply contractual terms, and will consider provisions that "significantly restrict the ability or willingness" to participate in competitors, but do not otherwise expressly require exclusivity.

The first four "indicia of non-exclusivity" above will often be of limited relevance to ACOs and the exclusivity of hospital participation. First, if participation in the Medicare Shared Savings Program is modest or lower than expected, there may be many markets in which there is no more than one viable ACO. A hospital's participation in only one ACO in such situations would bear no relationship to the ACO's exclusivity requirements. Similarly, such situations would prevent hospitals from actually participating in or receiving significant revenues from competing ACOs, and the measure of "de-participation" in competing ACOs would be irrelevant.

Moreover, there are *bona fide* reasons that a hospital may not participate, or seek to participate, in more than one ACO, even where there is a viable competing ACO in the market. For example, a hospital might have contributed significant capital to an ACO, and may therefore be financially unable or unwilling to make the required capital commitment to another ACO. Depending upon the policies, procedures, information technology, reporting requirements and other infrastructure implemented by an ACO, it may be administratively impracticable for a hospital to join another ACO with incompatible polices, requirements and/or infrastructure. Additionally, if the hospital happens to employ any primary care physicians billing under its tax identification number, the hospital *must* be exclusive to a single ACO as a condition of participation in the Medicare Shared Savings Plan under the proposed ACO regulations issued by the Centers for Medicare & Medicaid Services ("CMS"). Finally, a hospital may strategically choose not to participate in another ACO, or an ACO may strategically decide not to invite a hospital (or additional hospital) to participate, in order to lower antitrust enforcement risks and/or to avoid antitrust review. Therefore, the first four indicia or non-exclusivity should be deemphasized in determining exclusivity in the context of hospital participation in ACOs.

The last indicia of non-exclusivity is more relevant in the context of exclusivity of hospital participation in ACOs. This indicium addresses the anticompetitive threat of ACOs as set forth in the Policy Statement, their ability to reduce quality of care and raise prices with commercial insurers above competitive levels. Specifically, this indicator seeks to prevent price-fixing and cartel activity among competitors under the umbrella of an ACO. However, it is not clear whether requiring a hospital to participate in multiple ACOs would increase or decrease the risk of such activities.

Outside of coordinated anticompetitive behavior among competitors, as discussed above, a hospital's exclusive participation in an ACO may not, in fact, raise additional antitrust risk, including the risk that a hospital's exclusivity could result in the improper exercise of market power. The Primary Service Area share calculations, expedited antitrust review mechanisms (optional or mandatory), and the various requirements that ACOs not *require* the exclusivity of certain providers (e.g., hospitals, ambulatory surgery centers, dominant providers, certain rural providers, etc.) in order to fall within the "safety zone" should all adequately ensure that an ACO will not improperly obtain and/or exploit market power, regardless of whether an ACO's hospitals or other providers actually participate in other ACOs. Moreover, it has been posited that an ACO driven by physicians only could be successful (perhaps more successful) in achieving cost savings and enhancing the quality of care without any hospital or other institutional participation. Therefore, even if a hospital were contractually *required* to be exclusive to an ACO, there might be little harm to competition.

All considered, we request that the FTC and DOJ issue additional guidance or indicia to assist in determining whether a hospital is non-exclusive with respect to an ACO, or amend this requirement as to not mandate that a hospital to be non-exclusive "in fact." Such indicia should focus on the requirement in the ACO regulations proposed by CMS. The CMS proposed regulations require that "ACO participant TINs upon which beneficiary assignment is not dependent . . . must not *be required to be* exclusive to a single ACO." (emphasis added) Accordingly, the indicia should measure whether the ACO, expressly or effectively, *requires* the hospital to be exclusive to the ACO, not whether the hospitals is, *in fact*, exclusive to the ACO. Possible indicia of non-exclusivity could include, without limitation:

1. Absence of contractual provisions prohibiting a hospital from participating in another ACO; and

2. Absence of contractual provisions or other ACO policies or procedures that provide disincentives or impediments for a hospital to participate in another ACO.

Additionally, the dominant provider limitation requires that any ACO participant that is a dominant provider (as defined), which would include certain hospitals, "must be *non-exclusive* to the ACO to fall within the safety zone." The definition of "non-exclusive" in this context appears to be equivalent to that in the context of hospital and ambulatory surgery center exclusivity discussed above, which requires de facto non-exclusivity. For the same reasons discussed above, there are many *bona fide* reasons that a hospital might not participate in another ACO (e.g., lack of other ACOs in the market, financial restraints, compatibility limitations, antitrust concerns, strategic reasons, etc.). Therefore, we also request that the FTC and DOJ issue additional guidance as to the non-exclusivity requirements of dominant providers in order to meet the "safety zone." We believe that this guidance should state that while an ACO cannot expressly or effectively *require* a dominant provider to be exclusive to the ACO, the dominant provider is not required to actually participate in another ACO.

Finally, where an ACO does not qualify for a "safety zone," it is not clear to what extent the FTC and DOJ consider exclusivity of hospital participation relevant to the antitrust analysis. Therefore, we also request that the FTC and DOJ issue additional guidance as to the implications of hospital exclusivity in ACOs falling outside of the "safety zone" and subject to discretionary or mandatory review. The exclusivity of hospital participation in ACOs, in fact, should not be viewed unfavorably in assessing antitrust risks absent express or effective requirements of exclusivity by the ACO or other evidence of anticompetitive behavior. As explained above, there are many *bona fide* reasons that a hospital may not participate, or seek to participate, in another ACO. The fact that a hospital only participates in a single ACO should not, itself, demonstrate a likelihood of any anticompetitive conduct. Ultimately, such a requirement,

whether as a condition to falling within a "safety zone" or as a factor considered in antitrust review, might dissuade many hospitals from forming or participating in ACOs as such would also require the hospital to, in effect, seek to participate in another ACO as well.

We would like to thank you for your attention and consideration of this matter.

Sincerely,

STEVENS & LEE

Charles M. Honart

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Daniel J. Hennessey