American Hospital Association

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Submitted electronically

June 2, 2011

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Office of Inspector General
Department of Health & Human Services
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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 more than 5,000 member hospitals, health systems and other health care organizations, and the nearly 200,000 employed physicians within those organizations, the American Hospital Association (AHA) appreciates the opportunity to comment on the Notice from the Centers for Medicare & Medicaid Services (CMS) and Office of Inspector General (OIG) (collectively, the Agencies) requesting input on the need for waivers of the application of the fraud and abuse laws to Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (ACO Program).

The AHA appreciates the Agencies' unprecedented effort to break from their traditional enforcement silos and work jointly in the interest of developing waivers to enable success of the ACO Program. The AHA has long advocated for the removal of fraud and abuse barriers that limit the ability of hospitals and other providers and practitioners to work together to improve the quality and coordination of care for Medicare patients. We believe the broad waiver authority Congress granted the Secretary of Health and Human Services to remove the legal and regulatory barriers to care coordination creates a unique opportunity. We welcome the Agencies' recognition that the current fraud and abuse laws create barriers to achieving the goals of the ACO Program. The AHA believes, however, that the Agencies' waiver approach outlined in the Notice falls far short of what is needed.

The Agencies' proposal will provide little practical value to hospitals and others interested in pursuing participation in the ACO Program or integration activities similar to an ACO. The Notice offers, at most, a waiver for the distribution of potential shared savings received from CMS, which would become relevant deep into the three-year agreement and only to the extent that any savings are realized. All other arrangements from formation to start-up and through ongoing operation, are either unaddressed or are effectively left with no protection. The suggested "limited waiver" that is dependent on compliance with the self-referral (Stark) law does not provide meaningful protection.

Quality improvement and care coordination are the hallmarks of clinically integrated care that should be available to all Medicare patients, not only those assigned to ACOs. The ACO Program is only one vehicle through which hospitals, physicians, and other providers and practitioners can work together to achieve the benefits of clinically integrated care. By focusing only on the ACO Program and exercising the Secretary's waiver authority in the narrowest possible way, the fraud and abuse laws will continue to stand as barriers to the success of the ACO Program and more generally to the success of clinically integrated providers and practitioners working together to improve care coordination for Medicare patients.

The AHA urges the Secretary to use the full scope of the combined authority granted by Congress under the *Patient Protection and Affordable Care Act* to issue waivers to enable Medicare providers and suppliers to offer the benefits of clinically integrated care to Medicare patients as participants in an ACO or through other clinically integrated organizations providing accountable care. Specific to the ACO Program, we urge that an "ACO Waiver" be created covering the formation and operation of an ACO.

AN "ACO WAIVER" IS NECESSARY TO ACHIEVE THE GOALS OF THE ACO PROGRAM

The new ACO model of coordinated care requires a redesigned enforcement template. While the Agencies have acknowledged that ACOs are intended to enable a new world of coordinated care, the "waiver" approach outlined in the Notice largely continues the current enforcement regime. The Notice suggests that the Agencies intended to propose broad and consistent waivers across all types of ACOs.

But the waiver described in the Notice for shared savings received from CMS would apply in the narrowest of circumstances. For all of the relationships and arrangements that will be the predicate for the formation and operation of an ACO there is only a "limited waiver." In these situations the only protection offered is a waiver of the application of the Antikickback statute (AKS) and the civil monetary penalty prohibiting payments to reduce or limit services (CMP Law) *only if* they comply with the Stark law. ACOs would be left to fend for themselves under the Stark law. For example, the Stark law could be implicated if a hospital compensates physicians by organizing and paying for the costly analysis required by the Federal Trade Commission and Department of Justice to determine physicians' share of "primary service

areas." There is no indication in the Notice that a waiver for such activities or expenses is being considered. Using the Stark law as the enforcement template for ACOs is clearly not a waiver and, as will be discussed later in this letter, is a major barrier to the kinds of relationships that will be a mainstay of ACOs. The Agencies' approach will deprive ACO participants of the tools essential to innovation – certainty and flexibility to form and operate new health care delivery systems within the letter of the law. And in many respects, these limited waivers will create a regulatory regime that will be redundant to the protections already embedded in the ACO Program for the Medicare program and patients.

An ACO Waiver makes good policy and enforcement sense. It is the ACO that has ultimate accountability for meeting the requirements of the ACO Program and achieving the program goals. ACO participants are expected to work together towards the larger goals of coordinated care. ACO waivers should track the reality of the ACO Program – a waiver should apply to the ACO so its participants can take the steps necessary to implement and succeed at coordinating care.

In contrast, the Agencies' focus in the Notice is at the transaction level. That thinking reflects the status quo and is out of step with the underpinnings of an ACO model built on collaboration and coordination. The Agencies should redesign their proposals to accept and adapt to the new reality of the ACO Program. When entities form arrangements like ACOs, their incentives change and the financial context in which their participants operate also changes. ACOs will create more immediate oversight of quality of care, admission and treatment decisions among its participants than if they were practicing or operating separately and independently. ACOs have built in compliance mechanisms. The waiver of fraud and abuse laws should be based on the ACO Program. Creating an ACO Waiver recognizes the role of the ACO and acknowledges the accountability and oversight already built into the ACO Program that CMS is responsible for administering. **The Agencies should create an ACO Waiver covering its activities from formation through the end of participation in the ACO Program.**

Current Waivers for MCOs Validate Waivers for ACOs

Creating a waiver for ACOs would not be the first time the fraud and abuse laws have been waived for an entity doing business with the Medicare program. The statutory safe harbor for managed care organizations (MCOs) under the AKS does effectively that. MCOs are permitted to operate within a protected zone so they can carry out their operations without unnecessary enforcement constraints. The ACO model and the MCO model share many similarities, and ACOs should similarly have a protected zone within which to enter into relationships necessary to their success. Just as with MCOs, the additional protections built into the ACO model make it feasible to establish an ACO protected zone. The requirements imposed on ACOs more than satisfy the underlying concerns that fraud and abuse laws are intended to address. In fact, they can do it better because they are tailored to the specific expectations and responsibilities inherent in the ACO Program.

When implementing the statutory MCO safe harbor more than 15 years ago, the OIG acknowledged that an ongoing contractual relationship with health care providers "that includes

monitoring and utilization review of the services provided to plan enrollees…is different from the usual relationship between buyers and sellers." 61 Fed. Reg. 2122, 2134 (Jan. 25, 1996). Largely because of their structure and built-in protections against the types of program abuses the AKS is designed to prevent, OIG recognized that the fraud and abuse laws were, in effect, a redundancy that could inhibit the cost and quality benefits MCOs were designed to deliver. For example, the traditional cost-sharing requirement for beneficiaries was not needed because of alternative means to control unnecessary utilization. See: 57 Fed. Reg. 52723, 52725 (Nov. 5, 1992). (See also Section 1877(b)(3) of the *Social Security Act*, creating a broad waiver of the Stark law for managed care organization activities.) Similarly, the OIG observed that contractual prohibitions against beneficiary discrimination minimized the risk of improperly favoring healthy beneficiaries or encouraging their utilization of services. **ACOs share MCO characteristics and should, for the same reasons, have the benefit of a waiver from the fraud and abuse laws. As in the MCO context, limited, narrow waivers as currently proposed with redundant monitoring and control features will unnecessarily chill the formation of ACOs.**

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

The ACO Program will include substantial compliance requirements for ACOs, including contract, program integrity, reporting and transparency requirements. Yet the Agencies' Notice expresses concerns about potential program abuses without any mention or discussion of the built-in safeguards of the ACO Program. While participation in the ACO Program and execution of an agreement is a precondition for the proposed "waivers," there is no explanation of what is missing in the oversight of ACOs. Instead, the traditional fraud and abuse framework is layered on the ACO Program.

When examined, the ACO Program safeguards address the concerns underlying the fraud and abuse laws. The ACO contracts required by the ACO Program, for example, will give CMS new avenues of oversight over ACO participants that are quite similar to the protections afforded by the fraud and abuse laws. The contracts between CMS and ACOs will contain provisions to guard against and limit potential overutilization that are designed to achieve the same results as the fraud and abuse laws. The ACO Program makes transparency a core element, while the fraud and abuse laws are largely designed to guard against covert payments and influence over health care professionals. An ACO must make significant financial and quality information publicly available. In addition, extensive and detailed reporting must be made to CMS on the quality, cost and overall care of the Medicare fee-for-service beneficiaries. Site visits and audits will be part of CMS' oversight throughout the three years of the ACO agreement, in addition to ongoing reviews of financial and quality measurement data as well as complaints by or on behalf of beneficiaries. The ACO Program also will adapt and apply program integrity provisions to the ACO (*e.g.*, certifications of compliance with program requirements, certifications of the accuracy, truthfulness and completeness of information submitted, and compliance programs).

Under the ACO Program, CMS will be uniquely engaged in the oversight and operation of ACOs.

Given the strong compliance and transparency foundation already present in the ACO Program, overlaying the traditional fraud and abuse framework appears to be a decision made in a vacuum. Fraud and abuse laws were built on the assumption that ACO Program-type protections were not in place. **There is no justification for applying the traditional fraud and abuse laws to ACOs or other types of clinically integrated organizations that engage in the same type of accountable, coordinated care activities as ACOs.**

THE WAIVERS DESCRIBED IN THE NOTICE WILL IMPEDE SUCCESSFUL IMPLEMENTATION OF THE ACO PROGRAM

The linchpin of an ACO's success will be the ability of its participants to work together and provide seamlessly integrated care. The participants will have to start their collaboration long before the ACO begins operations and to do that they will need waiver protection that spans the spectrum of activities from the planning stages through completion of the three-year agreement. The waivers discussed in the Notice, however, do not begin to address those needs. Except for the distribution of shared savings received from CMS, which will be protected by a waiver applicable to those very limited circumstances, none of the other activities of the ACO are protected by a general waiver. Instead, the Agencies propose to use the Stark law as the regulatory regime against which other ACO activities would be evaluated. This approach is very disappointing and entirely ineffective. **Conceptually the Stark regime does not fit the ACO Program, and from a practical perspective it will not work. ACOs are premised on collaboration and integration, innovation, and contributions from all participants – often in-kind – towards success of the overall operation. The Stark law is premised on keeping providers at arm's length, suspicion of remuneration, rigorous and detailed formalities, and strict liability.** The Stark law assumes the old models of care, while ACOs and other clinically integrated organizations are premised on a new model of care.

As hospitals, physicians and other entities move into this new model of care, collaboration is expected. Collaboration of the type clearly envisioned by Congress and the ACO Program will require exchanges of value between and among the ACO founders and between the ACO and those providing items and services to patients served by the ACO. Under the broad definition of remuneration that governs these relationships today, any such exchange of value could be an exchange of remuneration that is problematic. Value will necessarily be exchanged, in cash and in-kind, as ACO participants prepare to operate an ACO.

Developing an ACO infrastructure will require the investment or donation of staff, technology, time and other resources. A physician practice might be called upon to contribute office space for meetings. A hospital could contribute staff to complete ACO-related tasks and technology to coordinate efforts. Once operational, an ACO may want to include incentives in arrangements with home care providers even in the absence of quantifiable savings to help prevent unnecessary

readmissions. The waivers proposed in the Notice would not account for these types of non-traditional exchanges of value. As explained below, the structure and formalities of the Stark law exceptions are insufficient to permit the types of in-kind remuneration needed to form an ACO or the variety of incentives that might be developed to improve its performance. Failure to broadly waive the restrictions of the fraud and abuse laws will chill not only the formation of ACOs but the creativity and innovation necessary to the success of ACOs and the ACO Program.

The "Limited Waivers" Proposal Will Not Work

From a practical perspective, the Agencies' proposed "limited waiver" will not work. The Agencies have created a two-part test. The limited waiver is available only for a financial relationship that (1) is "necessary for and directly related to the ACO's participation in and operations under the ACO Program," and (2) satisfies an exception under the Stark law. Determining whether a relationship is "necessary for or directly related to" creates the classic after-the-fact analysis with second guessing by the Agencies. By its nature, it would be impossible to analyze whether an arrangement is "necessary" until the ACO is actually formed and participating in the program. As a result, ACO participants will have to gamble on whether the Agencies will consider their investments or donations necessary and directly related to the ACO's participation in the program before deciding whether to engage in the transaction at issue. The effect of the Notice is to place ACOs in the position of either foregoing arrangements that facilitate the ACO's formation or undertake the arrangements with the knowledge that the Agencies may later determine them to be unprotected and therefore violate the fraud and abuse laws. Without having assurance that it can safely engage in the investment of forming an ACO, the risk-reward analysis will lead potential participants to opt not to participate.

Offering protection only to an ACO's financial arrangements that can be shoe-horned into the existing list of cookie-cutter Stark exceptions ignores the value of innovative relationships the ACO Program is designed to foster. If the goal of the ACO Program is to foster the development of *new* kinds of relationships between and among providers, then by definition those relationships will not fit within a list of prescriptive exceptions developed over the past two decades.

Structurally and at the most basic of levels, existing Stark exceptions simply do not contemplate the exchange of value contemplated by the kind of collaboration on which ACOs are premised. For example, the Stark law's prohibitions can be triggered by transfers of in-kind remuneration, but the in-kind arrangements necessary to a clinically integrated ACO would be difficult if not impossible to fit within the statute's exceptions. The Stark exceptions are based on cash payments, arm's length negotiations, an "hours-worked" analysis, with a detailed written agreement in advance. That prescriptive approach to waiver is at odds with the goal of creating space for providers to design new kinds of arrangements, financial and otherwise, that are to be the hallmark of an ACO. In short, the Agencies' reliance on the Stark law seeks to unnecessarily impose rigid and arbitrary limitations on the collaborative process and relationships that are expected to define a functioning ACO.

In addition to the conceptual and practical difficulties of applying the Stark law, there is the risk of draconian penalties for being even slightly out of compliance with the law. The Stark law was established to provide a "bright line" test. The line-drawing typically involved with that approach is aggravated by the over-emphasis in the regulations on easily auditable paper trails. Any signature missed, or lapse in renewing an agreement on deadline, is a "violation" and treated the same as a violation of a core requirement. Placing new models of integration under that regime is unfair and unworkable. The Agencies' proposed limited waiver approach also fails to address other barriers that need to be waived. For example, it is not clear whether arrangements that do not implicate the Stark law – in other words that do not involve physicians or their family members – have any protection. Also, there is no protection for an ACO providing the kinds of free services (*e.g.*, transportation, in-home visits or counseling) that will assist beneficiaries in maintaining their health and managing their medical conditions.

Designing waivers for the ACO Program or other organizations providing similar accountable and coordinated care based on the current fraud and abuse laws will simply maintain the current barriers. We look forward to working with CMS and the OIG to develop waivers for ACOs and other clinically integrated organizations that improve the quality and care coordination for all Medicare patients. If you have any questions about our comments, please contact Maureen Mudron, deputy general counsel, at (202) 626-2301 or mmudron@aha.org.

Sincerely,

/S/
Rick Pollack
Executive Vice President