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2400 N Street, NW
Washington, DC 20037-1153
USA

202.375.6000
800.253.4636
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www.CardioSource.org

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June 6, 2011

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1345-P
PO Box 8013
Baltimore MD 21244-8013

Re: Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center [CMS-1345-NC2]

Dear Dr. Berwick:

The American College of Cardiology (ACC) is pleased to submit comments in response to the notice on proposed waivers to the Federal anti-kickback statute (AKS), the Physician Self-Referral (Stark) law, and certain provisions of the civil monetary penalties (CMP) law in connection with the Medicare Shared Savings Program as published in the April 7, 2011, *Federal Register*. The College is a 40,000-member nonprofit medical society composed of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The ACC is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The College provides professional education and operates national registries for the measurement and improvement of quality care. We appreciate the opportunity to furnish input to CMS on this important issue.

A key element of the Patient Protection and Affordable Care Act of 2010 (ACA), the Medicare Shared Savings Program has significant implications for a number of the federal fraud and abuse laws, namely the AKS, the Stark law and provisions of the CMP law. Central to the design and success of the Medicare Shared Savings Program is the concept that physicians in various organizations work jointly to coordinate patient care, thereby reducing unnecessary visits, tests and procedures. As a reward for reducing unnecessary services and maintaining or increasing the quality of care furnished, participating physicians are to be rewarded with a share of

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy

savings. While most of the time discussions of the federal fraud and abuse laws involve concerns regarding potential influences that serve to increase the value or volume of services, concerns here are centered on potential incentives to reduce the value or volume of services beneath appropriate levels. The ACC is pleased that the Centers for Medicare and Medicaid Services (CMS) and the Office of the Inspector General (OIG) recognize the need to explore alternate models of payment for Medicare services and have demonstrated that recognition with the issuance of this rule.

That said, the ACC is concerned that CMS and the OIG are considering such limited waivers as contained within the proposal. As proposed, the waivers of the aforementioned federal fraud and abuse laws are limited to distribution of the shared savings. No consideration is made for the significant upfront financial investment that will be required. Nor does the proposed rule consider the potential for novel financial arrangements that might be created to deal with the complexities that arise from increased clinical integration across multiple organizations. Such arrangements might not be necessary in a fee-for-service system but might be vital in the context of accountable care organizations created in response to the Medicare Shared Savings Program.

Much of the resistance to issuing broader waivers results from concerns regarding patient care. As discussed herein, there have been some questions raised that allowing physicians to partake in savings achieved through care coordination could incentivize them to reduce the quality of care received by patients. While the ACC understands those concerns, the reality is that the overwhelming majority of physicians are primarily focused on patient care and have the best interests of their patients in mind when they make recommendations with respect to that care.

Waiving portions of the federal fraud and abuse laws solely for the purposes of distributing shared savings does not extend quite far enough. The initial startup costs for an entity forming an accountable care organization will be formidable. No provision is made to allow for creativity in the funding arrangements for such a venture. Nor does the proposed rule consider the extensive ongoing operating and maintenance costs that will be generated. Providing the opportunity for creativity will not increase the likelihood that the involved individuals or organizations will place their own financial interests above the interests of their patients; instead, it will allow them to focus on furnishing appropriate and necessary care in coordination with other physicians, the primary goal of the Medicare Shared Savings Program. Failure to allow for more creativity in arrangements for the initial and ongoing financing of an accountable care organization will inhibit the creation of such organizations. Given this, the ACC urges CMS and the OIG to create broader waivers to the AKS, Stark law, and CMP law that will encourage and support physicians and other entities interested in experimenting with various models of coordinated patient care.

The ACC appreciates the opportunity to provide CMS with input pertaining to the waivers of federal fraud and abuse laws as they pertain to the Medicare Shared Savings Program and would welcome the opportunity to discuss these comments further. We look

forward to working with CMS on this and future issues. Please direct any questions or concerns to Lisa P. Goldstein at (202) 375-6527 or lgoldstein@acc.org.

Sincerely,



David R. Holmes, Jr., M.D., F.A.C.C.
President

Cc: Jack Lewin, M.D. – CEO, ACC