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

Re: Comments on Proposed Federal Regulations ("Proposed Regulations") issued by the Centers for Medicare & Medicaid Services ("CMS") in connection with the Medicare Shared Savings Program ("Program") of Section 3022 of the Affordable Care Act.

Dear Dr. Berwick:

The Commonwealth of Massachusetts (the "Commonwealth") is pleased to offer comments on the Proposed Regulations issued on April 7, 2011 (42 CFR Part 425), and supports CMS' efforts to establish a framework on how to implement ACOs. The Commonwealth supports the ACO model of care to encourage physicians, hospitals and other providers to provide more coordinated and better quality of care, and create payment systems that hold health care providers accountable for the care they deliver.

The Commonwealth has also undertaken a broad initiative to promote ACO development as part of its efforts to transform the health care system in the Commonwealth by restructuring the delivery of care and changing reimbursement for health care services. The Commonwealth's reform efforts include initiatives to develop patient-centered medical homes and changing the way primary care is reimbursed, bundled payments, integrated care models for the provision of services to individuals eligible for both Medicaid and Medicare, and pending state legislation to promote ACOs and a multi-payer transition to the use of alternative payment methodologies throughout the Commonwealth.



The Commonwealth's reform plans include encouraging the formation and establishment of ACOs of different levels of integration, structures, and sizes. To do so, the Commonwealth and other states need maximum flexibility to promote a wide variety of integrated care programs and implement payment reform. The Commonwealth recognizes that entities that form an ACO for purposes of the Medicare Shared Savings Program will likely want and need to operate as an ACO for other programs, including state ACO initiatives. The Commonwealth's comments are therefore geared toward promoting federal regulations that are sufficiently flexible to allow ACO formation among a wide variety of provider types and structures, which will provide states maximum flexibility in designing new models of integrated care, payment, and cost savings.

The comments are listed below in the order of appearance of the applicable section in the Proposed Regulations, and not in order of their importance. Thank you for your consideration.

I. Eligibility and Governance Requirements -- § 425.5 of the Proposed Regulations

The wide range of entities eligible for participation under the Proposed Regulations may serve as a model of breadth and flexibility for states as to the types and structures ACOs may form. The Commonwealth agrees it makes sense to require that an ACO be a recognized legal entity under state law. The Commonwealth also supports requiring physician and other clinician representation in ACO governance structures, as well as consumer representation on them.

However, the detailed legal, governance, management and other requirements may favor hospitals and existing highly integrated organizations serving as the ACO. Large, integrated organizations and hospitals are already set up in a manner similar to and most consistent with these rules, as they likely have many of these structures largely already in place, and could make needed changes more easily than smaller organizations. While smaller primary care practices may serve as the ACO under the Proposed Regulations, they may lack the infrastructure to implement all the legal, governance, and management requirements.

In addition, smaller organizations may face greater challenges ensuring sufficient numbers of primary care clinicians within the ACO. Moreover, some of the organizational and governance requirements may be overly prescriptive even for highly integrated organizations; for example, it may be challenging and unwieldy for any ACO to have "at least 75 percent control of the ACO's governing body" held by "ACO participants." The Commonwealth requests that CMS consider a more flexible set of governance requirements to promote greater participation in the Program.

CMS solicits comments on whether separate incorporation should be required for ACOs. The Commonwealth believes that ACOs should not be required to incorporate separately, but should be required to comply with a minimum set of governance requirements.

II. Assignment of Medicare Beneficiaries to ACOs -- § 425.6 of the Proposed Regulations

The Commonwealth appreciates the challenges of devising an assignment or alignment methodology, and of the issues raised by prospective as well as retrospective assignment. Retrospective assignment may be preferable to prospective assignment in some ways. The Commonwealth supports preserving and promoting the ability of patients to maintain freedom of choice of provider, as indicated in the Proposed Regulations, and ensuring that any assignment methodology promotes freedom of choice as well.

However, under the retrospective assignment method set forth in the Proposed Regulations, ACOs may have difficulty in designing care improvements to assigned beneficiaries, when they do not know who they are. It may be difficult for ACOs to determine whether and how to meet required quality measures (and meet their benchmarks for savings) if they do not know what population they are serving prospectively.

In addition, since the assignment method is based on allowed charges, not visits, it could result in beneficiaries not being assigned to the ACO or provider where they are seen most frequently. Moreover, excluding specialty providers from the determination of “plurality” of primary care services may not be appropriate in some cases, where many receive primary care from specialty providers, particularly in the elder and chronically ill population. Furthermore, many primary care services are provided by non-physician clinicians; this assignment method does not seem consistent with the trend to use non-physicians as primary care providers. Finally, if beneficiaries are not assigned initially to a particular ACO, it is not clear that they will have adequate incentives for receiving services from any designated ACO.

CMS solicits comments on whether the retrospective method set forth in the Proposed Regulations should be used, or whether an alternative assignment approach should be used. The Commonwealth recommends offering prospective ACOs a choice between prospective and retrospective alignment methodologies, as CMS has recently outlined in its Pioneer ACO Initiative. The Commonwealth also recommends broadening the definition of primary care services, as outlined above, to ensure greater accuracy of any assignment methodology.

III. Payment and Treatment of Savings -- § 425.7 of the Proposed Regulations

The Proposed Regulations establish some clear parameters for the Program payment methodologies. While both models ultimately require ACOs to take on risk, the one sided model permits ACOs just to share in savings and not take on risk for the first two years, permitting some flexibility for different types of ACOs who are not yet ready to take on risk in the first year. There are incentives for ACOs that take on risk in year one which may be appealing to those entities that are ready and willing to do so.

Where both models require that ACOs take on risk, they may operate as a disincentive for smaller, less integrated entities to participate at all, if they do not feel prepared to take on any risk. Moreover, the financial incentives to participate in the two-sided model versus the one-sided model may not be significant enough to encourage providers to take on the extra risk.

In addition, ACOs with fewer numbers of beneficiaries must achieve a higher minimum savings ratio before they can realize any savings. As a result, smaller groups of providers contemplating becoming an ACO may be deterred from doing so given that the standard set for them may be difficult to attain. In this way, the Proposed Regulations may favor larger, more integrated organizations in a manner that may thwart diversity of ACO formation and development.

Overall, the shared savings models may pose too many barriers and risks to encourage adequate participation by a wide range of providers and ACOs. To further to goal of supporting ACO formation, the Commonwealth recommends that CMS modify the Proposed Regulations as follows: 1) make the one-sided model risk-free (upside only); 2) increase the shared savings rate for both models; and 3) adjust the expenditure benchmark to account for regional cost variation.

IV. Overlap with other CMS Shared Savings Initiatives -- § 425.24 of the Proposed Regulations

The Proposed Regulations prohibit Medicare providers and suppliers from participating in the Shared Savings Program as ACO participants if they participate in “any other Medicare initiative that involves shared savings,” including models tested under section 1115A. The Proposed Regulations provide that CMS will “reject an ACO’s application if ACO participants are participating in another Medicare initiative that involves shared savings payments.”

While the Commonwealth appreciates the desire to avoid “duplicate shared savings payments” to entities, this prohibition will be a *significant* barrier to ACO formation and the Commonwealth’s other efforts to promote integrated care and coordination, particularly for dually eligible individuals (those eligible for both Medicare and Medicaid). The Commonwealth is currently working with the Center for Medicare and Medicaid Innovation to design an innovative financing and service delivery model for dually eligible individuals.

Preliminary actuarial analysis supports the prospect for savings across the Medicare and Medicaid programs if beneficiaries’ care is delivered and coordinated through an integrated entity. Under the Proposed Rule, it would not be possible for provider groups to form an ACO and, at the same time, to be an integrated care entity for the Commonwealth’s dually eligible population, for example. This prohibition represents a major barrier since the Commonwealth is working to design a model that is attractive to

patients and providers. Provider participation is crucial to the success of this initiative and other similar initiatives involving shared savings.

Providers will be less likely to participate in the Commonwealth's duals project and other initiatives such as patient-centered medical homes due to uncertainty about future participation in Medicare Shared Savings Programs as an ACO. Overall, this prohibition hampers the Commonwealth's current and future endeavors to integrate care across entities to deliver quality care. The Commonwealth recommends removing this prohibition in order to allow maximum provider participation in integrated and coordinated care for all residents.

V. Proposed Waiver Designs

CMS and the Office of the Inspector General ("OIG") are seeking comments on proposed waivers of the federal Stark law, anti-kickback statute, and civil monetary penalties ("CMP") law ("Proposed Waivers"). The Commonwealth appreciates the multi-agency effort to launch the Program and promote ACO development. The Commonwealth has included below the comments it is submitting contemporaneously with the OIG and CMS, as indicated in the notice, in connection with the Proposed Waivers.

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 Regulations and looks forward to continuing to work with CMS and other federal agencies to implement the Affordable Care Act.

Sincerely,



Judy Ann Bigby, M.D.
Secretary