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May 31, 2011

Donald S. Clark, Secretary
Federal Trade Commission
Office of the Secretary
Room H–113 (Annex W)
600 Pennsylvania Avenue, NW.
Washington, DC 20580

The Honorable Christine Varney
Assistant Attorney General
Antitrust Division
U. S. Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

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

Dear Mr. Clark and Ms. Varney,

We appreciate the opportunity the Federal Trade Commission (FTC) and the U.S. Department of Justice Antitrust Division (DOJ) have given interested parties to provide comments on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program ("Proposed Antitrust Statement"), issued on March 31, 2011.[1] The Medicare Shared Savings Program (MSSP), as the antitrust agencies recognize, could have a significant impact on how health care is delivered to patients covered by public and private health insurance plans. As such, it is important that the Proposed Antitrust Statement provide clear guidance and not present any barriers to the formation or operation of accountable care organizations (ACOs).

The Section of Antitrust Law of the American Bar Association has put together comments that we believe merit significant consideration by the FTC and the DOJ. Rather than duplicating the efforts of the Antitrust Section, we have chosen to limit our comments to questions and issues not covered in the Antitrust Section's comments.

[1] 76 Fed. Reg. 21,894 (April 19, 2011).

I. Exemption from CMS Requirements

The Centers for Medicare & Medicaid Services' (CMS) proposed rule, Medicare Shared Savings Program: Accountable Care Organizations ("Proposed ACO Rule"),[2] requires those ACOs with a Primary Service Area (PSA) share of greater than 50 percent for any common service that two or more ACO participants provide to submit to a mandatory antitrust review and, as part of that review, obtain from the reviewing antitrust agency a letter stating that the agency has no present intent to challenge the conduct of the ACO.[3] An ACO is exempt from the §425.5(d)(2)(i) and (ii) requirements, though, if it qualifies for the Rural Exception or "other controlling guidance from the antitrust agencies." We read this provision in the Proposed ACO Rule as allowing the antitrust agencies to create an exemption, which could be done by the antitrust agencies clearly articulating who the ACOs are that should be subject to the mandatory review. By stating in the Proposed Antitrust Statement—the controlling document for the mandatory reviews—that it applies only to "collaborations among otherwise independent providers and provider groups, formed after March 23, 2010, that seek to participate, or have otherwise been approved to participate, in the Shared Savings Program," the antitrust agencies appear to be exercising the exemption right CMS has given them. If, in fact, the antitrust agencies are creating an exemption, they should clearly state that, if the Proposed Antitrust Statement does not apply to an ACO, that ACO, depending on its PSA share, need not comply with §425.5(d)(2)(i)(A) and (B) or §425.5(d)(2)(ii)(A) and (B). If it is not the intent of the antitrust agencies to create an exemption, then an explanation is needed as to why the Proposed Antitrust Statement only applies to those collaborations "formed after March 23, 2010" and how the ACOs to which the Proposed Antitrust Statement does not apply will comply with §425.5(d)(2)(i) or (ii) of the Proposed ACO Rule.

II. Understanding and Verifying "Formed"

Assuming that there is an intent to exempt certain ACOs from compliance with §425.5(d)(2)(i) or (ii) of the Proposed ACO Rule and the requirements of the Proposed Antitrust Statement, it is of utmost importance for ACOs to know whether or not they must comply. The Proposed Antitrust Statement's applicability language is, however, less than clear and leaves open the question as to who is subject to its requirements.

The Proposed Antitrust Statement purports to apply only to ACOs "formed after March 23, 2010." But the word "formed" is not defined, leaving room for debate. Does it mean "incorporated" or "operational" or "actively contracting with health insurance plans and other payors" or something else entirely? Footnote 7 widens the possibilities by modifying the original statement to "formed in whole or in part." We ask that the antitrust agencies clarify what "formed" means. And we respectively suggest that the definition of "formed" be tied to an act or event that involves one or more contemporaneous writings, such as a State's acceptance of

[2] 76 Fed. Reg. 19,528 (Apr. 7, 2011) (to be codified at 42 C.F.R. pt. 425).

[3] *Id.* at §425.5(d)(2).

an ACO's articles of incorporation or the entry of a contract between the ACO and a payor. By ensuring there are contemporaneous written documents, the ACO can readily prove, and CMS or the antitrust agencies can verify, whether the Proposed Antitrust Statement applies—and, presumably, whether it is subject to §425.5(d)(2)(i) or (ii) of the Proposed ACO Rule.

We agree with the Antitrust Section's comment that "it is not apparent that an entity's *formation* before or after March 23, 2010 would be a meaningful indicator of its antitrust character or likely impact on the marketplace." If the antitrust agencies, in responding to this comment and others, choose to adopt a different standard than "formed after March 23, 2010" for applicability of the Proposed Antitrust Statement, we suggest that the standard be one which ACOs can easily prove and the antitrust agencies and CMS can readily verify. We make this request because it is likely that, as part of the CMS application process, ACOs will need to show either compliance with, or exemption from, the Proposed Antitrust Statement.

III. Treatment of Merged Entities

By defining ACOs to whom the Proposed Antitrust Statement applies as "collaborations among otherwise independent providers and provider groups," the antitrust agencies make clear that the Proposed Antitrust Statement does not apply to an ACO that is an integrated physician practice group or a hospital and its employed physicians. But after providing such clarity, the antitrust agencies then state, "Merger transactions…will be evaluated under the Agencies' *Horizontal Merger Guidelines*." There is no explanation of when, or why, ACOs formed through mergers will be evaluated; simply a statement of how.

Both the Proposed ACO Rule and the Proposed Antitrust Statement explain that an antitrust review is mandated only for ACOs whose PSA share exceeds "50 percent for any common service that <u>two or more independent ACO participants</u> provide to patients."[4] The underlined text makes clear that, if an ACO is an integrated entity that has no independent participants (i.e., a physician group practice or a hospital and its employed physicians), the ACO will not be subject to a mandatory antitrust review, regardless of its PSA share(s). Are we to assume, then, that merged entity ACOs will not be subject to an antitrust review unless the merger is subject to reporting under the Hart-Scott-Rodino Act (a rare occurrence in physician practice mergers and acquisitions) or someone complains to the antitrust agencies? If that is truly the case, the antitrust agencies seem to have set a double standard, particularly if, as the antitrust agencies state, "The key issue is whether the ACO, on balance, will provide consumers with high-quality, cost-effective health care or, instead, increase price and reduce consumer choice and value."

[4] §425.5(d)(2)(i); Proposed Antitrust Statement, *supra* note 1, at 21,897 (emphasis added).

IV. The Five "No-Nos"

In an effort to help ACOs "reduce significantly the likelihood of an antitrust investigation," the antitrust agencies created a list of five types of conduct that they recommend ACOs avoid. This list could be viewed merely as helpful guidance if it were not given greater significance by CMS stating in §425.5(d)(2)(ii) of the Proposed ACO Rule that, unless it qualifies for an exception, "an ACO with a PSA share…greater than 30 percent and less than or equal to 50 percent may do one[5] of the following: … (C) Begin to operate and abide by a list of conduct restrictions, reducing significantly the likelihood of antitrust concern."[6] Thus, readers are given the misimpression that the five types of conduct are anticompetitive, even if the ACO does not have sufficiently high PSA shares to warrant agency review for market power concerns.[7]

Types 1 through 4 on the list, though, are unlikely to restrain competition if the ACO does not have market power and, in fact, may be procompetitive. Conduct type 1—preventing or discouraging commercial payers from directing or incentivizing patients to choose certain providers—provides a good example. An ACO may be able to offer a payor a better price for the ACO participants' services if the ACO has a guaranteed volume of patients, which it will only have if the payor directs, or incentivizes, patients to use the ACO providers (and directs or incentivizes patients not to choose non-ACO providers). In addition, an ACO that obtains steering or tiered co-pay provisions from a payor will be more likely to achieve the efficiencies of its collaboration and integration. The FTC staff recognized this in its letter to TriState Health Partners:

> One potential area of concern regarding the [TriState clinical integration] program's ability to provide integrated care and achieve potential efficiencies, which you acknowledge, is the possibility of "leakage" of patients to non-TriState providers where a contracting employer or other payer allows enrollees to seek care out of network – for example by separately contracting for additional access to a broader network, such as InforMed's Community Health Partners network.[40] In addition to

[5] We note that CMS likely meant "one or more" because an ACO cannot exercise option B unless it has first exercised option A, and Section 425.5(d)(2)(iv)(A) makes clear that if an ACO exercises option A and receives a negative letter (eliminating option B), the ACO is ineligible to participate in the MSSP.

[6] §425.5(d)(2)(ii) (*emphasis added*).

[7] We concede that Type 5—sharing competitively sensitive pricing and other data—is conduct that is best avoided, regardless of an ACO's market share. We note, though, that there is a difference between sharing the individual participant's competitively sensitive information and sharing the ACO's competitively sensitive information. With the exception of quality information, there is rarely a justification for sharing the former information, but there is some necessity for the sharing of the latter information. For example, ACO participants will need to know the prices the ACO has negotiated on their behalf so that they can ensure they are charging and/or collecting the proper amounts. So long as an ACO takes steps to prevent spillover collusion, the ACO is unlikely to facilitate anticompetitive conduct by sharing among its participants the competitive terms of the ACO's contracts.

> removing patients from TriState's integrated care systems, this may create gaps in the information available to TriState regarding the patients' treatment and health status. These types of potential gaps in care coordination and information for the proposed program, while perhaps unavoidable, nevertheless could prove to be problematic for TriState in achieving its integration and efficiency goals.

Similar examples can be given for conduct types 2, 3, and 4. Thus, we encourage the antitrust agencies to reconsider whether they truly want ACOs to avoid all five types of conduct. At the very least, the antitrust agencies should acknowledge that conduct types 1 through 4 may be procompetitive.

The antitrust agencies should consider carefully how this list, and the conduct thereon, can be taken out of context and used by inappropriately by payors and plaintiffs. Although the Proposed Antitrust Statement would not have the force of law, like the 1996 Statements of Antitrust Enforcement Policy in Healthcare the Proposed Antitrust Statement will be used by courts and antitrust enforcers in analyzing health care providers conduct. Complainants and plaintiffs could significantly reduce the potential for health care provider collaborations to achieve procompetitive efficiencies if they use the antitrust agencies' "no-no list" to prevent ACOs from engaging ancillary restraints with procompetitive justifications.

V. Conclusion

The importance of ACOs and the MSSP cannot be overstated. The antitrust agencies perceive, and our clients have confirmed, that there remains a great deal of uncertainty and significant barriers to the development of ACOs to participate in the MSSP. Anything the antitrust agencies can do to alleviate the uncertainty and reduce the barriers will improve the likelihood of health care providers forming ACOs.

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