HAP

THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

May 31, 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 V100017

Dear Assistant Attorney General Varney and Commissioner Leibowitz:

On behalf of The Hospital & Healthsystem Association of Pennsylvania (HAP), which represents approximately 250 member institutions, including 125 stand-alone hospitals and another 120 hospitals that comprise 32 health systems across the Commonwealth of Pennsylvania, HAP appreciates the opportunity to respond to the Proposed Statement of Antitrust Enforcement Policy (Statement) regarding Accountable Care Organizations (ACO) participating in the Medicare Shared Savings Program (MSSP).

HAP recognizes the value of establishing ACOs as a means to improve the coordination of care for patients across the health care continuum, enhance the quality of the services for consumers, and achieve greater efficiencies for all patients— not just Medicare beneficiaries. HAP appreciates the collaboration between the Federal Trade Commission, the Department of Justice, and the Centers for Medicare & Medicaid Services (CMS) in the development of a proposal for ACOs as it is critical that waivers be established for ACOs, along with antitrust protections. HAP is pleased with the fact that the Statement applies the rule-of-reason as the standard by which Medicare ACOs would be reviewed by the antitrust agencies, as it balances pro-competitive potential against anti-competitive risk. Nonetheless, HAP has serious concerns that the Statement presents an unnecessary barrier to participation in the MSSP and does not provide the guidance necessary to spur adoption, of and continued innovation in, clinical integration beyond the Medicare program. In addition, HAP believes that in order for a Medicare ACO to be most successful, it is important to allow for the exclusivity of hospitals in the model.

4750 Lindle Road
P.O. Box 8600
Harrisburg, PA 17105-8600
717.564.9200 Phone
717.561.5334 Fax
haponline.org

Exclusivity will likely be an important tool to ensure that a Medicare ACO is able to meet the quality reporting and health information technology meaningful use requirements, among others, in the CMS rule.

HAP's comments focus on the following aspects of the proposed Statement: reasons why the Statement needs to be revised, a recommendation that the proposed formulas be abandoned, the elimination of the mandatory review for the Medicare ACO program, and allowance of exclusivity for ACO participants.

The Need for Revision

HAP agrees with the American Hospital Association (AHA) that the guidance in the proposed policy Statement should be changed. HAP believes that in order for the Medicare ACO program to achieve its ambitious goal of helping to transform the way in which health care is paid for and delivered to benefit patients and communities, the antitrust agencies must make fundamental changes in their approach. Unfortunately in its current form, the Statement will serve as a significant barrier to participation in the Medicare ACO program and will not provide the guidance needed to promote continued work toward the development of a clinically integrated health care delivery system beyond the Medicare program, which is critical for the success of achieving health reform.

Therefore, HAP joins the (AHA) in urging substantial revisions to the Statement. HAP suggests the establishment of clean and user-friendly guidance on how the agencies will analyze, under the rule-of-reason, clinically integrated organizations, to avoid or minimize antitrust risk with the opportunity for comment by all of those affected. Guidance from the agencies on how any analysis would be applied would assist hospitals and other providers in forming and operating such clinically integrated organizations. Also, any specific approval should not be a prerequisite for participation in the Medicare ACO program; instead, the agencies should continue to respond to concerns as they arise in the marketplace.

Abandon the Proposed Formulas

The Statement proposes a new, untested formula to determine the market shares of each prospective ACO participant in its "Primary Service Area" (PSA), which HAP finds problematic. This formula is critical as the Statement sets it as the basis for determining whether as ACO meets the "safety zone" and whether certain ACOs must specific FTC or DOJ approval prior to participating in the MSSP.

Market shares must be calculated for *each* common service to be provided by *each* participating hospital and doctor (or group of doctors) within *each* provider's PSA. PSA is defined as the lowest number of contiguous zip codes from which the provider draws at least 75 percent of its patients.

This untested method of analysis would be expensive, extremely complicated, and would be quite burdensome. Specific concerns as outlined by the AHA, and supported by HAP, are as follows:

- Calculating PSA shares on the basis of Medicare fee-for-service data is likely to be unreliable, and will likely be unavailable for any service or medical specialty that does not routinely provide services to Medicare patients, such as obstetrics, pediatrics, burn units and HIV services, for example. The data also will overstate the market shares of providers who care for large numbers of Medicare patients and understate the shares of those who restrict their practices to commercially-insured patients. Even where Medicare fee-for-service data might be available, it will be extremely difficult for physicians to pull zip code data and match it with billing records to obtain the services provided.
- Calculating PSA shares on the basis of contiguous zip codes likely will be burdensome and costly, and require substantial judgment calls.
- The "Stark" law requires that compensation for health care providers be fixed in advance and paid only for hours worked. The Stark law could be implicated if a hospital compensates physicians by organizing and paying for the costly analysis required to determine physician PSA shares. There is no indication in the notice issued by CMS and the Office of Inspector General on waivers in connection with the Medicare ACO program or that a waiver for such activities and expenses is being considered.
- The formula appears to be incongruous with the traditional rule of reason analysis, which typically does not define a market in the manner described in the formula, nor does it typically allow concerns over one minor service dictate the result, when there is no concern over the vast majority of services.

In light of these concerns, HAP strongly suggests that an alternative formula be established. In the event that the agencies decide to implement this proposed method, then CMS should provide the necessary data to potential Medicare ACOs as a way of minimizing the burden and cost of conducting the analysis independently.

Eliminate a Mandatory Review Requirement

Although HAP understands the importance of ensuring that ACOs do not pose an anti-competitive risk that could have potential negative impacts on consumer choice and/or access to health care services, **HAP disagrees with the agencies' proposal for a mandatory review of any prospective Medicare ACO applicant** that receives a PSA score of 50 percent or above for any service or specialty. It seems unreasonable that a mandatory review would be required even if the PSA score is for a non-Medicare service, such as pediatrics, and even if the ACO applicant's PSA share is well below 50 percent for the vast majority of services provided. Furthermore, there is no negotiation of rates in the Medicare fee-for-service program, so the anti-competitive risks associated with rate setting are virtually non-existent.

The proposed approach inappropriately delegates to the antitrust agencies the authority to determine which prospective ACO will be permitted to apply for the Medicare ACO program based on concerns about whether the ACO could impact price competition in the private sector. 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.

Mandatory review is not confined to the specific service(s) over 50 percent, but will subject the entire Medicare ACO applicant to antitrust scrutiny. Practically, this means that a prospective applicant with even a single PSA above 50 percent would need to: (1) submit a large number of documents (that do not overlap with those required by other agencies); and (2) obtain a time-consuming and expensive antitrust analysis from an antitrust practitioner, to be prepared to defend its ACO application before one of the agencies. HAP believes that many ACOs will voluntarily seek an antitrust review by the agencies. It would be beneficial if the antitrust agencies could develop a truly streamlined process (90 days or less) that *allows* prospective Medicare ACO applicants to obtain antitrust guidance at the same time CMS is reviewing the application, but does not mandate such a review. Such a process also would aid other clinically integrated organizations.

ACO Exclusivity Should be Allowed

As mentioned above, HAP believes that it is important for ACO participants to be able to establish an exclusive arrangement with an ACO, and that they should not be required to contract with other ACOs in order to qualify for the safety zone.

Exclusivity is an important aspect of an ACO as it would assist the ACO in ensuring that all its participants are aligned with the ACO's quality and financial performance goals. HAP suggests that the safety zone proposed by the agencies at 30 percent or less is too low and should be increased to at least 35 percent. **The promise of a safety zone is seriously compromised if it is too low and exclusivity is not permitted.**

Other Concerns That Should be Addressed

As raised by the AHA and supported by HAP, there are other concerns about the Statements that should be addressed:

- The indicia of "clinical integration" included in the CMS rule and relied on by the antitrust agencies is overly prescriptive and unnecessary. This includes, for example, a "leadership and management structure" that anticipates a formal governing body where "ACO participants hold at least 75 percent control." The antitrust agencies should specify which criteria are related to antitrust issues and applicable to clinically integrated health care organizations.
- The rural exception is too narrow. Having a larger share of non-hospital providers where necessary should be allowed under the exception if the providers are nonexclusive (available to work with others).

HAP appreciates the collaboration among the agencies that was required to develop the proposed Statement. HAP trusts that the spirit of collaboration will continue as the agencies work to make modifications to the Statement. It is critical that the agencies work together to remove the unnecessary barriers to Medicare ACO formation and operation, and to encourage the health care industry to move toward true health care delivery system reform. HAP hopes the antitrust agencies will take this opportunity to revise the Statement and provide more meaningful guidance and a streamlined and voluntary process to obtain advice from the agencies. HAP looks forward to working with the agencies to make the Medicare ACO program a success and to lay a stronger foundation for other clinically integrated arrangements to flourish.

If you have any questions, please feel free to contact me at (717) 561-5344; Lynn Leighton, vice president, health services, at (717) 561-5308; or Pamela Clarke, vice president, healthcare finance and managed care, at (215) 575-3755.

Sincerely,

PAULA A. BUSSARD
Senior Vice President
Policy & Regulatory Services