



Arizona Hospital and Healthcare Association

June 6, 2011

Donald M. Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
Daniel R. Levinson
Inspector General
Department of Health and Human Services
Attention: CMS-1345-NC2
P.O. Box 8013
Baltimore, MD 21244-8013

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 our 104 member hospitals and health care organizations, the Arizona Hospital and Healthcare Association (AzHHA) is providing comments to your respective agencies on the need for waivers of the application of certain fraud and abuse laws to Accountable Care Organizations (ACOs) that participate in the Medicare Shared Savings Program (ACO program).

We appreciate the Centers for Medicare & Medicaid Services' (CMS) and the Office of Inspector General's (OIG) recognition that current laws create barriers to the integration and care coordination necessary to achieve the goals of the ACO program. We welcome your willingness to break from the traditional enforcement silos and work jointly in establishing waivers in connection with the ACO program. For the reasons explained below, however, we believe the agencies' proposal falls far short of what is needed, and we urge CMS and OIG to create an "ACO waiver" that covers the initial formation and operation of an ACO. Furthermore, the fraud and abuse laws also create barriers for providers to improve care coordination in clinically integrated organizations that are not ACOs, and we urge you to work jointly to create a waiver to remove those barriers as well.

AN ACO WAIVER IS NEEDED TO ACHIEVE THE GOALS OF THE ACO PROGRAM

The ACO program is a new approach to the delivery of care and one of the key delivery system reforms of the *Patient Protection and Affordable Care Act*. Comprised of Medicare providers and suppliers (hospitals, post-acute providers, physicians and other practitioners, among others) that will come together to manage and coordinate care for Medicare patients, an ACO is designed as one vehicle for achieving better care coordination, efficiency, and cost reductions. For the ACO program to succeed, ACOs must succeed.

By design, an ACO is expected to create and maintain the infrastructure, resources and systems necessary to achieve program goals. Each ACO will be expected to invest financial and human resources in the integrated effort, as well as bear the financial costs of program development and compliance. The infrastructure and integration that these organizations will require creates concerns under current Fraud and Abuse and Stark laws.

The only “waiver” under consideration by CMS and the OIG would, at best, come into play deep into the three-year agreement and apply only to the distribution of shared savings dollars received from CMS, if and to the extent that any are realized. The discussion in the agencies’ notice requesting input assumes that the current fraud and abuse rules need to be layered over the new ACO program. Those rules were not designed for ACOs or the provider relationships required within an ACO structure. As a result, any organization that attempts to develop an ACO inherently risks violating existing laws and rules. Most providers are unwilling to take these risks, so most providers and organizations are not developing ACOs. Lack of participation will limit the overall success of the ACO program, unless a better waiver proposal is developed.

THE ACO PROGRAM WILL HAVE SAFEGUARDS ADDRESSING THE SAME CONCERNS AS THE FRAUD AND ABUSE LAWS

The proposed ACO program has built-in protections for the Medicare program and its beneficiaries. Chief among them are transparency, accountability and oversight. For example, an ACO must publicly report detailed and extensive data to CMS on the quality, cost, and overall care of Medicare fee-for-service beneficiaries. Site visits and audits will be part of CMS’ oversight throughout the three years of the agreement, in addition to ongoing reviews of financial and quality measurement data, and complaints by or on behalf of beneficiaries. These protections will safeguard the program and beneficiaries against overutilization and inappropriate influence of clinical decision making, the concerns underlying the fraud and abuse laws. These laws are designed in great part to

counter the incentives for overutilization that are inherent in a fee for service payment structure. In contrast, the proposed ACO program provides incentives to provide the appropriate level of care at the most appropriate time, by the most appropriate provider – the exact intent of the fraud and abuse laws. As a result, in a shared savings program such as is proposed in the ACO rules, the goals of protection against fraud and abuse would be met. There is no reason to layer on the traditional fraud and abuse rules that were built on the assumption that ACO program-type protections were not in place, or to apply them to ACO-like organizations.

THE NOTICE’S APPROACH TO WAIVERS WILL IMPEDE SUCCESSFUL IMPLEMENTATION OF THE ACO PROGRAM

Under the ACO program, hospitals, physicians and other providers must work together, aligned through clinical data and financial incentives, as a cohesive team. Such work requires a new forward-thinking oversight framework. Instead, the agencies’ notice takes a piecemeal approach to ACO waivers--as a series of separate transactions to be scrutinized rather than as a cohesive unit. The agencies’ request for detailed input on an arrangement-by-arrangement basis reflects that compartmentalized approach. As we have explained, we believe the better approach is to focus on the appropriate and extensive safeguards already available in the proposed ACO program. To illustrate our specific concerns we will outline some of the impediments to the formation of ACOs that will still exist under the proposed notice:

1. The obligations of a potential ACO begin before an application is filed with CMS.

In order to make an application, the applicants must already have the relationships and resources in place to meet the requirements of an ACO. The “waivers” described in the notice provide no protection for ACO development and startup operations.

2. An ACO is financially responsible for its ongoing operations.

The “waivers” provide little-to-no protection for the activities and financial expenditures involved in the ongoing operation of an ACO.

3. The protection for the distribution of shared savings dollars may never come into play.

At best, the earliest the protection could be relevant is halfway through the three-year commitment.

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We also point out that the only other “waivers” under consideration are based on meeting an exception to the Stark law, which contains no exception specific to the operations of the shared savings program. This will not provide the flexibility needed for the financial and in-kind contributions required to form and operate an ACO. In addition, achieving the ACO program goals requires outreach and intervention with beneficiaries. The notice provides no protection for an ACO providing the kinds of free services (e.g., transportation, in-home visits or counseling) to assist beneficiaries in maintaining their health and managing their medical conditions.

The new ACO program is designed to change the delivery of care for beneficiaries, providing incentives for the delivery of more appropriate, higher quality, and more cost-effective care. These goals are consistent with, not at odds with, the fraud and abuse laws. The HHS Secretary should take steps to remove all unnecessary barriers to care coordination and use the full scope of authority granted by Congress to create an ACO waiver covering the formation and operation of an ACO, as well as a waiver for other clinically integrated organizations like an ACO.

Thank you for the opportunity to comment on the agencies’ consideration of waivers for ACOs.

Sincerely,

A handwritten signature in blue ink that reads "James F. Haynes". The signature is written in a cursive, flowing style.

James F. Haynes
Senior Vice President and Chief Financial Officer