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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 Federal Trade Commission:

On behalf of the law firm Polsinelli Shughart PC ("Polsinelli"), I would like to provide comments to the Federal Trade Commission ("FTC") and the Antitrust Division of the Department of Justice ("DOJ") (collectively, the "Agencies") in regard to the Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program ("MSSP"). Polsinelli is a Kansas City-based law firm that serves numerous local, regional, and national health-care clients, including hospitals, physician groups, and other entities that may be interested in forming accountable care organizations ("ACOs"). Because some of our clients may want to participate in the MSSP, Polsinelli has a significant interest in the proposed enforcement policy, the clarity of the applicable antitrust regulations, and their impact on the effective operation of ACOs.

Polsinelli applauds the efforts of the FTC and DOJ to provide clarity and guidance regarding the antitrust analysis that will be applied to collaborations seeking to participate in the MSSP. The proposed antitrust enforcement policy represents a solid foundation for the successful operation of ACOs. However, in the interest of further promoting the workability of ACOs and the MSSP, Polsinelli offers the following comments.

COMMENTS

1. The use of a provider's primary service area ("PSA") for antitrust market share purposes is overly restrictive. Generally, a seller's trade/service area is not synonymous to the relevant geographic market. Applying the PSA as the relevant geographic market in the proposed enforcement policy may prevent the participation of qualified ACOs who have over a 50 percent PSA market share, but actually maintain a far lower share of a properly defined relevant geographic market. ACOs should be allowed to use other sources of

data and methodologies, when available, to more accurately calculate market shares of common services.

2. Protection under the safety zone described in the proposed enforcement policy should not be limited to collaborative ventures formed after March 23, 2010. Collaborative ventures formed prior to March 23, 2010 should also be given the ability to qualify for such protection. To the extent the Agencies limit rule-of-reason treatment to collaborative ventures formed after March 23, 2010, we request that the Agencies provide clarification on what they mean by the term "formed" and whether this term is limited to the legal formation of an ACO entity.

3. ACOs that include more than one provider of a common service within the same PSA (or relevant geographic market), with a total PSA share over 30 percent, should be included in the safety zone as long as the participation of each of the applicable providers in the ACO is non-exclusive.

4. The proposed enforcement policy provides that the Agencies may revoke the safety zone treatment of an ACO if the ACO's provider composition changes significantly. However, there is no indication of what constitutes a significant change in provider composition. It is quite likely that ACO provider composition will change during the term of its agreement with CMS, resulting in uncertainty whether there has been a loss of safety zone treatment. Polsinelli urges the Agencies to provide guidance regarding the definition or further indicators of a significant change in composition.

5. Further explanation needs to be provided regarding what it means to participate in an ACO on a "non-exclusive basis". Polsinelli urges the Agencies to clarify that applicable non-exclusivity requirements are met as long as the provider maintains, or is open to participating in, at least one material payor relationship negotiated outside of the ACO.

6. For purposes of the rural exception, it is unclear whether the inclusion of a Rural Hospital would include all of the physician employees of such Rural Hospital. Polsinelli urges the Agencies to clarify that an ACO with a Rural Hospital, whose physician employees have a share of a common service that exceeds 30 percent in their PSA, is deemed to meet the rural exception and not be subject to an antitrust review (regardless of the PSA share of the employed physicians).

7. Although CMS has indicated that a primary care physician may only participate in one ACO, the proposed antitrust regulations state that a dominant provider cannot be exclusive to the ACO for the ACO to qualify for the safety zone. We are thus unclear about how we would proceed if one of the potential ACO participants is a group of primary care physicians that has more than a 50 percent share of its PSA. In this situation, the group of primary care physicians would have to be exclusive to the ACO per the CMS proposed regulations and thereby may not qualify for the safety zone under the dominant provider limitation. Accordingly, we propose that a single group of

primary care physicians that collectively has more than 50 percent share in its PSA be allowed to include a portion of its primary care physicians in one ACO and another portion in another ACO. This would ensure that the group of primary care physicians would qualify for the safety zone without having to invoke the dominant provider limitation.

8. In the alternative to our proposal in Comment No. 7, we suggest that the Agencies create an exception to the dominant provider limitation for primary care physicians. As currently drafted, there appears to be an inconsistency between the requirement that a dominant provider must participate in the ACO on a non-exclusive basis and the fact that primary care providers are only allowed to be in one ACO.

9. The Agencies should provide an indication of the types of additional information and data (beyond PSA market share) that will be considered in the antitrust review of ACOs with a PSA share above 50 percent.

10. The Agencies state in the proposed regulations that they will approve or deny an application for antitrust review within 90 days of the application. We request that the Agencies provide guidance about the steps of review to be taken by the Agencies. For example, the Agencies could commit to informing ACOs within 30 of the submission of an application if additional materials are necessary to complete the review, or the Agencies could further break down the 90-day timeline for expedited review. This would allow ACOs to correct any problems with their applications on a timely basis and to be more adequately informed about the ACO antitrust review process.

11. The proposed regulations provide that an ACO subject to mandatory review should submit documents related to the ACO's PSA share calculations and other market information related to all of its PSAs. We request that the Agencies allow ACOs subject to antitrust review to submit information limited to the common PSAs that exceed the 50 percent threshold, instead of information about their entire market or PSA analysis. This will save significant resources to the Agencies and to ACOs, and will facilitate the Agencies' ability to meet the 90-day expedited-review timeline.

12. The proposed regulations provide that "the Agencies will provide rule of reason treatment to an ACO if . . . the ACO uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the [MSSP]." However, some ACOs may decide not to participate in the MSSP due to cost or other concerns. These ACOs, provided that they meet certain safeguards, would also provide competitive and other benefits to consumers and, as a result, should also be given rule of reason treatment by the Agencies. Accordingly, we propose that the Agencies allow an ACO to qualify for rule of reason treatment if it meets safeguards similar to those required by CMS relating to the ACO's governance and leadership structure and clinical integration, even if the ACO chooses not to participate in the MSSP.

13. The Agencies are not currently required to provide ACO applicants with any information regarding the basis for the Agencies' likely challenge of an ACO. Polsinelli urges the Agencies to revise the proposed enforcement policy to require the reviewing agency to explain its decision, so that the ACO can address any applicable concerns.

14. There is currently no indication of the right of an ACO to appeal a letter from the reviewing agency that indicates the agency is likely to challenge the ACO. ACOs should be given a reasonable opportunity to appeal and the enforcement policy should describe the appeal process.

Polsinelli appreciates your attention to this matter and the opportunity to submit the foregoing comments on the Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program. Should you wish to contact Polsinelli regarding any of its comments, please do not hesitate to call Mark Woodbury, at (816)364-2117. Thank you for your consideration.

Sincerely,

POLSINELLI SHUGHART PC