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Federal Trade Commission
Office of the Secretary
Room H-113 (Annex W)
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Submitted electronically to https://ftcpublic.commentworks.com/ftc/acoenforcementpolicy

Re: **Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017 (FTC/Antitrust Division, DOJ)**

Dear Madam or Sir:

The American Nurses Association (ANA) is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses (RNs), the single largest group of health care professionals in the United States. ANA represents RNs in all roles and practice settings, through our state and constituent member nurses associations, and affiliated nursing specialty organizations. Registered nurses provide services to Medicare beneficiaries and deliver health care in a wide variety of settings in collaboration with other professionals.

On March 31, 2011, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) (hereinafter “the Agencies”) released a Policy Statement proposing an enforcement policy on the application of antitrust laws to healthcare collaborations among otherwise independent providers and provider groups seeking to participate as an accountable care organization (ACO) under the Centers for Medicare and Medicaid (CMS) Medicare Shared Savings Program (MSSP) with a comment period ending May 31, 2011. ANA appreciates the opportunity to comment on the FTC/DOJ Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program (referred to hereinafter as “Antitrust Policy”).

Comments of the American Nurses Association

Generally, and subject to the comments below, ANA supports the approach taken by the Agencies with respect to applying a rule of reason analysis to ACOs that maintains the structure and processes used for the Shared Savings Program. This approach reflects the balance between the goals of the MSSP and the need to protect the public from anti-competitive activity in the healthcare industry. ANA also supports the idea of a “safety zone” and triggers for mandatory review by the Agencies.

However, there are shortcomings to the ACO regulatory scheme that should be addressed both by CMS and the Agencies.

A. Guidance in the Proposed Antitrust Policy Should Consider the Critical Role of Registered Nurses in the ACO Leadership Structure

Under the Antitrust Policy, the Agencies will provide a rule of reason treatment to an ACO if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administrative processes as it uses to qualify for and participate in the Program. This analysis will apply to an ACO for the duration of its participation in the Shared Savings Program. The problem with the Agencies deferring to the CMS definition for an ACO's structure is that leadership and clinical and administrative process within the ACO under the CMS proposed definition is exclusive to physicians and does not permit highly qualified registered nurses to assume such roles.

In ANA's comments to CMS in response to the proposed regulation implementing the Accountable Care Organizations (ACOs) provision of the Affordable Care Act (ACA), *Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations,* published on April 7, 2011 [Fed. Reg. Vol. 76, No. 67, pp.19528 – 19654], ANA asserts that the ACA does not include a statutory provision requiring physician leadership of ACO clinical management and oversight, nor for quality assurance and process improvement. The inference in the proposed regulation -- that a physician is automatically more qualified than other healthcare professionals to lead such processes -- is not supported by research or in practice.

Further, the health care quality literature, clinical practice, and managerial evidence support the role of registered nurses, nurse practitioners and clinical nurse specialists as highly qualified professionals to lead clinical management and oversight committees and other quality assurance and process improvement mechanisms within institutions and organizations. The Institute of Medicine, in its 2011 report "The Future of Nursing: Leading Change, Advancing Health," recommends that nurses be full partners with physicians and other healthcare professionals and that nurses should act as leaders in implementing systems such as ACOs.[1] This is true across the spectrum of institutions and organizations regardless of size, geographic location, patient demographics, and other defining characteristics.

ANA believes that CMS has largely neglected to include the contributions of nursing in its provisions and parameters describing integrated practice in general, and the ACO in particular. ANA urges the Agencies not to make the same mistake in the Antitrust Policy. Care coordination is a building block on which much of the ACO quality improvement and cost control provisions are built. And care coordination is a core competency for the nursing profession. Yet the CMS proposed rule largely disregards the contributions of professional nursing in both clinical services and patient management, and as a result, loses the opportunity for real cost savings under the new ACO health delivery model.

[1] Institute of Medicine (IOM). 2011. *The Future of Nursing: Leading Change, Advancing Health,* Washington, DC: The National Academies Press.

Further, and of particular significance to the Agencies, the failure to recognize the critical role of nurses who operate both independently and in collaboration with physicians in primary care and care coordination is anticompetitive in impact. This oversight has the potential to ignore the needs of the many Medicare patients who call a nurse practitioner, clinical nurse specialist or certified nurse midwife their "primary care provider." This can create confusion that threatens patient choice and the patient-provider relationship.

ANA recommends that the Antitrust Policy guidance regarding an ACO's structure be expanded so that management and oversight processes/bodies led by appropriately qualified healthcare professionals such as advanced practice registered nurses would meet ACO eligibility requirements without requiring an implicit exception. Such a change would better reflect the cost savings and collaborative intent of ACOs and be in the best interests of patients. ANA requests that the Agencies' guidance be modified to include other qualified health professionals as leaders in these areas.

B. Other Sources of Data Exist to Determine Relevant PSA Shares

Under the Antitrust Policy Statement, the Agencies will evaluate an ACO's share of services in each ACO participant's Primary Service Area (PSA), and note that a higher ACO share of the services within the PSA indicates a greater risk the ACO will be anticompetitive, absent competing ACOs or sufficient unaffiliated providers and physicians. A PSA is defined as the lowest number of contiguous postal zip codes from which an ACO participant draws at least 75 percent of its patients for the service involved. To fall within the Policy Statement's Antitrust Safety Zone, independent ACO participants that provide a common service must have a combined share of 30 percent or less for each common service in each participant's PSA, wherever two or more ACO participants provide that service to patients from that PSA. Registered nurses and other non-physician health care practitioners are not included in the Agencies' definition of ACO participant for purposes of calculation the PSA share.

In fact, the Antitrust Policy contains an Appendix explaining how to calculate the PSA shares of common services. Notably, only the services of physicians, inpatient facilities, and outpatient facilities (ambulatory surgery centers or hospitals) appear to be considered for purposes of making this calculation. Language in the Appendix states, "Specialty Codes 01 (general practice), 08 (family practice), 11 (internal medicine), and 38 (geriatric medicine) are considered "Primary Care" specialties, and are treated as a single service for the purposes of this Policy Statement." The Agency guidance does not provide an explanation for how this calculation was derived or rationale for excluding certain categories of possible ACO participants like nurses.

Again, the restriction of the PSA shares calculation to only the services of physicians and larger provider entities and the restriction of the definition of primary care services to only those provided by physicians could be detrimental to nurses wishing to participate in ACOs, as well as the patients who rely on their services. In addition, the PSA calculation potentially skews the Agencies' understanding of market share and provision of non-physician delivered primary care services in a given PSA. In other words, the Agencies will not have an accurate picture of the true primary care services provided nationally, a percentage of which are provided through highly qualified registered nurses, among other healthcare practitioners.

This relates to the beneficiary assignment methodology described in the CMS ACO proposed rule, which fails to incorporate primary care services provided by ACO professionals other than physicians and misrepresents from whom a beneficiary accesses care. The ACA specifies in section 1899:‘‘(c) Assignment Of Medicare Fee-For-Service Beneficiaries To ACOs.— The Secretary shall determine an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in subsection (h)(1)(A).” ANA fully understands that assignment refers to ACO professionals who are doctors of medicine and osteopathy. However, ANA believes that the Secretary may have inadvertently created a situation that artificially separates some patients from their preferred primary care provider, in her statutory discretion to determine “an appropriate method to assign Medicare beneficiaries.”

In its comments to CMS, ANA requests revision to the CMS ACO beneficiary assignment “plurality rule,” because a beneficiary who receives the plurality of primary care services from his or her advanced practice registered nurse (APRN) who is not affiliated with an ACO would simply not be assigned to an ACO. While this would still promote continuity of care and preserve the relationship between the patient and his or her primary care APRN provider, it would potentially deprive the patient (and CMS) the hoped for benefits of that beneficiary being part of the ACO. In addition, the beneficiary assignment, from which the PSA calculation method appears to flow, is inconsistent with CMS’ express intent to avoid interfering with beneficiaries’ ability to choose their own providers, and is inconsistent with the pro-competitive model espoused by the Agencies in the Antitrust Statement.

ANA respectfully requests that the services of advanced practice registered nurses providing primary care services be considered in the PSA.

Expedited Review Documentation Issues

The Agencies request comment regarding whether providing the documents and information required to obtain an expedited antitrust review will present an undue burden on ACO applicants.

The fact that the ACO must send a copy of the documentation requests to both Agencies so that the Agencies may then decide which will respond also seems overly burdensome. Less paperwork would be created by identifying one central office and contact to which to send all expedited review documentation. ANA asserts that providing documentation of various ACO requirements may become burdensome and divert healthcare professionals from delivering care. As ANA states in its comments to CMS regarding this issue generally, the amount of documentation required should be carefully balanced between what is necessary to validate care while not diverting health professionals and care coordinators from the actual delivery of care.

ANA respectfully requests that the Agencies continue to carefully consider the consequences of additional administrative burden as it may affect direct patient care.

ANA requests that due consideration be given to these comments. Thank you, again, for the opportunity to comment on the Antitrust Policy. We look forward to a continuing dialogue with the Agencies on these issues as they apply to the nursing profession. Should you have any questions or comments, please contact Cynthia Haney at (301) 628- 5131 or via email at Cynthia.Haney@ana.org.

Sincerely,

Marla Weston, PhD, RN
Chief Executive Officer
American Nurses Association

cc: Karen Daley, PhD, MPH, RN, FAAN
President, American Nurses Association