

June 6, 2011

Donald Berwick, M.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1345-NC2: Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center

Dear Dr. Berwick:

On behalf of the Brookings Institution's Engelberg Center for Health Care Reform and The Dartmouth Institute for Health Policy and Clinical Policy ("Brookings and Dartmouth"), we write to provide our comments on the **Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center** which was published by the Centers for Medicare & Medicaid Services ("CMS") and the U.S. Department of Health & Human Services Office of Inspector General ("OIG") (collectively, "the agencies") in the April 7, 2011 Federal Register ("Proposed Waiver Rule").

Brookings and Dartmouth have been a leading voice for payment and delivery reforms in our health care system to help providers deliver better care to patients and we have been actively involved in the development of the "accountable care organization" ("ACO") concept. For the past two and half years, we have worked with over 200 organizations to help them build the capacities to put this concept into practice through five ACO pilot sites and our ACO Learning Network (for a list of this year's members go to: www.ACOLearningNetwork.org). Through these efforts we have had the opportunity to test, lead, and evaluate core ACO implementation concepts and our comments on the waiver designs in connection with the Medicare Shared Savings Program and the Innovation Center are largely informed by this work.

Brookings and Dartmouth strongly support the goal of the agencies to address the application of federal fraud and abuse laws to ACOs formed pursuant to the Medicare Shared Savings Program ("Shared Savings Program") so that the laws do not interfere with the development of beneficial ACOs. We also agree with the agencies that ACO arrangements must not be misused for fraudulent or abusive purposes that harm patients or Federal health care programs.

Brookings and Dartmouth believe that the Proposed Waiver Rule does a reasonably good job in balancing these important objectives. However, we also believe that there are a number of clarifications and changes that would improve the likelihood that the Proposed Waiver Rule will achieve its principal goals of "better health, better care, and lower cost."

I. Comments on Proposed Waivers (Section II)

- a. **Process/Application.** The Proposed Waiver Rule states that the agencies' expect to "issue waivers applicable to ACOs" participating in the Shared Savings Program "concurrently" with CMS's publication of final Shared Savings Program regulations. The Proposed Waiver Rule further states that the agencies "intend to apply these waivers uniformly to all qualified ACOs, ACO participants, and ACO providers/suppliers participating" in the Shared Savings Program. This seems to suggest that the agencies' will not be granting "waivers" to individual ACO's based upon a specific arrangement; but rather, waivers will be granted based upon conditions met or satisfied by the ACO, similar to exceptions and safe harbors used in existing fraud and abuse laws. Brookings and Dartmouth seek clarification of this process. Due to the varying design of ACOs already existing in the market place and the purposeful design flexibility of the ACO model, Brookings and Dartmouth also recommend that a process be put in place to accommodate the need for more individualized waivers.
- b. **Threshold Qualifications for Proposed Waiver.** The Proposed Waiver Rule states that in order to qualify for a waiver, "ACOs, ACO participants, and ACO providers/suppliers would be required to comply with the agreement, section 1899 of the Act, and its implementing regulations (including, without limitation, all transparency, reporting, and monitoring requirements)." This section seems to indicate that an ACO could lose qualification for the waiver at any time it is out of compliance with any number of program requirements. This is an unreasonable threshold that should be eliminated and replaced with a simple threshold for waiver qualification.
- c. **Scope of Proposed Waivers - Stark Law.** Brookings and Dartmouth request that the agencies clarify application of the Proposed Waiver Rule to the Stark Law. The waivers seem to apply only to remuneration when it is distributed as shared savings. As allowed by the Shared Savings Program many physicians will have direct or indirect ownership interests in ACOs. Brookings and Dartmouth believe that types of interests should be permitted without implicating the Stark Law. Brookings and Dartmouth request that the agencies clarify that an ACO will not create Stark law issues through these arrangements or be considered a "furnishing entity" as defined in 42 C.F.R. § 411.351.
- d. **Scope of Proposed Waivers - Anti-Kickback Statute.** Brookings and Dartmouth request clarification on the Proposed Waiver Rule as it applies to the Anti-Kickback Statute:
 1. **Intermediaries.** The Proposed Waiver Rule permits "distributions of shared savings received by an ACO from CMS" under the Shared

Savings Program “to” or “among” ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO. ACOs will likely distribute shared savings to both individual physicians, hospitals and other ACO participants/providers/suppliers; they may also distribute shared savings payments from CMS to intermediaries (e.g., a physician group practice or an independent practice association) which will then apportion the shared savings payment among individual ACO participants according to agreements between the parties. Brookings and Dartmouth would like confirmation that such “downstream” distributions will be covered/protected under the Anti-Kickback Statute ACO waiver.

2. Return on Investments. Remuneration (returns on investment) from an ownership interest held by providers, suppliers or others in an ACO will not be protected under the Anti-Kickback Statute’s small entity investment safe harbor, 42 C.F.R. § 1001.952(a)(2), due (in large part) to the safe harbor’s so-called “60-40” rules. Brookings and Dartmouth urge the agencies to enhance the protection offered by the Proposed Waiver Rule (or create a new safe harbor) to cover such investments/returns provided:

- the conditions set forth in 42 C.F.R. § 1001.952(a)(2)(ii)-(v), (vii)-(viii) are satisfied; or
- the conditions set forth in 42 C.F.R. § 1001.952(a)(3)(i)(B)-(E), (G)-(H) are satisfied; or
- the conditions set forth in 42 C.F.R. § 1001.952(a)(3)(ii) are satisfied.

e. Scope of Proposed Waivers - Services Reduction CMP. Hospitals may have an ownership interest in an ACO. Brookings and Dartmouth request that the agencies clarify that a payment to a physician from an ACO that is owned, in part, by a hospital is not a “payment, directly or indirectly, to a physician” from the hospital for purposes of the Services Reduction CMP.

II. Comments on Additional Waiver Design Considerations (Section III)

Brookings and Dartmouth offer the following additional comments in response to the agencies’ request for comments In Section III of the Proposed Waiver Rule:


- ACO Operating Arrangements. As stated above, the agencies should expand the proposed waivers to include financial arrangements beyond

those arrangements for shared savings. ACO's must have clarity that compensation paid by an ACO to a participant/provider/supplier fall within the shared savings distribution category or some other permissible category. Definitions must be clear and cover a broad range of payment arrangements to accommodate multiple participant scenarios.

- **Other Arrangements**. Brookings and Dartmouth believe that it is important for the agencies to address remuneration that does not take the form of shared savings distributions, including (but not limited to) remuneration that takes the form of (1) investments in ACOs and (2) returns on such investments. These arrangements will evolve, so the agencies should proactively promulgate additional clarifications and exceptions/safe harbors as other arrangements are contemplated.
- **“Necessary For “and “Directly Related To” Standard**. The Proposed Waiver Rule provides that compensation must be for activities “necessary for” and “directly related to” the ACO's participation in and operations under the Shared Savings Program. However, the agencies have not defined the terms “necessary” and “directly.” Brookings and Dartmouth urge the agencies to clearly define this standard to mean that the activities at issue must be “related to” the “ACO's participation in and operations under” the Shared Savings Program.
- **Timing**. ACOs will need as much time as possible, so Brookings and Dartmouth urge the agencies to issue the waivers either before or at the same time as the publication of the Shared Savings Program final rule.

We would like to thank the agencies for this opportunity to comment on the Proposed Waiver Rule. Please feel free to contact us if Brookings and Dartmouth can provide further assistance.

Respectfully submitted,



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