



*A Passionate Voice for Compassionate Care*

June 6, 2011

Donald M. Berwick, MD, MPP  
Administrator  
Centers for Medicare & Medicaid Services  
Daniel R. Levinson  
Inspector General  
Office of the Inspector General  
Department of Health and Human Services  
Room 445-G, Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Submitted electronically to <http://www.regulations.gov>

Re: CMS-1345-NC2; Request for Comments, Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center

Dear Dr. Berwick and Mr. Levinson:

On behalf of the Catholic Health Association of the United States (CHA), the national leadership organization of more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations, I welcome the opportunity to submit comments on the Notice published on April 7, 2011 regarding waiver designs in connection with Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (MSSP) and the Center for Medicare and Medicaid Innovation (Innovation Center). CHA and its members are committed to transforming the U.S. health care system so that it will serve patients better and more efficiently. We believe ACOs offer a promising opportunity to achieve those goals through improved integration of inpatient and outpatient care and joint accountability for care delivery across providers and over time.

The manner in which the Physician Self-Referral (Stark) law, the Federal Anti-kickback statute, and Civil Money Penalties Prohibiting Hospital Payments to Physicians to Reduce or Limit Services (collectively "Fraud and Abuse laws") are applied to ACOs under the MSSP, or under an Innovation Center demonstration program, will have an enormous impact on the viability of these new collaborations of institutional providers of services, physicians, and suppliers as they strive to better coordinate care, improve quality and promote efficiency in the delivery of health

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care services to Medicare beneficiaries. We appreciate that the Centers for Medicare and Medicaid Services (CMS) and the Office of the Inspector General (OIG) proposed waivers of the Fraud and Abuse laws for distributions of shared savings among ACO participants and ACO provider and suppliers; we believe this to be a requisite initial step to successful operation of ACOs under Medicare. We further appreciate the proposed coordination of waivers under the anti-kickback and civil money penalties with an exception to the Stark law; it is precisely this type of coordination between CMS and the OIG with respect to the fraud and abuse laws that can provide some certainty to providers and practitioners considering collaboration as an ACO. However, we are concerned that the waivers proposed in the Notice do not sufficiently ease the significant burdens on providers of services, physicians, and suppliers seeking to collaborate to deliver better quality and more efficient care through an ACO under the MSSP.

The current exceptions and safe harbors under the Fraud and Abuse laws do not provide sufficient guidance or assurances to these new collaborations under the MSSP and may well result in penalties for conduct of even the most beneficial of collaborations given the types of financial relationships or arrangements that are necessitated to carry out the policy of the statute. We believe that the proposed waivers afford no protection for the formation and start up operations of an ACO applying to participate under the MSSP and insufficient protection for the ongoing operations of the ACO. Given the complexity and the substantial costs associated with the formation and operation of an ACO, the limited waivers proposed in the Notice will not likely incent many providers and suppliers to apply to CMS for the MSSP given the reasonable legal concerns with respect to the application of the Fraud and Abuse laws left unanswered by the waivers proposed in the Notice and the absence of proposals for additional waivers. If the Fraud and Abuse laws, and associated guidance, exceptions, and safe harbors, are applied in the same manner as they are applied in the Medicare fee-for-service context, it is unclear how an ACO could avoid running afoul of one or more given the kind of collaboration among participants, providers, and suppliers necessary to establish and operate an MSSP ACO.

To carry out the policy of the statute, hospitals, physicians, post-acute care providers of services, and other suppliers must coordinate to deliver efficient care. An ACO under the statute must be clinically integrated, must establish and maintain shared infrastructure, resources and systems, and must establish financial relationships and arrangements among the ACO participants and ACO providers and suppliers. CHA proposes that CMS and the OIG develop a broad waiver policy for ACOs operating under the MSSP. Any CMS or OIG concern over potential violations of the Fraud and Abuse laws by ACOs participating in the MSSP should be significantly mitigated given that the MSSP imposes substantial oversight requirements (including site visits and audits), ensures transparency and accountability (including data on beneficiary complaints), and measures the very quality and efficiency that any ACO would be expected to provide. Given the level of oversight and accountability under the MSSP, CMS and the OIG should ease the burdens associated with the formation and operation of an ACO under the Medicare program and provide for far greater flexibility under its waiver policies, including with respect to other

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financial relationships among ACOs, ACO participants, provider and suppliers to enable and encourage additional collaborative activities that promote accountability, improve care coordination, and incentivize higher quality of care.

We hope the preceding comments are helpful. We share your desire to see the MSSP succeed in leading the way to a new paradigm of integrated care in our nation health care system, and look forward to working with you to achieve that goal. If you have any questions about these comments or need more information, please do not hesitate to contact me or Kathy Curran, Senior Director Public Policy, at 202-721-6300.

Sincerely,

A handwritten signature in black ink that reads "Michael Rodgers". The signature is written in a cursive style with a long horizontal flourish at the end.

Michael Rodgers  
Senior Vice President  
Public Policy and Advocacy