Submitted Electronically

May 26, 2011

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, N.W.
Washington, DC 20580

Re: **PROPOSED STATEMENT OF ANTITRUST ENFORCEMENT POLICY REGARDING ACOs PARTICIPATING IN THE MEDICARE SHARED SAVINGS PROGRAM, MATTER V1000017**

Dear Assistant Attorney General Varney and Commissioner Leibowitz:

On behalf of VHA Inc. (VHA), I am writing to provide comments on the Proposed Statement of Antitrust Enforcement Policy published by the Federal Trade Commission and the U.S. Department of Justice, Antitrust Division (collectively, "the Agencies"), in the April 19, 2011, *Federal Register* (the "Proposed Statement").

Founded in 1977, VHA is dedicated to the success of nonprofit, community-based health care. Based in Irving, Texas, VHA is a national health care network that serves more than 1,400 not-for-profit hospitals and more than 23,000 non-acute health care organizations nationwide. VHA helps its members deliver safe, effective, and cost-efficient health care through both national and local support. VHA has 16 regional offices covering 47 states, as well as an office in Washington, D.C.

VHA has been actively involved in the development of the "accountable care organization" (ACO) concept. VHA appreciates the agencies' efforts, to provide guidance on the application of antitrust laws to ACOs formed in connection with the Medicare Shared Savings Program (MSSP). Recognizing the importance of ensuring that ACO arrangements are used to provide the highest quality health care at the lowest possible cost but not to thwart competition is important to ensure the success of the program.

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While the Proposed Statement goes a considerable distance in achieving this objective, VHA believes that there are a number of modifications and clarifications that would improve the Proposed Statement and would significantly increase the likelihood that the MSSP will achieve its principal goals: "better health, better care, and lower cost."

Proposed "Safety Zones"

The Proposed Statement sets forth parameters of safety zones and required filings for three different market share zones: 0 to 30 percent; 30 to 50 percent; above 50 percent of the "same service" or a "common service." An ACO will have a difficult time calculating its share of the market in any primary service area (PSA) for a number of reasons. Specifically, hospitals will need to await the publication of the total Medicare same or common service data for every PSA, then calculate its total Medicare allowed charges for claims billed in those services for the identical time period and then extrapolate or speculate as to whether any increase or decrease in the ACO's business in future known periods make any difference. Second, it is not at all plain how and why these particular market share zones were determined. In other health care contexts, 35 percent market share is the benchmark used for certain joint activity as a "safe harbor." Third, using contiguous zip codes drawing at least 75 percent of patients is a new way to define a geographic market for antitrust purposes and is a measurement tool fraught with problems. Patients regularly seek health care services several zip codes away from their homes and closer to where they work.

Finally, the Proposed Statement requires antitrust review for the entire ACO if only one or a few common services exceed 50 percent. That will impose an expensive and time consuming burden on an ACO if there is only one or few small fee generating common services in which 50 percent threshold is reached. An ACO will likely not provide that particular service or will be unlikely to spend the time and money to participate in the Medicare Shared Savings Program at all in such circumstances.

While VHA appreciates the guidance offered under the Proposed Statement in establishing the safety zones, we remain concerned about the validity of the calculations used to determine PSAs and recommend the agencies consider a different measurement that more accurately reflects market share. If PSAs are determined to be the best method of determining competitiveness in the health care marketplace, VHA suggests increasing the safety zone threshold to no less than 35 percent.

Hospital Exclusivity

The Proposed Statement includes a statement that "[a]ny 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 [market] share." Such a judgment does not make sense at the 30 or less percent

safety zone. Exclusivity arrangements have long been an appropriate part of relationships created in response to managed care, and there is no reason to treat hospitals and ambulatory surgery centers differently than physicians and other providers for ACO antitrust review purposes.

Timing of Antitrust Review

The Proposed Statement includes a statement that the antitrust review will be completed within 90 days after information is submitted. Nothing requires the agencies to comply with this deadline or be stopped from taking action or a position if they miss the deadline. And nothing prevents the agencies from seeking more and additional information or stating that the information provided is insufficient or not in compliance and thus extends the process. Since the purpose of the statute and regulations is to encourage ACOs, the regulations should allow ACOs to go forward if the agencies do not complete their review within 90 days. Further, strict limits should be placed on the agencies' ability to seek additional information, which could cause delays in the process. Providers will be discouraged from joining or forming ACOs if this type of certainty and timeliness are not mandated.

Expansion of Guidance for Providers

The Proposed Statement is helpful in that it confirms that Medicare ACOs will be reviewed using "rule of reason" analysis, which requires balancing an arrangement's anticompetitive risks against its precompetitive potential benefits. However, providers would benefit significantly if the Proposed Statement were expanded to include additional guidance about how that analysis will be applied in the ACO context as well as in reviewing the creation and operation of other clinically-integrated care delivery arrangements.

The hospital sector in particular has needed additional guidance on clinical integration from the agencies for some time. In 1996 the agencies issued the Statements of Antitrust Enforcement Policy in Healthcare, which recognized the importance of clinical integration in reviewing collaborative arrangements among health care providers. Since then, numerous stakeholders—including hospitals, members of Congress and others—have called upon the agencies to provide additional guidance in this arena, to date without success.

In general, hospitals and other providers considering taking part in the MSSP are seeking certainty about the potential legal and financial risks they face in participating in the MSSP. The agencies can help ease those concerns by providing additional guidance indicating how the agencies will apply "rule of reason" analysis to the creation and operation of ACOs in the MSSP as well as to other similar clinically-integrated organizations.

Conclusion

On behalf of VHA, I would like to thank the agencies for providing us this opportunity to comment on the Proposed Statement. We look forward to working with the agencies to help create a strong foundation through which providers can deliver integrated, coordinated, high-quality care. Please feel free to contact me at (202) 354-2607 if you have any questions or if VHA can provide any assistance as you consider these issues.

Sincerely,

Edward N. Goodman
Vice President, Public Policy