

Oct. 15, 2010

Given the new direction for the nation's health system, the AMA has developed *Health System Reform Insight* to help you understand the health system reform legislation and what it means to you and your patients.

AMA urges changes to antitrust and fraud and abuse laws at federal workshop on ACOs

AMA President Cecil B. Wilson, MD, participated in an Oct. 5 federal workshop on legal issues and accountable care organizations (ACOs). The Federal Trade Commission (FTC), the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) sponsored the workshop.

Among the topics covered during the workshop was the ACO/Shared Savings model, which is one method of delivery and payment reform authorized in the Affordable Care Act (ACA). The CMS must implement this voluntary program beginning Jan. 1, 2012, and is drafting a proposed rule that will specify the structure and requirements any entity must meet in order to voluntarily participate in the program. The proposed rule is expected to be issued by the end of this year.

The AMA has long argued that antitrust enforcement and applications of the fraud and abuse statutes, such as the Stark, anti-kickback and civil monetary penalties, conflict with efforts by physicians to implement innovative delivery reforms around care coordination and integration, such as adopting health IT.

Recognizing the potential for these laws to hamper the adoption of delivery reforms that encourage



KEYDATES

Oct. 27

The AMA will host "Understanding your Medicare choices: Preparing for the 2011 Medicare participation decision," a webinar at 7 p.m. Eastern time Oct. 27. The program will explain the three options physicians have with regard to Medicare—participation, nonparticipation, or opting out and privately contracting with patients—and spell out the advantages and disadvantages of each. [Register today.](#)

Dec. 1

Medicare payments for physician services are scheduled to be cut by more than 23 percent.

Dec. 31

From mid-November through Dec. 31, physicians will have their annual opportunity to review and perhaps change their participation status with the Medicare program.

IMPORTANT LINKS

[AMA comments on ACA implementation regulations](#)

[Investments in disease prevention and wellness initiatives under the Affordable](#)

integration, such as ACOs, the FTC, the CMS and the OIG have been working in an unprecedented cross-agency collaboration to address physicians' and other providers' concerns.

During the workshop, FTC Chairman Jon Leibowitz and Inspector General Dan Levinson both said they are willing to contemplate certain safe harbors or waivers from the application of the antitrust and fraud and abuse statutes for entities that volunteer and qualify for the ACO/Shared Savings program.

AMA recommendations

The [AMA's written comments](#) and Dr. Wilson's comments during the workshop included the following:

"Physicians in solo or small practices will need to coordinate their activities with one another in order to successfully serve as ACOs. This is where the intersection between ACO formation, antitrust enforcement policy and the nation's fraud and abuse laws occurs and where legal barriers must be lifted.

"Physicians cannot completely transform their practices only for their Medicare patients while being prevented by antitrust laws, as well as other legal prohibitions, from pursuing integrated care for their privately insured patients.

"Physicians must have the legal ability to transform their practices and pursue integrated care for both their Medicare and non-Medicare patients. In this era of pursuing new payment and delivery reforms, greater flexibility in antitrust and other laws is necessary to enable physicians to successfully organize, take part in and sustain system reforms that improve the quality of health care services and lower health care costs.

"This will ensure that delivery reforms are physician-led and do not result in more consolidation of large hospital-dominated networks or already existing large physician groups."

Accordingly, the AMA supports the establishment of a full range of waivers and safe harbors that will enable independent physicians to effectively

[Care Act](#) 

[New HHS Web portal to help consumers buy health insurance](#)

[AMA summary and analysis: 2011 Medicare Physician Payment Proposed Rule](#) 

[Pathways for physician success under health care payment and delivery reforms](#) 

[How reform law integrity provisions impact your practice](#) 

[Medicare payment adjustments made for 2010](#) 

[Independent Payment Advisory Board](#) 

[New payment and delivery reform models](#) 

[Overview of major provisions relating to coverage](#) 

[Taxes and credits in the health system reform law](#) 

[Major Medicare savings under health reform legislation](#) 

[Health reform law raises GPCIs](#) 

[How health system reform affects patients](#) 

[How health system reform impacts physicians' practices](#)

FOLLOWUS

participate in ACOs.

Antitrust safe harbors

Regarding antitrust safe harbors, the AMA recommends the following.

ACO efforts should not fall under the per se rule

To encourage a variety of physician group practices, networks of individual practices, and partnerships between hospitals and health care professionals to participate as ACOs, those that meet the ACA eligibility criteria for designation as an ACO should be deemed sufficiently integrated for purposes of avoiding the antitrust per se rule against price-fixing. This is necessary to accommodate the varying organizational structures that physicians will need to form to participate in the program.

Market power and exclusivity dealings should be reconsidered in the context of ACOs

Because of geography and through no fault of their own, some physician networks that wish to participate as ACOs will have large market shares. They also will likely need to engage in exclusive dealing to develop and maintain ACOs, including clinical integration initiatives.

High market share and engagement in exclusive dealing that ultimately benefit consumers and lower health care costs should pass antitrust muster. Greater flexibility in antitrust enforcement policy pertaining to market power and exclusivity dealings is needed to encourage physician participation in ACO efforts.

Safe harbors, exceptions, exemptions or waivers should continue beyond the expiration of the Shared Savings program

Any safe harbors, exceptions, exemptions or waivers allowed under the Shared Savings program should continue beyond the program's expiration date so that any organizational structure participating as an ACO does not become illegal overnight simply because the program is discontinued. Physicians will be discouraged from investing and taking part in new delivery and payment models if the legal protections afforded to



them suddenly expire.

Fraud and abuse safe harbors

Regarding fraud and abuse safe harbors, the AMA recommends the following.

Waiver of—or safe harbor under—the requirements of the civil monetary penalty statute section

The civil monetary penalty statute is a significant barrier to the development of gain-sharing programs that have the potential to lower health care costs and improve the quality of care. The AMA recommends that the OIG adopt a safe harbor for gain-sharing arrangements that meet criteria similar to those identified in the OIG Advisory Opinions on such arrangements.

Waiver of—or safe harbor under—the requirements of the anti-kickback statute

Physician-driven networks seeking to create an ACO are not on a level playing field with hospitals and health insurers in terms of existing anti-kickback statute safe harbor protection. While physician organizations may employ physicians and thereby take advantage of the anti-kickback statute employment safe harbor, that safe harbor may have limited application to many physician organizations interested in forming an ACO.

Accordingly, physician organizations that are integrating in an effort to become ACOs must have a safe harbor as well. Those organizations are likely to exercise a commensurate degree of control over the physician members' referrals and practice patterns, as do hospitals and health insurers under their applicable safe harbors.

Waiver of—or exception to—the requirements of the Stark law

Lack of certainty with regard to the Stark law will hinder physicians' efforts to form ACOs, because any noncompliance with the Stark law requirements results in sanctions, regardless of a physician's best efforts.

Accordingly, 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.

Conclusion

The AMA will continue to urge the FTC, the CMS and the OIG to adopt the above safe harbors and waivers. Stay up-to-date on [the AMA's efforts on this front](#).

Feedback

If you have specific comments on this edition of *Health System Reform Insight* simply reply to this message. For more general feedback on *Health System Reform Insight*, send an e-mail to hsr@ama-assn.org to alert the editor of your comments and concerns.

You are signed up as bklynacade@aol.com

[Update your e-mail address](#)

To unsubscribe: [click here](#) to bring up a new e-mail message and click "send." No subject line is necessary.