Michael D. Maves, MD, MBA, Executive Vice President, CEO

June 3, 2011

Daniel R. Levinson
Inspector General
Office of the Inspector General
U.S. Department of Health & Human Services

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services

Attention: CMS-1345-NC2
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Inspector General Levinson and Administrator Berwick:

On behalf of the physician and medical student members of the American Medical Association (AMA), we appreciate the opportunity to provide comments on the proposed *Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center*. The AMA strongly supports the overall effort to propose waivers of federal program integrity laws in order to test new payment models and methods that improve patient outcomes and promote value. At the same time, we strongly urge the Office of the Inspector General of the U.S. Department of Health & Human Services (OIG) and (CMS) to address a number of barriers that remain in the context of federal and state program integrity laws that will inhibit or chill the development of the Accountable Care Organizations (ACOs) that were not fully addressed in the proposed rule. **Further, similar to our above request for the ACO proposed rule, we urge CMS to issue an interim final rule, rather than a final rule, so that CMS maintains the flexibility to modify and improve the program integrity regulations in relation to ACOs as CMS learns more about the ACO model.**

The Patient Protection and Affordable Care Act (ACA) explicitly authorizes the HHS Secretary to waive requirements under section 1128A, and 1128B, and Title XVIII of the Social Security Act that contain the Civil Monetary Penalty (CMP) statute, the federal anti-kickback statute (AKS), and the Ethics in Patient Referrals (Stark) law. The AMA previously commented that the establishment of a full range of waivers, safe harbors, and/or exceptions are needed so that the marketplace can benefit from physician-led ACO integration models. We strongly support

the decision to establish waivers to Stark, AKS, and the CMP statute. We applaud the decision to extend waivers outside of the ACO for "activities necessary for" and "directly related to" the ACO's participation in and operations under the Medicare ACO Program. We support the clarification that the waivers extend to CMP and AKS and agree that such waivers make headway toward easing the burden on entities that establish ACOs in a manner consistent with the Stark Law regulatory exceptions.

Given the new and evolving nature of ACOs, we urge the government to adopt inter-agency enforcement guidelines establishing that there is a strong presumption that activities necessary for the planning, formation, and operation of ACOs are "necessary for" and "directly related to" the ACO participation in, and operations under, the ACO Program. Similarly, we strongly recommend a similar recommendation with regard "medical necessity" in the context of the CMP statute. As with any new regulation or policy, there is concern that these standards have the potential to be evaluated in a subjective and potentially inconsistent or confusing fashion. We recommend that the government adopt internal inter-agency guidance and protocols that emphasize the importance of ensuring that ACO participants are afforded a meaningful opportunity to work with regulators to address any concerns without threat of substantial monetary and criminal sanctions. We are also concerned that the proposed waiver is not sufficiently broad to facilitate the kind of ACO development intended by the ACA. In light of the infusion of a substantial sum of funds into federal and state health care law enforcement efforts, we have significant concern that tools to combat program integrity threats based on the current payment model will stymie efforts to construct and transition to new payment methods.

While we are enthusiastic about the application of the waivers outside of the ACO participants in the context of the Medicare ACO Program, we urge you to expand these flexibilities to the distribution of underlying Medicare payments for service, not just shared savings. **We recommend allowing distributions—both underlying Medicare payments for service and shared savings—to providers who are not formally participants in the ACO, such as specialists. It will be a very difficult barrier to scale, if not insurmountable, if ACO participants are prohibited from working with providers outside of the ACO to improve care and meet quality performance standards, even when these activities do not generate shared savings for distribution.**

<u>Duration of Proposed Waivers</u>

The proposed waivers are too limited in duration and may discourage independent practicing physicians who have not already done so from developing an organization that could potentially be accepted into the shared savings program. As proposed, waivers would only be available once CMS has accepted the ACO into the ACO Program. But a great many tasks requiring significant financial resources and physician sweat equity may have to be completed prior to submitting an application to CMS. For example, physicians will have to form new and diverse financial relationships among themselves and third parties, such as medical groups, independent practice associations, and hospitals in order to acquire the financial resources and other expertise

necessary to determine whether or not taking affirmative steps toward ACO creation will best serve the community and otherwise make sense. This analysis will include, but not be limited to, market studies, e.g., an evaluation of the ACO's actual and potential competitors, business planning, analysis of the demographics and health status of the patient population that the ACO may serve, studies determining the optimal number and identity of the primary care physicians and specialists that should comprise the ACO, and analyses of utilization rate for likely ACO participants across a wide range of service lines and settings with respect to beneficiaries who may be assigned to the ACO. They will likely require staff hiring or retention of consultants, and the resources for this staff or consultant expertise will likely come at least in part via new financial relationships among physicians themselves and in some cases institutional health care providers. For example, an independent practice association or a hospital might be willing to fund the lion's share of the costs of retaining consultant services on behalf of interested physicians, or provide in kind support such as training or staff to such physicians. Additionally, interested physicians might vary considerably in the amount that they personally invest in the ACO and/or receive from organizations such as an independent practice association. Unless waivers are extended to these kinds of exploratory ACO activities, many financial relationships may implicate significant fraud and abuse liability exposure.

It is also crucial that the waivers be available to financial relationships that are necessary to create the extensive infrastructure that an ACO must have in order to be accepted into the ACO Program. Again, physicians and other health care providers without the significant financial capital will have to obtain financial assistance to develop this infrastructure. Infrastructure will include, but not be limited to, mechanisms to coordinate care among ACO participants, health information technology, quality and cost data reporting systems, staff hiring, systems that will operationalize performance measurements in ACO participants' practices and allocate performance results and payments accordingly. Again, physicians may contribute at least some of the needed financial resources, but will also require financial assistance, in cash and in kind, from larger organizations. Additionally, the ACO may need to establish referral relationships between ACO participants, as well as referral relationships between ACO participants and specialists or facilities that do not participate in the ACO. The provision of this financial assistance, as well as new referral relationships, will inevitably create financial relationships that, absent the extension of waivers, will raise the specter of liability exposure.

The proposed waiver period should also extend beyond the termination of the three-year term of the ACO agreement. Based on the lessons learned so far from the Physician Group Practice (PGP) demonstration project, it seems likely that many ACOs will not see any shared savings within the three-year agreement period. After four years' participation in the PGP, five out of ten of some of the most integrated group practices in the country received shared savings. Lacking analogous integrative development, ACOs resulting largely from the efforts of independent practicing physicians and physician organizations, such as independent practice associations, will likely require more time to produce shared savings than the PGP participants. Accordingly, it is highly unlikely that independently practicing physicians or organizations of such physicians will seriously consider investing the $1.7 million that CMS has estimated will be

needed to fund the average ACO in its start up and initial operations phases, unless waiver protection extends significantly beyond the three-year agreement period.

Failure to extend waiver protection as proposed by the AMA will probably discourage most, if not all, independent physicians from seriously considering joining with other physicians and other health care providers to create an ACO that could apply for approval in the shared savings program. If the federal government does not want to limit the ACO Program to incumbent integrated delivery systems, then the OIG and CMS must be prepared to make the waivers available to the activities outlined in the comments that physicians and their potential ACO collaborators undertake in good faith.

Additional Recommendations

As referenced above, we urge the government to expand the above waivers to other financial arrangements necessary for, and directly related to, the operations of ACOs. To have practical consequence, as well as to be effective, the waivers must apply to distributions of the underlying diagnosis related group (DRG), Medicare fee-for-service and other fee-for-service (FFS) payments that ACO providers will be receiving. It is far too restrictive to apply the waivers to distributions of the shared savings alone. For example, primary care physicians, specialists, or experienced clinical leadership may have to be recruited or otherwise incentivized to participate in the ACO. Other types of compensation arrangements will have to be created that will necessarily need to include, but not be limited to, innovative medical directorship agreements and participation agreements that utilize incentive-based compensation tied to quality or cost measures.

Although the Stark Law exceptions that shield certain percentage- and unit-based compensation arrangements that would be extended to waive AKS liability in the proposed rule may adequately cover some of these particular financial arrangements, there will likely be considerable uncertainty regarding the extent to which existing Stark exceptions can accommodate these types of cutting-edge compensation arrangements. And, even in those circumstances where an exception from a *provider's perspective* might arguably apply, attempting to adhere to an exception is likely to create considerable uncertainty and impose significant costs to the extent the exception requires a fair market value evaluation. Obtaining an evaluation is often expensive (especially multiple evaluations), takes time, could be of limited utility in the context of innovative incentive-based compensation arrangements given that the fair market value evaluation of such arrangements may in large part be speculative, and not provide the perceived protection that evaluations of more conventional arrangements are often thought to provide. Accordingly, waivers should not be limited to distribution of shared savings, but extend to any compensation arrangement that is necessary to form an ACO.

In the same vein, we strongly urge the government to finalize the proposed rule to extend waiver protection to the distribution of shared savings from private payors to the ACO. Establishing an ACO solely for the Medicare population would unduly inhibit the creation of ACOs by limiting

the economies of scale that a cross-section of patients and payors provide and present significant governance and management complexities that may pose competing and irreconcilable obligations.

CMS and the OIG have sought comments on whether additional waivers are needed to address the two-sided risk options laid out in the CMS proposed rule covering ACOs generally. We have already expressed our extensive concerns with both options contained in the proposed rule and incorporate those comments here.

In addition, waiving the CMP law prohibiting inappropriate inducements provided to Medicare beneficiaries is essential to establishing a viable ACO. ACOs are likely to provide services that Medicare beneficiaries do not receive now—care management, extended office hours, online and telephone consultations are a few examples. It is important to waive CMP so these extra services are not viewed as inappropriate (illegal) inducements.

While we are generally supportive of the decision to propose ACO-related waivers, we urge the Secretary to issue **separate waivers that are broader under the authority granted by Section 1115A** of the Social Security Act, enacted under the ACA through the Center for Medicare and Medicaid Innovation.

<u>State Fraud and Abuse Laws</u>

We are concerned that the proposed rule does not address the impact or options available to waive state fraud and abuse laws. This could present a significant barrier to participation in the ACO, particularly for those physicians and organizations that serve beneficiaries who are dually eligible for Medicare and Medicaid. As a result of the ACA, states have received a significant new investment in program integrity funding and many have either already adopted or are in the process of adopting new laws that parallel federal program integrity laws. At least 37 states have enacted an anti-kickback statute and at least 34 states have enacted a statute prohibiting self-referral. Some of the state laws mirror the federal AKS and Stark Law, while others differ considerably. In addition, some of the state laws apply only to state health programs, such as Medicaid, while others apply to any referral of health care services.

The following is simply one example of the complexity of navigating the state and federal program integrity laws. The purpose of which is to police financial arrangement based on a different payment model—fee for service—with also different expectations about integration.

New Jersey has a state anti-kickback and self-referral law. New Jersey's anti-kickback law which applies to the Medicaid program, prohibits any provider, person, firm, partnership, corporation, or entity from soliciting, offering, or receiving any kickback, rebate or bribe in connection with furnishing items or services paid by the Medicaid program or receiving any benefit or payment by the Medicaid program. Any person who violates this law would be guilty

of a crime of the third degree and liable for a penalty of not less than $15,000 and not more than $25,000 for each violation.

New Jersey's self-referral law applies to health care practitioners and prohibits practitioners from referring a patient or directing an employee to refer a patient to a health care service in which the practitioner, or the practitioner's immediate family has a significant beneficial interest. This provision is subject to some exceptions, but even if the referral is permitted, the practitioner must disclose the financial interest to the patient in a written disclosure form as prescribed by the State Board of Medical Examiners. The disclosure form must also be posted in a conspicuous place in the office. We urge CMS and the OIG, to the maximum extent practicable, to preempt parallel state laws or set up a means of assisting providers to work with states to address these barriers.

<u>Conclusion</u>

We appreciate the opportunity to provide our comments and remain interested in working with the government to develop a viable pathway for physician groups to lead and participate in ACO formation. The AMA is committed to providing feedback to CMS and OIG on a continuous basis to further enhance payment reform models that increase value and quality.

Sincerely,

Michael D. Maves, MD, MBA