May 31, 2011

Via Electronic and Overnight Mail

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

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

Dear Mr. Clark:

The American Health Care Association ("AHCA") and the Alliance for Quality Nursing Home Care (the "Alliance") appreciate the opportunity to comment on the Proposed Statement, "Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program," 76 *Fed. Reg.* 21894 (April 19, 2011) ("Proposed Statement"), proposing an enforcement policy regarding the application of the antitrust laws to health care collaborations that seek to participate, or have otherwise been approved to participate, as accountable care organizations ("ACOs") under the Medicare Shared Savings Program ("MSSP"), Section 3022 of the *Patient Protection and Affordable Care Act* (Public Law 111-48) and *Health Care and Education Reconciliation Act of 2010* (Public Law 111-52).

Collectively, AHCA and the Alliance represent more than 11,000 non-profit and proprietary facilities which deliver the professional, compassionate, and quality long term and post-acute care that more than 1.5 million American seniors and individuals with disabilities rely on each day. Indeed, AHCA and the Alliance represent a majority of the skilled nursing facilities ("SNFs") in the United States.

We fully understand the impetus for the *Affordable Care Act's ("ACA's")* provisions addressing the delivery of health care, the payment for health care, and the quality of health care. The *ACA's* MSSP, which promotes the formation and operation of ACOs, attempts to encourage physicians, hospitals, and other health care providers to become accountable for a specific Medicare patient population through integrated health care delivery systems. ACOs hold the promise of reducing unnecessary diagnostic tests and procedures, dangerous drug interactions, and unnecessary drug treatments; facilitating access to needed care; and ensuring effective communication among all members of the patient's clinical team. However, in order to promote the success of ACOs, skilled nursing facilities ("SNFs") and

other post-acute care facilities must contribute to and participate in ACOs. The robust inclusion of SNFs and other post-acute care facilities in ACOs would provide a significant benefit to Medicare beneficiaries and the MSSP. For example, SNFs and post-acute care facilities are integral to a seamless and effective care continuum and successful care transitions for post-acute patients transitioning back into the community.

AHCA and the Alliance agree with the Federal Trade Commission's ("FTC's") and Department of Justice's ("DOJ's") (collectively, the "Agencies'") assertion that while ACOs may generate opportunities for health care providers to innovate and achieve benefits for Medicare beneficiaries and other consumers, not all such ACOs are likely to benefit consumers, and under certain conditions, an ACO could reduce competition and harm consumers through higher prices or lower quality care. Therefore, AHCA and the Alliance concur that the antitrust analysis of ACO applicants to the MSSP must ensure that ACOs have an opportunity to achieve substantial efficiencies, but must be sufficiently rigorous to protect both Medicare beneficiaries and commercially insured patients from potential anticompetitive harm. While AHCA and the Alliance agree with the Agencies' goals in developing the Proposed Statement, and appreciate the Agencies' efforts at clarifying antitrust treatment of ACOs, it has concerns regarding the Proposed Statement, which are articulated below.

Implications of Mandatory Screening

Under the Proposed Statement, there is a mandatory antitrust agency review for ACOs that exceed 50 percent of the PSA share threshold. This mandatory screening will likely require that providers that desire to participate in the MSSP expend a fair amount of money and time in order to develop an accurate assessment of the ACO's market share. The mandatory screening and associated, necessary assessment of an ACO's market share would become another burden for many ACOs, creating a further disincentive for providers to participate in the MSSP. AHCA and the Alliance would recommend that the Agencies consider some sort of pre-screening process which would allow an ACO applicant and the Agencies to efficiently determine whether there is a need to conduct a PSA analysis given the market realities of a particular ACO.

Proposed Statement's Application to SNFs and Other Post-Acute Care Facilities

AHCA and the Alliance request that the Agencies provide further guidance and more information on how SNFs' and other post-acute care providers' participation in an ACO would impact the antitrust analysis. For example, the Proposed Statement provides examples for how an ACO's PSA shares would be calculated for physician groups, hospitals, and ambulatory surgery centers, but does not provide an example for how an ACO's PSA shares would be calculated for a SNF or other post-acute care facility. Because it is expected that many ACOs will involve SNFs and other post-acute care facilities in some capacity, whether as an ACO participant, ACO provider, an advisory board member, or community stakeholder, additional antitrust guidance would provide much needed direction to ACOs.

Clarification on the Agencies' Interpretation of Non-Exclusivity Requirement

The Centers for Centers for Medicare & Medicaid Services' ("CMS"") proposed MSSP rule, 42 C.F.R. § 425.5(c)(3) states that "ACO participant TINs upon which beneficiary assignment is not dependent are required to commit to a 3-year agreement to the ACO, ***and the ACO participant must not be required to be exclusive to a single ACO.***"[1] The Proposed Statement states:

> Any 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 PSA share. In a non-exclusive ACO, a hospital or ASC is allowed to contract individually or affiliate with other ACOs or commercial payers. The safety zone for physician and other provider services (regardless of whether the physicians or other providers are hospital employees) does not differ based on whether the physicians or other providers are exclusive or nonexclusive to the ACO, unless they fall within the rural exception or dominant provider limitation described below.

How does the Proposed Statement's language, mentioned above, correspond to the proposed MSSP rule's language stating "***the ACO participant must not be required to be exclusive to a single ACO***?" For purposes of antitrust enforcement, how will the Agencies interpret "not be required?"

Limitations of the Proposed Statement

The Proposed Statement stipulates that the Agencies' favorable treatment of ACOs applies only to ACOs participating in the MSSP. Thus, antitrust enforcement actions are a viable threat for any ACO contracting with private payors that is not eligible for participation in the MSSP or at any point fails to meet the requirements of or is terminated from the MSSP.

The Pioneer ACO request for applications issued by the Center for Medicare and Medicaid Innovation on May 17, 2011 highlights the aforementioned issue because a key component of the Pioneer ACO model is the requirement that the Pioneer ACO "commit to entering outcomes-based contracts with other purchasers (private health plans, state Medicaid agencies, and/or self-insured employers) such that the majority of the ACO's total revenues (including from Medicare) will be derived from such arrangements, by the end of the second performance period in December 2013."[2] Thus, while the Pioneer ACO application requires information regarding market share and indicates that CMS may share the information with the Agencies, the Proposed Statement might clarify how ACOs formed in response to the

[1] 76 *Fed. Reg.* 19,528, 19,642 (April 7, 2011)(emphasis added).

[2] CMMI Pioneer ACO Request for Application, p. 13 (available at: http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/pioneer-aco-application/).

Pioneer ACO request for applications can be assured of favorable antitrust analysis as suggested by the Proposed Statement.

Due to operational complexity of creating and operating an ACO in a fee-for-service environment, as reflected in CMS' proposed rule regarding ACOs and the MSSP, providers might be reluctant to participate in the MSSP. Without the additional antitrust enforcement protection provided by participation in the MSSP, antitrust laws remain a significant barrier for some developing ACOs that do not desire, or are not capable of, participation in the MSSP. As a consequence, with respect to antitrust laws, if the federal government truly wishes to promote the development of ACOs, it must decrease the burdens associated with participating in the MSSP, increase the incentives for participating in the MSSP, or expand the protection from antitrust enforcement available to ACOs.

In addition, the Proposed Statement contains further limitations that could possibly hinder participation in the MSSP. Examples include:

(1) The Proposed Statement only applies to ACOs formed after March 23, 2010;

(2) Changes in an ACOs network composition can change an ACO's eligibility for the antitrust safety zones developed in the Proposed Statement or trigger mandatory review; and

(3) Termination of an ACO's MSSP agreement with CMS would terminate any protection afforded by the Proposed Statement.

The last example is particularly troubling because an ACO agreement could be terminated for reasons not entirely under the ACO's control, for example, an ACO's MSSP agreement will be terminated if the ACO fails to meet the requisite floor of 5,000 Medicare beneficiaries for two consecutive years.

Finally, the Proposed Statement says:

> The Agencies have determined that CMS's proposed eligibility criteria are broadly consistent with the indicia of clinical integration that the Agencies previously set forth in the Health Care Statements and identified in the context of specific proposals for clinical integration from health care providers. The Agencies also have determined that organizations meeting the CMS criteria for approval as an ACO are reasonably likely to be bona fide arrangements intended to improve the quality, and reduce the costs, of providing medical and other health care services through their participants' joint efforts. Further, if a CMS approved ACO provides the same or essentially the same services in the commercial market, the Agencies have determined that the integration criteria are sufficiently rigorous that joint negotiations with private-sector payers will be treated as subordinate and reasonably related to the ACO's primary purpose of improving health care services.

The aforementioned language from the Proposed Statement implies that an ACO operating under the MSSP or an ACO that provides the same or essentially the same services in the commercial market would be considered integrated for purposes of antitrust analysis. However, it is important for the Agencies to provide further guidance on when an ACO operating under the MSSP or in the commercial market would not be considered integrated for purposes of antitrust analysis.

Again, AHCA and the Alliance appreciate the opportunity to provide comment on the Proposed Statement.

Sincerely,

Governor Mark Parkinson
President & CEO
American Health Care Association

Alan G. Rosenbloom
President
Alliance for Quality Nursing Home Care