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June 6, 2011

Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services

Daniel R. Levinson
Inspector General
Office of the Inspector General

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1345-NC2
P.O. Box 8013,
Baltimore, MD 21244-8013

Re: Comments on Proposed Waivers of Federal Stark, Anti-kickback, and Civil Monetary Penalty Laws in connection with the Medicare Shared Savings Program ("Program") of Section 3022 of the Affordable Care Act.

Dear Dr. Berwick and Mr. Levinson:

The Commonwealth of Massachusetts (the "Commonwealth") is pleased to offer comments on the proposed waivers of the federal Stark law, anti-kickback statute, and civil monetary penalties ("CMP") law ("Proposed Waivers") in connection with proposed federal ACO regulations issued on April 7, 2011 implementing the Program ("Proposed Regulations"). The Commonwealth is submitting comments on the Proposed Regulations contemporaneously under separate cover. The Commonwealth appreciates the multi-agency effort of the Office of the Inspector General ("OIG") and the Centers for Medicare and Medicaid Services ("CMS") to launch the Program and promote ACO development, and submits comments on the Proposed Waivers below.



Proposed Waiver Designs

The waiver notice asks whether the Proposed Waivers should be expanded to address the various start-up and implementation costs for forming ACOs. The notice also asks whether the Proposed Waivers should be expanded to cover a broader range of financial arrangements, whether they should be required to be commercially reasonable and reflect fair market value, whether other safeguards are necessary, and what the appropriate duration of the Proposed Waivers should be. The Commonwealth feels the Proposed Waivers should be expanded to account for the above, for the reasons noted below.

The Proposed Waivers provide some important protections from the application of the fraud and abuse and CMP laws for entities that form ACOs for purposes of the Program. The Proposed Waivers grant protection to the core ACO function of distributing savings under the Program, providing some assurance to organizations that participate in the Program of protection from investigation and regulatory and criminal penalties in this context.

However, the Proposed Waivers are quite limited in scope and, unless they are modified to cover a broader set of arrangements and programs, the fraud and abuse and CMP laws may continue to operate as a significant barrier to ACO formation. The three year time limit on the effectiveness of the Proposed Waivers is also problematic, as entities forming ACOs will want the protection to survive the period of the Program.

The Proposed Waivers offer limited protection beyond the distribution of shared savings. The Proposed Waivers do not address or protect any other financial relationships, such as those that may arise due to needs for capitalization, formation, and operations of the ACO, prior to and apart from any savings distribution. The Proposed Waivers therefore favor entities that are currently operating in a highly integrated manner and that are in essence functioning as an ACO.

Providers that join together for purposes of becoming an ACO in connection with the Program are only protected by the Proposed Waivers in arrangements relating to relationships specific to the Program's distribution of shared savings, and not other relationships, even if they also involve the distribution of shared savings, if they are not related to the Program. It may be difficult to determine which of the arrangements an organization enters into are solely for the Program; this may operate as another disincentive to participating in the Program and to ACO formation more generally. In addition, the Proposed Waivers do not address the fraud and abuse ramifications of providing incentives to Medicare beneficiaries to promote the ACO goals of improving quality and reducing costs.

For entities that wish to join together and may need to enter into agreements to build the functions and capacities needed to form an ACO, the Proposed Waivers would be inadequate protection from the fraud and abuse laws, unless another one of the existing Stark Law exceptions applied. Stark Law exceptions are quite specific and limited. Structuring financial arrangements that are designed to promote collaboration among hospitals, physicians and other providers in a way that comports and fits within existing exceptions to the Stark Law will take a major effort and cost. Moreover, the existing exceptions may not apply to the new relationships

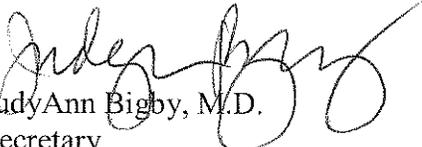
needed for ACO formation.. Therefore, the limited scope of the Proposed Waivers is likely to impede providers' ability to form and operate ACOs.

The infrastructure requirements and investment of resources required to form an ACO are very substantial. Provider organizations that undertake to form an ACO will need greater flexibility to encourage participant and beneficiary actions that will enable the ACO to achieve the dual goals of improving quality and reducing costs. The Commonwealth believes that greater waiver protection from the federal government of the fraud and abuse laws will be needed to promote the Program as well as other state ACO related activities.

The Proposed Waivers only apply to the Medicare Shared Savings Program, not to other publicly funded programs. The Commonwealth requests that the OIG and CMS consider similar fraud and abuse waivers for the Medicaid program (and the rest of the Medicare program), to permit and encourage the formation of ACOs for the coordination and provision of services to Medicaid and other publicly funded populations.

The Commonwealth of Massachusetts appreciates the opportunity to comment on the Proposed Waivers and looks forward to continuing to work with the OIG and CMS to implement the Affordable Care Act.

Sincerely,


JudyAnn Bigby, M.D.
Secretary