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June 6, 2011

Donald Berwick, MD  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1345-NC2  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Electronically submitted via: <http://www.regulations.gov>.

**Re: Medicare Program; Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center [published April 7, 2011]**

File Code: CMS-1345-NC2

Dear Administrator Berwick:

On behalf of the American Nurses Association (ANA), the largest nursing organization in the U.S. representing the interests of the nation's 3.1 million Registered Nurses through its state nurses associations and affiliates nursing specialty organizations, we are pleased to offer comments regarding the possible waivers of the physician self-referral, federal anti-kickback, and certain civil monetary penalty statutory provisions as they apply to Accountable Care Organizations (ACOs). ANA would like to focus its remarks on one section of the notice.

1. **“Beneficiary Inducements” (p. 19660).** -- CMS solicits comments on waiving prohibitions of inducements for beneficiaries to participate in an ACO. It expresses the concern about beneficiaries not being “inappropriately induced to obtain services from ACO participants or ACO providers/suppliers.”

Section 1128A(a)(5) of the Social Security Act expressly prohibits such behavior, and provides for civil monetary penalties for violations.<sup>1</sup> However, HHS asks whether the contractual

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<sup>1</sup> “[O]ffers to or transfers remuneration to any individual eligible for benefits under title XVIII of this Act, or under a State health care program (as defined in section [1128\(h\)](#)) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under title XVIII, or a State health care program (as so defined);” (SSA §1128A(a)(5))

arrangements that fundamentally create an ACO might merit some sort of waiver so that ACO participants could, presumably, influence beneficiaries to seek care within the ACO. It is understandable that an ACO might wish to exert its influence on beneficiaries to stay within the web of ACO participants and providers/suppliers. If it is responsible for containing costs and providing coordinated, quality care, the ACO would have an interest in controlling the beneficiary's access to care. However, the ACO is designed as patient-centered care, not provider-centered care.

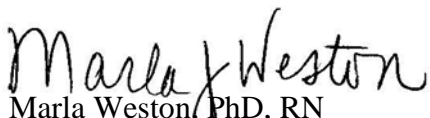
Such actions by the ACO would be in direct contravention of the repeated assurance, in both the Affordable Care Act and in the proposed Shared Savings rule, that beneficiaries retain their full rights to seek care from any provider or supplier that they want, regardless of whether that entity is within or outside the ACO.

It is of concern enough that ACOs might seek more subtle ways to influence beneficiary decisions about where and from whom to receive care. It should go without saying that it is impermissible to offer financial consideration, including waivers of coinsurance and deductible amounts, as well as free or below-market-value goods or services, to a beneficiary in exchange for staying within the ACO provider/supplier group. Very limited exceptions exist in the CMP law. ANA does not believe a waiver can be designed that could adequately protect the beneficiary's statutory rights.

Information regarding the impropriety of such financial consideration should be included in the marketing materials and activities approved by CMS that are intended to "educate, solicit, notify, or contact Medicare beneficiaries" about ACOs (section 425.4. Definitions). ACO proposed rule CMS-1345-P). This should accompany emphatic notice in every communication that beneficiaries have the right to seek care from any provider/supplier they wish, whether inside or outside the ACO arrangement.

ANA appreciates the opportunity to submit comments addressing patient protections in this proposed rule. If we can be of further assistance, or if you have any questions or comments, please feel free to contact Cynthia Haney, Esq., Senior Policy Fellow, Department of Nursing Practice and Policy, at [Cynthia.haney@ana.org](mailto:Cynthia.haney@ana.org), or 301-628-5131.

Sincerely,

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

cc: Karen Daley, PhD, MPH, RN, FAAN  
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