Statement

of the

American Medical Association

to the

Federal Trade Commission, the Centers for Medicare & Medicaid Services and the Office of Inspector General of the Department of Health and Human Services

Re: Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-kickback, and Civil Monetary Penalty Laws

September 27, 2010

25 Massachusetts Avenue, NW, Suite 600
Washington, DC 20001
Division of Government Affairs
202 789-7492

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The American Medical Association (AMA) welcomes the opportunity to take part in the Federal Trade Commission (FTC), the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) joint workshop to examine the intersection of accountable care organizations (ACOs) and antitrust, physician self-referral, anti-kickback, and civil monetary penalty (CMP) laws. Physicians want to participate in a health care delivery system that will allow them to deliver high quality and efficient care to their patients. In order to achieve the goal of higher quality and more efficient service delivery, the legal regime must enable independent physicians to use existing or new organizational structures to participate as ACOs. We look forward to working with you to remove legal barriers so that new payment and delivery reform models are successful in achieving their goals of managing costs and improving the quality of care.

I. AMA commitment and efforts

The AMA is committed to encouraging physicians to participate in the full range of innovative delivery reforms authorized in the Affordable Care Act (ACA), including ACOs, which are intended to achieve the goals of higher quality and more efficient service delivery. As we noted in our August 12, 2010, letter to CMS Administrator, Donald Berwick, MD, on Section 3022 of the ACA, the Medicare Shared Savings Program (attached), it is critical that the Administration develop delivery and payment reform policies that will enable the majority of U.S. physicians, including those who are in solo or small group practices, to participate effectively. We recognize that successful participation means that physicians throughout the country need to become familiar with the Shared Savings Program and that many physicians will have to change their

organizational structures and processes of care in order to participate in new delivery and payment reforms. The AMA has been diligently working to educate physicians about how structures like ACOs can help them deliver better care to their patients and how changes to their practices will enable them to succeed under new delivery and payment models. The AMA engaged Harold Miller of the Center for Healthcare Quality and Payment Reform to develop a white paper, "Pathways to Physician Success Under Healthcare Payment and Delivery Reforms," which we distributed to member physicians. The AMA is also conducting webinars and regional continuing medical education seminars for physicians featuring Mr. Miller and physician leaders involved in new payment models. We continue to inform physicians of new developments on payment reform and opportunities to improve health care delivery through communication vehicles such as *American Medical News* and our weekly electronic newsletter on health reform, *HSR Insight*. Information on these and other AMA resources for physicians can be found at www.ama-assn.org/go/paymentpathways.

We have received a very enthusiastic response from physicians to these educational materials and programs. It is clear that many physicians want to play a leadership role in creating a health care delivery system that will allow them to deliver high quality and efficient care to their patients. In drafting the ACA, Congress wisely allowed for a range of different organizational models to serve as ACOs, including physicians in "group practice arrangements" and "networks of individual practices" of physicians, because in most of the nation, patients receive their care from physicians in small, independent practices, not from large health systems. There are many examples of physician groups and independent practice associations across the country that take accountability for the overall cost and quality of care for their patients without having to deliver every service, including hospital care, for their patients. **We urge the Administration to do everything possible to facilitate participation by all types of provider structures authorized under the ACA, and not inadvertently bias participation in favor of large health systems and hospital-dominated networks.**

II. Policies to ensure the success of ACOs

There is no evidence showing that a particular type of provider or organizational structure is the most efficient for achieving the cost and quality objectives of the ACO provisions of the ACA. Accordingly, the ACA explicitly provides that a broad variety of entities—including group practices or networks of individual physician practice—are eligible to serve as ACOs. However, this statutory flexibility will be lost if present antitrust and Medicare fraud and abuse liability risks continue to be encountered by the many physicians in small or solo practices interested in forming ACOs.

As a practical matter, clinical integration efforts that are designated as ACOs for the purpose of Medicare reimbursement will need to function in commercial insurance markets as well. Creating an ACO is costly. Encouraging physician formation of ACOs requires the crafting of rules for ACOs that are transferable to the commercial health insurance market.

A. Unreasonable antitrust barriers must be eliminated

1. Rule of reason[1], not the per-se rule[2], must be applied to ACOs

Doctors typically practice in small firms. According to the latest AMA Physician Practice Information survey(2007-2008), 78 percent of office based physicians in the U.S. are in practices in sizes of nine physicians and under, with the majority of those physicians being in either solo practice or in practices of between 2 and 4 physicians. The antitrust laws treat as competitors firms that practice in the same or related specialty and are in the same geographic market. Therefore, the limitations, created by the antitrust laws, on competitor collaborations would apply to the formation and operation of ACOs.

ACOs consisting of individual physicians and physician firms will have to negotiate fees with individual payors. The FTC and Department of Justice have recognized that such negotiations are not always unlawful. Under present FTC-Department of Justice (DOJ) Statements of Enforcement Policy in Health Care, ("The Statements"), such negotiations are evaluated under the rule of reason if sufficient financial or clinical integration exists. The focus in the Statements on financial and clinical integration, however, imposes restrictions on physician networks organized as ACOs that are tighter than the restrictions required by antitrust law.

Outside the health care context, courts and the Agencies themselves apply a more flexible antitrust analysis than is found in the Statements. For example, in the Agencies' Guidelines on Competitor Collaboration, the Agencies make no mention of financial or clinical integration. Instead, the Competitor Collaboration Guidelines ask more generally whether a joint venture involves "an efficiency-enhancing integration of economic activity" and whether any restraints are "reasonably related to the integration and reasonably necessary to achieve its procompetitive benefits." The Supreme Court, too, in its joint venture cases has eschewed any fixed formulation of what may constitute integration sufficient to warrant rule of reason treatment. By focusing on risk sharing and clinical integration, the Statements have stunted the development of physician joint ventures that could substantially improve care and reduce costs. The AMA hopes that the FTC and the DOJ will not apply such a ridged framework to the development of ACOs.

The Agencies' present approach to integration has its origins in the Supreme Court's decision in *Arizona v. Maricopa County Medical Society*.[3] In a 4-3 decision, the

[1] The "rule of reason" has been the hallmark of judicial construction of the antitrust laws. Under its aegis, the anticompetitive consequences of a challenged practice are weighed against the business justifications upon which it is predicated and its putative pro-competitive impact, and a judgment with respect to its reasonableness is made.

[2] Per se illegality conclusively presumes the challenged practices to be unreasonable. In other words, when a per se offense (such as price fixing among competitors) is charged, all the government must establish is that the defendant has, in fact, engaged in the proscribed practice; illegality follows as a matter of law, no matter how slight the anticompetitive effect, how small the market share of the defendants, or how proper their motives.

[3] *Arizona v. Maricopa County Medical Society*, 457 U.S. 332 (1982).

Supreme Court held that a physician networks maximum fee schedules represented *per se* unlawful price-fixing agreements. In so holding, the Court distinguished the networks from "partnerships or other joint arrangements in which persons who would otherwise be competitors pool their capital and share the risks of loss as well as the opportunities for profit."[4] The physicians in the defendant networks did not put up capital; they did not accept capitation, but instead billed on a fee-for-service basis. Nor did the Court observe any other indicia of integration among the physician practices that comprised the networks. Nevertheless, Justice Powell and the two justices who joined his dissent reasoned that the networks were comparable to the joint licensing arrangements held subject to the rule of reason rather than the *per se* rule in *Broadcast Music Inc. v. CBS.*[5]

Antitrust law has matured significantly since *Maricopa* was decided. The Supreme Court has repeatedly cut back the scope of the *per se* rule. Conduct that was once squarely within the *per se* rule is now subject to the rule of reason. Along with this sharp narrowing of the *per se* rule, are the numerous statements by the Supreme Court that the *per se* rule should only apply to the most blatantly naked forms of price fixing that have no plausible efficiency justifications. Given the narrowing of the per se rule and the substantial efficiencies ACOs can create, ACOs should not be evaluated under the *per se* rule. As the Supreme Court recognized in *Broadcast Music Inc. v. CBS* the rule of reason analysis applies to arrangements prompted by (i) the need for better service to consumers, and (ii) by reaping otherwise unattainable efficiencies. This is precisely the case with ACOs. **Therefore, the AMA strongly recommends that the Agencies explicitly recognize under Supreme Court precedents, that ACOs should be protected by the antitrust laws and their fee negotiations should not be subject to the per-se rule.**

2. ACOs and financial integration: risk sharing arrangements

Risk sharing arrangements were popular in the 1990s. Since then, the market has decisively turned against risk sharing models of integration. It is thus unclear whether many physicians creating ACOs will pursue a risk sharing model. For those physicians and those markets where risk sharing arrangements are still viable, the Agencies should clarify the requirements for adequate financial integration within the context of ACOs. **Accordingly, the Agencies should acknowledge sufficient financial integration in the case of any contract employing: (1) capitation; (2) substantial withholds (15%-20%) range; (3) a percentage of premium; (4) global fees or all-inclusive case rates; (5) cost and utilization targets; or (6) any other pay-for-performance reimbursement models that involve risk.**

3. ACOs and clinical integration

Clinical integration is now an important model for physician collaboration. An understanding of the basic indicia of clinical integration has emerged over time in the market among health care policymakers, health care entities, and the antitrust agencies.

[4] *Id.* at 356.

[5] *Broadcast Music, Inc. v. Columbia Broadcasting System,* 441 U.S. 1 (1979).

The AMA in its 2008 publication entitled "Competing in the Marketplace: How physicians can improve quality and increase their value on the health care market through medical practice integration," describes some of the basic elements of a clinically integrated network as: (1) mechanisms that control utilization and establish quality benchmarks; (2) practice protocols that are designed to improve care; (3) information databases and sharing treatment information in order to streamline care and lower costs; (4) selectively choosing physicians that will actively participate in the operation of the clinically integrated network, follow the practice protocols and work towards achieving the quality benchmarks; and (5) investment of the financial capital needed to create necessary infrastructure.

The FTC/DOJ should clarify the clinical integration requirements an ACO should meet in order to avoid application of the per se rule. It is essential, however, that the FTC/DOJ not put forward ACO clinical integration requirements[6] that will themselves pose an unreasonable barrier to ACO development. The current clinical integration standards published in the Statements and FTC advisory opinions to date will deter the formation of ACOs. If the FTC/DOJ standards remain unaltered, the ACA's important invitation to physicians to form ACOs will be reduced to a mere gesture.

Substantial cost barriers face any physician organization endeavoring to establish compliance with existing FTC/DOJ standards.[7] The MedSouth and GRIPA FTC staff advisory letters demonstrate how high the bar has been set for physician networks seeking to qualify for rule of reason treatment through clinical integration. Both MedSouth and GRIPA made significant investments in capital and resources, using a cadre of consultants and technology experts to assist in the effort. Both networks invested in electronic medical records and tracking technology to share information on their patients and to monitor data relating to utilization and medical outcomes. And both networks developed clinical practice guidelines and procedures for monitoring compliance with them. In both instances, the FTC staff advisory letters noted no apparent anticompetitive motivation for the physicians' efforts.

Despite these features, neither MedSouth nor GRIPA achieved agency approval easily or without significant caveats. Both letters reflected intensive FTC investigation of the networks' histories, purposes, contracting mechanisms, disciplinary methods for non-

[6] Section 3022 of the ACA identified requirements that a qualified ACO must meet, including an agreement that an ACO shall "define processes to promote evidenced-based medicine and patient engagement, report on quality and cost measures, and coordinated care" (see (2)(G)). The law also authorizes the Secretary of HHS to determine appropriate measures to assess the quality of care furnished by the ACO (see (3)(A)), as well as allows the Secretary to determine appropriate reporting standards related to the Physician Quality Reporting Initiative. Recognizing that HHS has the authority to establish quality measures, the AMA has provided CMS with detailed recommendations with regard to the performance measurement and reporting needs for ACOs (see attached August 12, 2010, letter to CMS).

[7] In 2002, however, the FTC issued a staff advisory letter to MedSouth, Inc., an IPA based in Denver, Colorado with over 400 physicians.[7] And in 2007, the FTC issued a staff advisory letter to the Greater Rochester Independent Practice Association, Inc. (GRIPA), a network based in Rochester, New York with over 600 physician members. Letter from Markus H. Meier to Christi J. Braun & John J. Miles, Sept. 17, 2007 ("*GRIPA*").

compliant physicians, and strategies for producing efficiencies. Each involved a searching examination of the so-called "ancillarity" of the networks' pricing mechanisms to their efficiency-enhancing potential. Each left the FTC plenty of room to bring a later enforcement action if the networks' operations could not later be shown to produce significant efficiencies. The evidence to date strongly suggests that few if any clinical integration programs will ever recover their initial investment. For example, GRIPA has not come close to recovering their investment in their efforts to comply with the FTC's standards.[8]

The clinical integration programs that the FTC has approved to date should not become the litmus test governing the adequacy of physician ACO clinical integration programs.

4. The role of exclusive contracting

ACOs need the ability to negotiate with insurers on an exclusive basis. First, ACO physicians need to participate in any contract into which the ACO enters. This requirement will insure that ACOs can offer health insurers a complete physician panel, and prevent gaps that could undermine the clinical integration program's efforts to create efficiencies. Second, ACO physicians should contract with health insurers solely through the ACO. This requirement prevents health insurers from free riding on ACO clinical integration efforts and thereby take a significant portion of the value created by these efforts. If health insurers want to benefit from the ACOs clinical integration program, they must deal with the ACO directly.

Unfortunately, today clinical integration programs are generally non-exclusive. One of the reasons clinical integration programs have developed in this manner is the uncertainty created by the absence of FTC/DOJ advisory opinions on exclusive dealing and FTC/DOJ Statements that provide little guidance. Further, the unnecessarily low safe harbor threshold of a 20 percent market share for exclusive arrangements has created a strong impression that the FTC/DOJ view exclusive dealing arrangements with considerable suspicion. A 20 percent market share threshold is extremely low, and harkens back to the time when atomized markets were the fundamental goal of antitrust policy. Today, market shares in the 30 percent range are routinely deemed too low to support market power claims.

Non-exclusive clinical integration programs have not done well commercially, and this includes the non-exclusive networks that have received favorable advisory letters from the FTC. This is not surprising. Structuring a clinical integration program on a non-exclusive basis invites free riding. The hallmarks of a clinical integration program are (a) creating treatment protocols that improve outcomes and lower cost, (b) teaching these protocols to physicians, (c) making sure these protocols are being followed, and (d) creating the infrastructure needed to support the clinical integration efforts, such as HIT systems and interoperability to enable physicians and other clinicians to securely exchange health

[8] See "N.Y. IPA struggles to land clients," August 23, 2010, Modern Physician.

information about their patients. Developing such a program is expensive and requires both a substantial start-up investment and then continuing investments to maintain the program.

While a clinical integration program makes the delivery of physician services more efficient and generates savings that are passed along to insurers (not physicians), an ACO has to charge insurers for this service to survive. An individual health insurer has significantly less incentive to purchase this enhanced service from the ACO program, if it can sign contracts with individual physicians (whose practices have been advantaged by, for example, HIT training) and get some portion of the benefits created by the clinical integration program at no additional cost. Free riding can happen because physicians cannot practically discriminate between patients coming through the clinical integration program and patients coming through independently negotiated contracts. This is a textbook free ride.

If enough insurers take a free ride, the clinical integration program will fail and all or most of the efficiencies created by the program will be lost at some point. Also, the more likely this outcome, the less likely it becomes that physicians will set up such arrangements in the first place. Physicians, especially those in small practices, understand the overwhelming bargaining power of the major health insurers vis-à-vis small physician practices. They know that if the health insurers are free to cut deals around the ACO they will be successful because no small practice will be willing to decline the health insurers' offer and run the risk of being left out in the cold. Therefore, physicians will be unlikely to make the initial investment in a clinical integration program in the absence of ACO exclusive dealing.

Exclusive dealing arrangements are a critical tool that ACOs will need to use. This is not a radical or particularly new idea. Joint ventures in other industries routinely engage in exclusive dealing in order to prevent free riding and to align the interests of its members. Courts have recognized that exclusive dealing is both efficiency enhancing and frequently necessary for the efficient operation of a joint venture. It is time for the antitrust enforcement agencies to recognize these points in the case of ACOs.

5. Market power

A full discussion of the issue of market power for ACOs using an exclusive dealing model is beyond the scope of this paper, but the AMA welcomes the opportunity to discuss this issue further. As noted above, AMA believes that ACOs with substantially more than 20% of the market will often be procompetitive. The FTC/DOJ should also recognize that ACOs using a non-exclusive model will not raise market power concerns, except in the most unique and extreme circumstances.

6. Joint negotiations conducted at the request of the health insurer

The AMA shares the concern expressed by the DOJ that there are strong barriers to entry and expansion in health insurance markets. *See* remarks of Christine A. Varney prepared for the American Bar Association/Antitrust in Healthcare Conference, May 24, 2010. These problems may be ameliorated by the ACA's provisions both for state-based health

insurance marketplaces called exchanges and for consumer operated and oriented health plans.

By forming ACOs and jointly contracting, the physician community can offer new health insurance market entrants savings in transaction costs. ACOs can allow a new entrant to directly negotiate with a physician network, making it unnecessary for the new entrant to create its own network or to put in place the administrative structures needed to negotiate hundreds of individual contracts.

Physicians that form a non-exclusive ACO should know that if they engage in joint negotiations at the request of the health insurer, a contract rejection cannot be characterized as an antitrust conspiracy. This principle is a matter of common sense; the antitrust laws are a consumer welfare prescription and allow consumers to engage in negotiations they want. Moreover, there is directly supporting case authority. For example, in *Tunica Web Advertising v. Tunica Casino Operators Ass'n, Inc*, 496 F 3d 403 (5th Cir. 2007) the plaintiff had accused a casino trade association and it members of collectively refusing to deal with the plaintiff—a conspiracy in violation of the antitrust laws. The plaintiff, however, had made an offer to the association and its members and requested a joint response to its offer. The Fifth Circuit held that under these circumstances, the joint refusal to accept the offer did not constitute concerted conduct by the casino association and its members under the antitrust laws. The court stated: "Given the joint nature of TWA's initial proposal, which invited the casinos to respond together as a single entity, the casinos' decision to reject that proposal is not concerted action subject to section 1." *Id*. at 410. **Accordingly, the Agencies should adopt the principle that joint negotiations conducted at the request of the health insurer cannot constitute an antitrust conspiracy.**

7. Additional protections that should be considered

Physicians will be discouraged from investing and taking part in new delivery and payment models if the legal protections from civil penalties and criminal sanctions afforded to them could suddenly expire. Therefore any safe harbors, exceptions, exemptions, or waivers allowed under the Shared Savings Program should continue beyond the expiration date of the program so that any organizational structure participating as an ACO does not become illegal overnight simply because the program does not continue.

Finally, advising physicians that ACOs are subject to rule of reason rather than *per se* analysis, while necessary, may not be sufficient to support physician decisions to invest in ACOs. Physicians may for example, worry that an ACO might raise market power concerns. Networks need scale to participate as ACOs. The ACA itself requires that ACOs have primary care professionals sufficient to treat a beneficiary population of at least 5,000 beneficiaries. In many communities a combination of that scale requirement and the accident of geography (such as a small metropolitan area) would require physician networks to possess large market shares. Although proper interpretation of the antitrust laws is that they are a consumer welfare prescription, a high market share that

ultimately benefits consumers by allowing physician networks to serve as ACOs, might nonetheless trigger an antitrust challenge. Accordingly, states should be encouraged to enact laws that treat ACOs in metropolitan areas with small populations or ACOs in rural areas as natural monopolies subject to state regulation and thereby immune from the federal antitrust laws under the state action doctrine.

B. Waiver, safe harbors, and/or exceptions under sections 1128A, 1128B and title XVIII of the Social Security Act

The ACA explicitly authorizes the Secretary to waive requirements under section 1128A, and 1128B, and Title XVIII, of the Social Security Act. sections 1128A, 1128B, and Title XVIII contain the Civil Monetary Penalty (CMP) statute, the federal anti-kickback statute (AKS), and the Ethics in Patient Referrals (Stark) law. The AMA supports the establishment of a full range of waivers and/or the establishment of safe harbors or exceptions that will enable independent physicians to effectively participate in ACOs. Waivers are needed so that the marketplace can benefit from physician-led ACO integration models to the same extent as ACO strategies led by hospitals and health insurers.

1. Waiver of/or safe harbor under, the requirements of section 1128A of the Social Security Act

Section 1128A of Social Security Act includes a provision under the CMP statute that prohibits a hospital from knowingly paying a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries. The CMP statute imposes civil monetary penalties on hospital and/or physicians that violate this provision. The OIG has interpreted the CMP statute to prohibit such payments even if the services being reduced are not medically necessary or appropriate. Although the OIG has rendered a number of favorable opinions stating that specific, short term gainsharing arrangements between physicians and hospitals would not be subject to penalties under the CMP law, the OIG has not explicitly altered its interpretation of the CMP statute.

The CMP statute is a significant barrier to the development of gainsharing programs that save health care costs and improve the quality of patient care. Gainsharing has the potential to align hospital and physician incentives to provide more cost-effective care, for example, by encouraging more appropriate use of imaging and testing services; more careful choice among available generic and brand name drugs; reductions in medication errors; use of outpatient rather than inpatient services; use of disease management services to preclude the need for hospital admission; and reduction of avoidable readmissions. Nevertheless, because the OIG apparently continues to interpret the CMP statute to preclude payment mechanisms that would reduce *any* services, there is significant concern among physicians that participation in gainsharing programs will expose physicians to liability under the CMP statute.

The AMA recommends that the OIG adopt a safe harbor for gainsharing arrangements that meet criteria similar to those identified in the OIG Advisory

Opinions on such arrangements. The safe harbor could include the following elements, which are common to those gainsharing programs that have received OIG approval:

- specific, identifiable, and transparent cost saving actions and verifiable cost savings from those actions;
- a ceiling on how much of the realized savings participating physicians could receive, although ACOs should not be subject to a ceiling unless it is clear that ACOs operating in the absence of such a ceiling are subjecting public payment programs to a significant risk of fraud and abuse;
- arrangements of fixed duration, although the duration in the ACO context should not as a matter of policy be limited to the short durations cited in OIG Advisory Opinions;
- a floor on the minimum permissible use of certain services and materials, set in accordance with objective evidence;
- provisions for participating physicians to make a patient-by-patient determination of necessary care and other patient-care safeguards;
- disclosures to patients about the hospital and physician participation in cost-saving efforts;
- equal distribution of cost savings among all participating physicians; and
- reliance on third-parties to develop and monitor the gainsharing arrangement, although reliance on third parties should not be required unless it is clear that ACOs operating in the absence of a ceiling are subjecting public payment programs to a significant risk of fraud and abuse.

2. Waiver of/or safe harbor under, the requirements of section 1128B of the Social Security Act

Section 1128B of the Social Security Act contains the AKS, which prohibits one entity or person (the payor) from paying, or even offering to pay, remuneration, i.e., anything of value, to a person or entity (the payee) in exchange for the payee's making referrals to, or otherwise generating business for, the payor. The AKS contains a number of safe harbors, which, if satisfied, protect the parties to an arrangement from AKS exposure. Violations of the AKS can result in significant civil penalties, jail time, and/or exclusions from state and federal health care programs.

Given the consequences of violating the AKS, many physicians are reluctant to enter into innovative integration strategies with their colleagues due to uncertainty regarding potential AKS liability. This reluctance is well-placed in the current health care fraud enforcement climate. Expanded authorities under the ACA and a massive infusion of additional funding has increased the ability of prosecutors to bring AKS cases against individuals. A misstep by physicians attempting to innovate without bright line rules or without safe harbors carries substantial risks and consequences. The chilling effect of such enforcement will be pronounced without clear guidance and safe harbors. The uncertainty not only creates a significant barrier to the creation of physician-driven ACOs, it also places physicians at a marked disadvantage vis-à-vis hospitals and health insurer with respect to ACO formation.

Existing AKS safe harbors facilitate ACO formation by hospitals and health insurers. For example, the AKS contains a safe harbor applicable to remuneration paid by employers to bona fide employees. Under this safe harbor, an employed physician may make referrals to, or otherwise generate business for, an employer hospital or health insurer even though the hospital or health insurer remunerates the physician through salary, and bonuses based on quality or efficiency. This safe harbor also permits hospitals and health insurers to capture and direct physician referrals, and control clinical behavior and physician business practices, such as mandating compliance with performance measures. Health insurers endeavoring to form ACOs also enjoy additional safe harbors. For example, under a safe harbor entitled "Price reductions offered to health plans," a health insurer's payments to physicians do not constitute "remuneration" between the health insurer and contracted physician.

Physician-driven networks seeking to create an ACO are not on a level playing field with hospitals and health insurers in terms of safe harbor protection. While physician organizations may employ physicians and thereby take advantage of the AKS employment safe harbor, that safe harbor may have limited application to many physician organizations interested in forming an ACO. For example, many independent practice associations do not employ many, if not most, of their physicians. Although the AKS safe harbor for personal services arrangements *might* be able to protect shared savings payments made by physician networks to independent contractor physicians, such protection is not certain because that safe harbor requires the aggregate compensation paid to the physician to be set in advance, i.e., at the inception of the agreement between the network and the physician.

Unless the Secretary waives current AKS strictures on physicians' ability to integrate or creates a new safe harbor, it is unlikely that the U.S. health care delivery system will benefit from significant innovative ACO models that physicians might have otherwise been able to bring to market. The market should be able to benefit from physician-led innovations to the same extent that the market may enjoy the possibilities of innovations developed by hospitals or health insurers. **Accordingly, physician organizations that are integrating in an effort to become ACOs must have a safe harbor as well, since those organizations are likely to exercise a commensurate degree of control over the physician members' referrals and practice patterns as do hospital and health insurers under their applicable safe harbors.**

3. Waiver of/or exception to, the requirements of Title XVIII of the Social Security Act

Title XVIII of the Social Security Act contains the Stark statute and its implementing regulations (Stark Law). The Stark law prohibits a physician from referring a Medicare beneficiary to an entity for the furnishing of a designated health service (DHS) if the physician (or the physician's immediate family member) has a financial relationship with the entity, *unless a Stark Law exception applies*. A financial relationship can take the form of an ownership/investment interest, e.g., a physician's ownership interest in a physician practice. A financial arrangement may be compensation arrangement, e.g.,

remuneration in the form of a fee-for-service payment from a physician network to member physician, or salaries or bonuses paid by a hospital or health insurer to an employed physician. A violation of the Stark Law, even a technical violation, can result in massive civil penalties and program exclusions.

Existing exceptions to the Stark law appear to favor hospitals and health insurers vis-à-vis physicians when it comes to ACO formation. The Stark Law contains an exception for remuneration paid by an employer to an employee pursuant to a bona fide employment arrangement. Under this exception, a hospital or health insurer can exercise control over physician referrals and practice behavior, because compensation can be tied to compliance with practice guidelines and other measures so long as the compensation is consistent with fair market value and does not directly or indirectly take into account the volume or value of the physician's DHS referrals. However, although physician organizations can take advantage of the Stark Law employment exception, the exception will be of limited utility to many physician organizations wishing to become an ACO, since those organizations often do not employ all requisite physicians.

Similar to the AKS, the Stark Law contains exceptions that apply in managed care contexts. One exception applies in certain types of risk-sharing arrangements. Another exception applies to prepaid health plans. Both of these exceptions do not appear to be applicable to most, if not all, physician-driven organizations that are interested in becoming ACOs.

The Stark law does contain a number of exceptions that *might* in some circumstances protect remuneration paid by a physician network to participating physicians, e.g., the exceptions for personal services or fair market value payments. But this protection is far from certain, and the Stark Law is notoriously complex. Lack of certainty will hinder physician's efforts to form ACOs, because *any* noncompliance with Stark Law requirements results in sanctions, regardless of a physician's best efforts. Unfortunately, the ACA has only increased physicians' fears. As stated previously, the enforcement authority and capacity of regulators and prosecutors has been expanded significantly as a result of ACA. Ultimately, this means efforts at innovation will be closely scrutinized by a whole new cadre of auditors, investigators, agents, and prosecutors. In addition, ACA expands the ability to bring claims by whistleblowers and to establish technical/procedural violations of the Stark Law. For example, ACA requires certain self-referring physicians subject to an exception to the general bar against self-referral to provide written notices to patients of other service providers. ACA also increases liability where a Stark Law violation is found and a provider has a resultant overpayment. If the overpayment is not returned within a specified timeframe, it constitutes a violation of the False Claims Act.

In addition to the chilling effect on innovative physician lead efforts that is attributable to the expanded enforcement authority and enhanced penalties of the Stark Law as a result of ACA, current policy discussions among, for example, the Medicare Payment Advisory Commission seek to further narrow the designated health service exception to the general

prohibition on self-referral. This is a trend in the opposite direction of payment reform models that emphasize ACOs, integration of care, and medical home.

Unless the Secretary waives the current Stark Law restrictions or creates a new exception for physician-led ACOs, the U.S. health care delivery system will not benefit from the insight and expertise that only physicians can provide. Physicians who have sufficiently integrated, either clinically or by assuming financial risk, to qualify as ACOs will be highly motivate to control health care costs and promote quality. **Accordingly, remuneration if a physician organization is integrating as a means of becoming an ACO, that organization's payments to its constituent members should be excepted from the Stark law if the remuneration is consistent with the fair market value of members' services and not determined in a manner that takes into account the volume or value of any members' referrals.**

III. Conclusion

Antitrust relief along with other legal protections should be provided to physicians so that they can take the necessary transitional steps to develop and operate and participate in ACOs in order to improve the quality of care delivered to their Medicare and non-Medicare patients while reducing health care costs. We look forward to working closely with all key stakeholders as the rulemaking process moves forward and as CMS, FTC, and OIG consider changes to the antitrust, physician self-referral, the federal anti-kickback, and the civil monetary penalty laws in order to ensure successful physician participation in the Shared Savings Program.

AMA
AMERICAN
MEDICAL
ASSOCIATION

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

August 12, 2010

Donald M. Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Room 314G
Washington, DC 20201

Dear Dr. Berwick:

I am writing on behalf of the American Medical Association (AMA) to share our thoughts with you regarding ways that CMS can increase the likelihood of success for the program to create accountable care organizations (ACOs) established under the Affordable Care Act (ACA). The AMA appreciated the opportunity to participate in the special open door forum that the Centers for Medicare and Medicaid Services (CMS) convened on June 24th to discuss ACOs and our comments are reflected in the transcript of the call which CMS released on July 29th. We were also pleased to be included in the discussion at the White House regarding ACOs and antitrust issues, as well as the second CMS listening session at the Humphrey Building. We look forward to working with you to successfully implement this and other key payment and delivery reforms included in the ACA.

Promoting Participation by a Variety of Physician Practices

In order to achieve the goal of higher quality and more efficient service delivery for the Medicare program envisioned by Congress, we believe it is essential that the regulations implementing Section 3022 of the ACA enable the majority of U.S. physicians, including those who are in solo or small group practices, to participate effectively. We recognize that many physicians will need to change their organizational structures and processes of care in order to participate effectively, and toward that end, the AMA has been working to educate physicians about how new payment models, including ACOs, can help them deliver better care to their patients and how their practices may need to change in order to succeed under these new models. The AMA engaged Harold Miller of the Center for Healthcare Quality and Payment Reform to develop a white paper, "Pathways to Physician Success Under Healthcare Payment and Delivery Reforms," that we distributed to member physicians, and which Margaret Garikes has provided to you. The AMA is also conducting webinars and regional continuing medical education seminars for physicians featuring Mr. Miller and physician leaders involved in new payment models. We continue to inform physicians of new developments on payment reform and opportunities to improve health care delivery through communication vehicles such as *American Medical News* and our weekly electronic newsletter on health reform, *HSR Insight*. Information on these and other AMA resources for physicians can be found at www.ama-assn.org/go/paymentpathways.

American Medical Association 515 N. State St. Chicago IL 60654
phone: (312) 464-5000 fax: (312) 464-4184 www.ama-assn.org

We have received a very enthusiastic response from physicians to these educational materials and programs. It is clear that many physicians want to play a leadership role in creating a healthcare delivery system that will allow them to deliver high quality and efficient care to their patients. In drafting the ACA, Congress wisely allowed for a range of different organizational models to serve as ACOs, including physicians in "group practice arrangements" and "networks of individual practices" of physicians, because in most of the nation, patients receive their care from physicians in small, independent practices, not from large health systems. There are many examples of physician groups and independent practice associations across the country that take accountability for the overall cost and quality of care for their patients without having to deliver every service, including hospital care, for those patients. We urge that CMS, in preparing the regulations to implement Section 3022, do everything possible to facilitate participation by all the provider structures authorized in the law, and not inadvertently bias participation in favor of large health systems and hospital-dominated networks.

Antitrust and Anti-Kickback Safe Harbors Needed

The ACA explicitly authorizes the Secretary to waive requirements under the Civil Monetary Penalty statute, the Anti-Kickback statute, and the Ethics in Patient Referrals (Stark) law, and we urge you to establish a full range of waivers and safe harbors that will enable independent physicians to use existing or new organizational structures to participate as ACOs. In addition, we would urge you to work with the Federal Trade Commission to provide explicit exceptions to the antitrust laws for ACO participants. The AMA has argued throughout the debate on payment and delivery reform that physicians cannot completely transform their practices only for their Medicare patients, and antitrust enforcement could prevent them from creating clinical integration structures involving their privately insured patients. In addition, there needs to be provisions for continuing these waivers and safe harbors beyond the end of the initial agreement between the ACO and CMS (as defined in Section 1899(b)(2)(B)) so that any new organizational structures that are created to participate in the program do not suddenly become illegal simply because the shared savings program does not continue. To begin with, the AMA recommends that the government take the following steps:

- Establish a safe-harbor (from a presumption of anticompetitive market power) for independent physicians who join together to achieve the minimum scale necessary to participate in the Medicare shared savings programs, i.e., primary care professionals sufficient to treat a beneficiary population of 5,000 beneficiaries. In many communities, an ACO of this size would be viewed as having a large or dominant market share.

- Establish a safe-harbor for nonexclusive ACOs, i.e., those that do not prohibit their members, in law or in fact, from contracting with payers apart from the network.

- Recognize that an ACO may have a legitimate need to engage in exclusive dealing in order to eliminate free riding. Developing clinical integration programs is expensive and requires substantial investment to create and maintain the program. Once physicians are trained and have access to the necessary infrastructure, however, payers and physicians have incentives to "free ride" by cutting out the organization creating the clinical integration program. Exclusive dealing is a common method of preventing free rider problems and should be considered.

- Establish a safe harbor for innovative care delivery practices, such as physician practices offering additional services to patients in an effort to improve the quality and efficiency of the care they

receive, or other arrangements aimed at improving care coordination, quality and efficiency.

- Establish a safe harbor for gainsharing arrangements that meet criteria similar to those identified in the OIG Advisory Opinions on such arrangements. Features common to the permitted arrangements to date include:

    - specific, identifiable, and transparent cost saving actions and verifiable cost savings from those actions;
    - a ceiling on how much of the realized savings participating physicians could receive;
    - arrangements of fixed duration;
    - a floor on the minimum permissible use of certain services and materials, set in accordance with objective evidence;
    - provisions for participating physicians to make a patient-by-patient determination of necessary care and other patient-care safeguards;
    - disclosures to patients about the hospital and physician participation in cost-saving efforts;
    - equal distribution of cost savings among all participating physicians; and
    - reliance on third-parties to develop and monitor the gainsharing arrangement.

Multiple Payment Models and Transitional Approaches

It is important that payment changes be tailored as much as possible to support the specific changes in care delivery that will improve quality and control costs. Contrary to popular belief, physicians are willing to make changes that will result in higher-value care, but in many cases current payment systems do not give them the ability to do so or actually penalize them when they do. For example, physicians may be able to reduce the rate of hospitalizations and readmissions for chronic disease patients by employing nurse care managers to provide patient education and self-management support, but Medicare does not cover these care management services. The solution is not merely to give the physician a financial "incentive" to reduce hospitalizations, it is to provide the patient support resources the physician needs to do so.

A serious problem with the shared savings model in Section 3022 of the law is that it does nothing to provide physicians with the upfront resources and flexibility they need to reduce overall healthcare costs. Even if an improved program of care would ultimately reduce total costs and result in a shared savings payment that would cover the upfront costs of the program, many physicians cannot afford to make the upfront investment.

Moreover, particularly during the initial years of operation of an ACO, even if the ACO makes a significant impact on many aspects of care, it could fail to receive any shared savings payments if there are increases in the cost of the portions of care that it has not yet brought under control. This could discourage even large providers from making investments to improve portions of care delivery and transitioning to full accountability over time.

Fortunately, the final version of Section 3022 allows CMS to use partial capitation and "other payment models" to support an ACO in addition to the shared savings model. We urge CMS to implement the other payment models authorized by the ACA in order to support physician practices which need upfront resources and flexibility to transform care, and to support physician practices which could transition to full accountability over a period of several years. Innovative and flexible policies will benefit the

Medicare program by enabling more physicians to participate in the ACO program and to allow physician practices to take transitional steps toward better care coordination without making a sudden leap to a completely new delivery model. For example, physicians may want to offer a "warranty" on a particular set of services that they provide, hire care managers and accept comprehensive care payments for patients with a particular condition, or redesign care processes in other ways to improve quality and lower costs. Any of these actions would benefit the Medicare program and should be encouraged rather than discouraged.

Performance Measurement and Reporting

Congress clearly intended for the physician group practice (PGP) demonstrations to inform the ACO program, and the PGP projects do provide some important lessons, especially with regard to quality reporting:

- Patient selection and attribution methodologies are a major issue. The AMA understands that the patient assignment methodology used in the PGP demonstration was at times problematic, as beneficiary assignment was based on the plurality of care to any provider type regardless of specialty. It is hard to imagine that data precision and information sharing are going to evolve to such a degree in the next couple years that it will be possible to accurately assign all beneficiaries who may come in contact with one or more physicians affiliated with an ACO or to accurately attribute all the care that they receive. This will need to be a major CMS focus.

- The data collection tool used in the PGP demo was helpful in capturing and sharing data with CMS. The AMA urges that this tool also allow practices to verify the accuracy of their data prior to and after CMS makes incentive calculations. Further, CMS should explore making the data collection tool a secure web-based application rather than free-standing at each practice.

- The standards that may be appropriate for a pilot program in the Bronx may differ markedly from the standards for measuring results of a program serving patients in rural Texas. CMS should consult with measure developers like the AMA-convened Physician Consortium for Performance Improvement (PCPI) as it seeks to define "performance results," including whether this information is determined by a national benchmark or derived from individual group practice quality improvement that compares yearly progress.

The law does not require public reporting of ACO performance information, and we would urge that CMS approach both the collection and any reporting of such information thoughtfully to avoid having unintentional adverse consequences for patients. For example, neither physicians nor ACOs should be penalized for delivering care to individuals who are at higher risk for illness due to age, diagnosis, severity of illness, multiple co-morbidities, or who have economic and cultural characteristics that make them less adherent with established protocols, or literacy problems that make it difficult to comprehend basic medical information.

In setting up the quality measurement standards for ACOs, CMS should consider that the Physician Quality Reporting Initiative program includes only a small number of "intermediate" outcomes measures related to diabetes, chronic kidney disease, end-stage renal disease, and eye care. These focus on short-term outcomes, whereas true "outcome" measures are longitudinal and population-based. Additional resources and time are necessary to gather an evidence base, assess methodologies for risk-adjustment,

and test the measures for feasibility and reliability prior to broad based implementation across health care settings.

The AMA remains concerned about the low reliability of efficiency measures used in determining physician ratings or scores. Incorrect reporting of physician performance can mislead patients, disrupt patient/physician relationships, unfairly damage physician reputations, inappropriately redistribute physician compensation, and potentially generate negative unintended consequences for patient access to care. Currently, no single risk adjustment methodology is appropriate across a spectrum of conditions or episodes of care.

The success of any payment model for ACOs hinges on the use of an effective risk adjustment methodology. Successful ACOs will likely attract sicker patients (since they will receive better and more efficient care), and it is critical that those ACOs not be penalized for this. Development of a risk adjustment methodology must adequately address the complexities which arise from the multiple chronic conditions of the typical patient population. The process of risk adjustment model selection should be based on physician and other expert input and transparent to all stakeholders. It is essential that the risk-adjustment methodology be improved and standardized before savings targets are calculated and before any performance data is publicly reported.

The PCPI has long advocated for the use of measure sets. Reporting on a measurement set, as compared to a single measure in a set, provides a more comprehensive picture of the care being provided. Measure sets should include intermediate and long-term outcome measures based on a patient population.

ACOs should be allowed to report on a hybrid of nationally and locally focused quality measures related to their particular patient population, such as asthma measures if providing care in a region with poor air quality, or measures for a population where the ACO is explicitly seeking to reduce overutilization of services. Especially at this early stage when there is so much we do not yet know about ACOs, a one-size-fits-all approach would be a mistake.

Although the ACOs will need to report quality measures using health information technology, specifying quality measures for use in electronic health records is a complex, detailed process that requires the development of new specification sets. Measure developers, including the PCPI, are working on these specifications now, but they will need to be tested to ensure physicians can consistently use their electronic health record to accurately report quality measures.

Timely Provision of Performance Data

One of the biggest challenges that any physician organization will face in successfully serving as an ACO is getting recent data on the utilization of services by their current patients and getting rapid feedback on utilization of services during the course of the agreement period, particularly for services delivered by providers who are not part of the ACO organization. It is essential that CMS make such data available to providers well in advance of the initiation of the program, and that it provide timely performance information beginning with the first month of actual implementation. In addition, the AMA urges CMS to devote resources to providing technical support to small, independent physician practices and others who need to better develop the capabilities to be able to gather, analyze, review and act on data on their patients' care.

We look forward to working closely with CMS on these issues as the rulemaking process moves forward. Please do not hesitate to contact Margaret Garikes, Director of Federal Affairs, at 202-789-7409 or margaret.garikes@ama-assn.org if you have any questions or wish to discuss any of the topics we have raised.

Sincerely,

Michael D. Maves, MD, MBA