Minnesota Hospital Association

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May 31, 2011

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

The Hon. Jon Leibowitz
Chairman
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, DC 20580

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

Dear Assistant Attorney General Varney and Commissioner Leibowitz:

On behalf of the Minnesota Hospital Association (MHA), which represents 148 hospitals and 17 health systems located throughout Minnesota, we are providing comments in response to the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Proposed Statement). At the outset, we want to express our support for the positions taken and suggestions made in the American Hospital Association's (AHA) comment letter regarding this Proposed Statement. We offer the following comments to emphasize issues or concerns that are of particular importance to Minnesota's health care providers, as well as to amplify those raised by AHA.

Minnesota's health care system relies heavily upon clinically and financially integrated nonprofit health care delivery systems to provide high-quality, low-cost care to our residents. Some of these nonprofits are extremely large, complex organizations with an array of services, research and education functions, some include hospital-clinic-health plan structures, and others are relatively small critical access hospitals with attached nursing homes and local clinics. Throughout Minnesota, hospitals, physicians and other providers have already moved faster to clinical and financial integration models than most of the country. Therefore, we appreciate your agencies' recognition of the importance of integrated health organizations, like those in Minnesota and like the concept of ACOs proposed by the Centers for Medicare and Medicaid Services (CMS) Shared Savings Program.

Because Minnesota's health care providers compete in a delivery market that is more integrated than those in many other areas of the country, it is particularly important to our members that antitrust enforcement policy avoid creating new confusion for integrated providers, including those that do not participate in the Medicare Shared Savings Program. In other words, as the federal government strives to create the regulatory framework necessary to protect consumers, competitive markets and the evolution of ACOs, we encourage you to avoid enforcement policies that could bleed over and create new or confusing standards for existing providers operating in today's competitive marketplace.

MHA supports the development of ACOs, as well as other payment models that shift health care financing away from volume-of-care-provided incentives to high-quality-at-lower-cost incentives. MHA believes that rewarding providers for delivering high quality care as efficiently as possible better aligns patients', payers' and providers' interests. Unlike other payment methodologies, ACO models attempt to build in accompanying incentives for providers to address population health as well.

To successfully play their role in helping to achieve these public policy goals, health care providers need to understand the organizational structures and market activities that are permissible, as well as the legal and regulatory lines they cannot cross. Because implementing ACOs and other payment reforms will be accompanied by significant upfront costs for providers, it is even more important for them to understand these regulatory boundaries ahead of time. Even as Minnesota's highly integrated provider systems have adapted and grown over the years, surprising changes to antitrust regulations or interpretations have resulted in added confusion, cost and hardship for providers. Accordingly, MHA hopes that the Department of Justice (DOJ) and Federal Trade Commission (FTC) will make revisions to the Proposed Statement to improve the likelihood that ACOs will form and succeed, and to assure existing integrated provider systems with clear guidelines and expectations.

As AHA noted in its letter, MHA is concerned that the Proposed Statement will unnecessarily impede health care providers' formation of and participation in ACOs under the Medicare ACO Shared Savings Program. Moreover, because we believe the fundamental changes to health care must extend beyond the Medicare population, we are concerned that the Proposed Statement leaves ambiguity and confusion in the non-Medicare marketplace. Of course, if there is ambiguity and confusion in antitrust enforcement policy, the likelihood of enthusiastic adoption of ACO structures, innovation and clinical integration will be squelched.

Consequently, MHA echoes AHA's recommendation that the DOJ and the FTC issue a new, revised Proposed Statement that contains guidance that is user-friendly, easy to understand, and as specific and reliable as possible so that providers can understand clearly how enforcement agencies will analyze ACOs under the rule-of-reason. Moreover, we suggest making this new Proposed Statement as all-encompassing as possible rather than limiting it only to participants in the Medicare Shared Savings Program.

The current version of the Proposed Statement proposes to establish a process through which participants in the Medicare Shared Savings Program can or must obtain guidance relative to antitrust laws. Acknowledging the potential benefit of such guidance, MHA is concerned that the proposed process could end up being too narrow in scope, too late in ACO development, and too punitive in appearance.

First, providers would not begin the process to receive guidance until they have already formed an ACO and applied to Medicare for certification. In other words, they will have gone through the effort, expense and potentially anti-competitive negotiations before being able to benefit from any guidance. Meanwhile, other provider groups interested in other forms of ACOs or clinical integration will not be able to seek any guidance. And, ultimately, because the process is set up in a manner that suggests that providers in the guidance process tripped an antitrust alarm clouds the process with the appearance of an investigation or leading to punishment.

Instead, MHA suggests creating a more open, expedited and user-friendly process for providers interested in participating in the Shared Savings Program, as well as for those who do not intend to be part of the program but would like to pursue other forms of clinical integration. Recognizing that agencies have capacity limits and other restrictions they must be mindful of, MHA would hope to see a different kind of system in which providers could submit preliminary information about proposed ACO arrangements or structures and receive guidance that could be relied upon when bringing those proposed ACOs into action. This kind of process would give providers more certainty about what will be acceptable before spending the time and resources, and without unintentionally crossing antitrust lines. In short, we hope that a new Proposed Statement will include a more open, inviting, streamlined and user-friendly opportunity for interested providers to get guidance about how to successfully move into clinical integration and ACO arrangements.

MHA supports the decision to apply the rule-of-reason standard for Medicare ACOs contained in the Proposed Statement. This standard appropriately allows enforcement agencies to balance pro-competitive potential against anti-competitive risk. However, this rule-of-reason standard is ambiguous and unreliable for providers without further guidance from the agencies about how they will apply that analysis. The proposed Shared Savings Program is an opportunity for your agencies to provide guidance in the ACO context to help ensure that the health care community knows and can accurately predict how different integration or shared savings arrangements will fare when the rule-of-reason analysis is completed.

At this level of financial investment, care redesign expense and potentially initial collaboration among various stakeholders, it is reasonable to expect that antitrust issues are not relegated to speculation and hoping for the best. Instead, those attempting in good faith to comply with all of the laws and create new, innovative models should be able to discern with a high degree of certainty whether their approach will be acceptable under the rule-of-reason test or whether it will run afoul of that test.

MHA is concerned about the Proposed Statement's reliance on a new, complicated, unwieldy and seemingly arbitrary formula for determining the shares of each prospective ACO participant in its Primary Service Area (PSA). PSA is defined as the lowest number of contiguous zip codes from which the provider draws at least 75 percent of its patients. The Proposed Statement would require that shares be calculated for *each* common service to be provided by *each* participating hospital and doctor within *each* provider's PSA.

As AHA articulated in its letter, this formula will be extremely burdensome and costly to calculate, especially when larger health systems are involved. The formula becomes even more difficult to apply when the commercially insured population participates in an ACO. In Minnesota, the Medicare fee-for-service population is a relatively small portion of hospitals' and health systems' overall patient mix. Thus, basing any antitrust determination on this small pool of people will not provide an accurate assessment of the given market.

As a suggestion for the new Proposed Statement or the final statement, the DOJ and FTC could allow potential ACOs to use alternative calculation methods or placeholders, such as the number of physicians participating in the ACO v. the number in the community. Other options that provide a solid basis for assessing the general market factors could be included so there are easier, quicker and cheaper alternatives

Also, MHA opposes the suggestion to require mandatory reviews of ACO applicants with a PSA score above fifty percent. Assuming an ACO applicant is able to navigate the formula for each participating provider, any PSA score above fifty percent will be subject to a mandatory review by an antitrust agency. Apparently, this mandatory review will not be limited to the particular service line or provider that exceeds fifty percent, but rather could include the entire organization.

Any mandatory review will require a would-be ACO to assemble a large number of documents and then spend a considerable amount of resources on analysis, legal fees, and other expenses to defend its ACO application. This burden adds to the ultimate cost of ACO application and makes the Shared Savings Program less attractive to our members. As AHA noted, all of this analysis, expense and bureaucratic effort seems wasteful and unnecessary when the providers do not negotiate their prices with Medicare, but rather accept the payments determined by CMS.

This concern seems particularly misplaced because the application at issue would be to participate in the Medicare ACO program, a program in which there is no price competition, as the terms, conditions and reimbursement provided are dictated solely by a federal agency. Thus, MHA respectfully requests that your agencies abandon the mandatory review component of the Proposed Statement and, instead, provide more clear guidance as to what does or does not constitute antitrust behavior within the ACO environment.

On the other end of the equation, MHA appreciates the agencies attempting to establish safe harbors or safety zones for providers. The standard for staying within that safety zone – thirty percent or less – is too low, however. It is not uncommon for a hospital or health system to have

more than thirty percent of a particular service line and, in many of those situations, that organization should be able to benefit from the safety zone. In Minnesota, for example, there are a limited number of providers that offer Level 1 trauma centers, burn units, transplants, etc. Yet, those facilities offering such services should not be precluded from the certainty of the safety zone merely because they provide these important, and often costly, services to meet public needs that might otherwise go unfilled.

Likewise, MHA regards the proposed rural exception to be too narrowly constructed. If the federal government holds any hope of getting rural providers to participate in ACOs, either through the Shared Savings Program or other payment reform methodologies yet to be explored, then the DOJ and FTC will need to allow them to collaborate and clinically integrate with the understanding that competitive forces existing in more populated areas simply do not exist in rural communities.

This is an important concern for Minnesota's hospitals and health systems because a large portion of our population lives in rural communities. More than fifty percent of our hospitals participate in the critical access hospital program in order to ensure that our residents can receive the care they need within a reasonable period of time. Although few of our rural hospitals or health systems appear likely to participate in the Shared Savings Program because of its other limitations, many hope to participate in future ACO models. Therefore, guidance from your agencies granting waivers, exceptions or reasonable and practical safety zones for providers in markets with volumes too low to support meaningful competition would be very helpful.

Finally, MHA encourages the DOJ and FTC to provide as much latitude and flexibility as possible during this initial period of ACO development and innovation. Both public programs, including Medicare and Medicaid, and commercial payers will explore ACO models through the Shared Savings Program, Medicaid demonstrations, critical access hospital demonstrations, and private sector contracting.

While MHA understands and appreciates your agencies' roles in protecting against undue market force within a competitive industry like health care, we also recognize the urgent need to reorganize and restructure the way health care is paid for and provided. Meeting that challenge inherently requires regulatory flexibility. Otherwise, the health care community will be responding to calls for reform and reinvention while simultaneously being held to historical regulatory boundaries established and interpreted for traditional health care systems.

The Proposed Statement is an important and commendable first step toward the guidance and flexibility the health care community needs to move meaningful health care reform, including ACOs, forward. An important next step is for the DOJ and FTC to issue another Proposed Statement that includes more practical guidance for health care providers to confidently determine whether their particular ACO structures will fall within the scope of acceptable and lawful practices. We respectfully suggest that the second Proposed Statement include a new process through which providers can obtain timely advice from the agencies in case further clarification of the rule-of-reason analysis or safety zone application.

Minnesota's hospitals and health systems remain optimistic that the Shared Savings Program, upcoming ACO demonstrations and models, and other payment reform methodologies can be successfully implemented without jeopardizing the public policy goals underlying the antitrust laws. Your agencies have made significant progress toward that end and we hope that you will continue your efforts to provide the guidance, clarity and flexibility necessary.

Again, MHA is grateful for the opportunity to share these suggestions and comments with you. If you have any questions or concerns about our comments or suggestions, please feel free to contact me anytime.

Sincerely,

Matthew L. Anderson, J.D.
Vice President, Regulatory/Strategic Affairs