America's Health
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Centers for Medicare & Medicaid Services
Attn: ACO Legal Issues
Mail Stop C5-15-12
7500 Social Security Boulevard
Baltimore, MD 21244-1850

Sent via e-mail to: ACOlegalissues@cms.hhs.gov

Dear Sir or Madam:

I am writing on behalf of America's Health Insurance Plans (AHIP) in response to the invitation for comments or statements for discussion at the public workshop on certain legal issues related to Accountable Care Organizations (ACOs) to be hosted by the Federal Trade Commission (FTC), the Centers for Medicare & Medicaid Services (CMS), and the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS) on October 5, 2010.

AHIP is the national association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of health insurance products in the commercial marketplace and have demonstrated a strong commitment to participation in public programs.

AHIP and its members have devoted substantial time and resources to working with providers and others to provide consumers with higher quality, more affordable, and more accessible healthcare. We believe that ACOs offer both opportunities and challenges for the healthcare system. Those ACOs that face forward, representing novel and improved approaches to patient care and provider reimbursement, have tremendous promise. Those that face backward, however, representing simply the desire to engage in joint negotiation or aggregate market power, will leave consumers with decreased access, lower quality, and higher prices.

Specifically, we would like to make the following points for the agencies' consideration:

- ACOs can be an important part of transitioning from volume to value-based payment, improving quality, helping to bend the cost curve, and generally improving our health care system.

- ACOs, however, will not provide such benefits to consumers if they are mere vehicles for price fixing or aggregating market power, and the antitrust agencies must continue their efforts in this area, using enforcement, guidance, and other tools.
- The impact of the physician self-referral prohibition, the anti-kickback statute, and the Civil Monetary Penalties (CMP) laws on ACO formation is an appropriate subject for further examination. The agencies must continue their longstanding efforts, under these laws, to preserve the professional independence of health care providers and protect patients from improper relationships that may lead to inappropriate treatment or other potential harms. At the same time, to the extent that these laws pose specific impediments to the formation of beneficial ACOs and the impediments can be addressed without raising the possibility of consumer harm, the agencies should consider safe harbors, advisory opinions, or other regulatory mechanisms for reducing such impediments through narrowly tailored exceptions or waivers.

I. Antitrust Issues

A. Facing the Future: ACOs need to align incentives, utilize information, or otherwise lead to a more effective and efficient health care system

Much has been written on the potential benefits of ACOs, and we will not repeat that discussion here. AHIP and its members have been vital participants in the progression of ACOs from theoretical constructs to viable entities. Indeed, health insurance plans can play vital roles in ensuring that ACOs have risk sharing, information technology, and other resources necessary for them to deliver on their promise to consumers. The attached paper discusses, in greater detail, AHIP's perspective on the potential for ACOs, the role of health insurance plans in ACOs, and possible issues raised by ACOs.

From the perspective of the October 5 discussion, however, it is important to note that the very analysis that must be used to determine whether a particular ACO is a "positive" for patients, employers, and plans is the analysis that antitrust agencies have used in their rule of reason analysis, both generally and specifically with respect to provider joint ventures, for many years. That is, on balance, will the entity lead to net benefits to consumers—in the form of lower prices, higher quality, or both—or will it lead to net harm to consumers—in the form of higher prices, lower quality, or both. Those ACOs that, in a forward-facing fashion, use realigned incentives, better information, and other tools to lower the cost of care and improve quality are not merely sufficient to pass antitrust analysis, but may well be necessary to move our system into a "value not volume" era. AHIP and its members will be actively engaged in the process of creating, assisting, and working with such ACOs.

B. Facing the Past: ACOs should not be developed for primary purpose of joint negotiation or amassing market power to raise prices

The FTC and the Department of Justice have a long history of distinguishing between those provider ventures that are likely to benefit consumers and those that are likely to raise prices or otherwise result in consumer harm. Through advisory opinion letters, business reviews, statements, and other guidance, the agencies have provided a wealth of information for providers looking to "get it right" in working together. Similarly, various enforcement actions throughout the years, supplemented by the explanatory information provided by the agencies, provide detailed materials on the ways that such ventures can "get it wrong" under the antitrust laws. We applaud the agencies both for their extensive guidance and for their vigilance in ensuring that harmful practices are stopped and beneficial ones are allowed.

The October 5 workshop addresses the two key ways in which provider ventures can create problems under the antitrust laws. With respect to clinical integration, we believe the circumstances under which independent health care providers in an ACO can engage in joint price negotiations have been extensively covered by the various forms of agency guidance mentioned above. The formation of an ACO does not change the analysis contained in such guidance, but can and should be informed by this analysis.

The second portion of the program on the morning of October 5 will address an area in which there is perhaps less guidance to date. The specific topic—ways to encourage formation of multiple ACOs to generate the benefits of competition—is a complement to the issue of ensuring that ACO formation does not lead to problematic concentrations of market power. Indeed, AHIP recently held a panel discussion on the above subject that is intended to be part of an ongoing dialogue to further analysis in this area. The panel identified a number of issues that bear further consideration as the market power issue is examined. These include: (1) whether there is a minimum efficient scale for an ACO to achieve desired results; (2) whether it is possible and desirable to limit ACO participation to this scale; (3) whether different rules should govern ACO formation depending on total population and population density; (4) whether non-exclusivity offers meaningful protections of competition; and (5) whether exclusivity may, in fact, enhance competition if limited to ACOs below a certain scale. Panelists also noted that the concerns of ACO market power are not limited to the private market, but may undermine the incentives of ACOs to achieve savings goals in Medicare. We believe that the agencies should examine these and other factors in trying to achieve an appropriate balance of *clarity* to allow all market participants to assess antitrust issues in making ACO-related decisions and *flexibility* to recognize that specific market context is ultimately vital to whether market power can be created and exercised. We share the goal of ensuring that ACOs benefit patients through becoming competitors in the marketplace, rather than becoming the marketplace itself, and stand ready to provide further assistance to the agencies as desired.

C. Recommendations

To help ensure that intended quality and cost goals are met, we urge the agencies to facilitate competition by encouraging the exploration and formation of a wide range of structural models. A one-size-fits-all approach to structuring ACOs is not likely to result in any long-term success. Models need to vary based on several factors, including provider readiness and the individual needs of communities. Additionally, the structure, scope, and processes of models should evolve over time as needs, technology, sites of service, and clinical approaches change and as more is learned about current programs' effectiveness in engaging patients and providers and improving outcomes.

There are a variety of ACO models that have the potential to achieve quality and cost benefits. Such models not only include large integrated health systems, but also could include models that involve smaller physician groups, models that are formed by or in partnership with health plans, and alternative approaches that may be effective when providers are not equipped to assume high levels of risk. Encouraging the development of a range of structures will help promote innovation and drive improved quality and affordability of health care.

Three examples from health plans demonstrate both the commitment of health plans to ACOs and the variety that such models can and should reflect:

- **Geisinger Health System ProvenHealth Navigator, PA.** The ProvenHealth Navigator program redesigns primary care to delivery higher-quality, more efficient care through the principles of a patient-centered primary care in collaboration between the Geisinger Health Plan and Geisinger Health System physician practices. The program offers patients integrated, clinical care coordination and support management around the clock. Participating physician practices need to meet quality, member-experience, and efficiency targets to achieve success and include the following elements into their practice: patient-centered primary care team practice, integrated population management, care systems management, quality outcomes program, and a value reimbursement model.
- **CIGNA and Piedmont Physician's Group**. CIGNA has several collaborative accountable care efforts, such as this one, with medical groups and health systems throughout the United States. These partnerships are rooted in the improvement of quality and affordability on a population basis where physicians monitor and coordinate all aspects of an individual's medical care. They include enhanced care coordination programs which reward physicians through a modified reimbursement model combined with a pay-for-performance structure if target quality measures and medical costs improve.
- **Regence Blue Shield of Washington and Boeing.** The Intensive Outpatient Care Program is collaboration between Regence Blue Shield, medical groups, and Boeing to

identify and manage the health care quality and cost of Boeing employees with complex chronic conditions. The program aims to improve clinical quality, patient satisfaction, and patient health status by delivering quality health care resulting in lower costs for Boeing and long-term affordability for Boeing employees.

II. Fraud and Abuse Laws

A. Examining the Possibility of Narrow Exceptions, while Maintaining a Focus on Protecting Patients

Finally, we commend the agencies for taking a careful look at whether and how the fraud and abuse laws create impediments to beneficial ACOs. While we believe that the antitrust laws create no such impediments, we recognize that better information may need to be gathered as to whether, and how, the fraud and abuse laws may create impediments.

We caution, however, against sweeping changes to the laws intended to protect patients from over- and under-utilization under the federal health programs. Changing these laws runs the risk of harming patients by incentivizing compensation and reimbursement practices between hospitals and physicians that result in inappropriate and unnecessary treatment, under-provision of care, or limiting flexibility in designing treatment options tailored to individual patients. Instead, the agencies should issue narrowly tailored guidance, based upon the existing legal framework regarding the types of structural and compensation relationships permitted/allowed in connection with persons receiving bundled payments.

The agencies have existing authority to tailor specific exceptions to the fraud and abuse laws that will promote the independence of physician's treatment decisions and protect patients from harm while at the same time allowing sufficient flexibility in the development of ACOs. In addition, the agencies should conduct a study, after the guidance has been in effect for a period of time, to verify whether the exceptions are working to encourage the creation of ACOs without harming patients.

Thus, we commend the agencies' focus on detailed explanation of impediments to beneficial ACOs and how current exceptions and safe harbors may be inadequate to allow the creation of beneficial ACOs. Only with such information can the agencies decide whether any actions are necessary and, if so, what is the best approach to address such impediments. We will be addressing these issues in further detail in your panel on the afternoon of October 5.

B. Recommendations

To ensure that patients benefit both from the protections of the fraud and abuse laws and the improvements offered by ACOs, we urge the agencies to continue their careful examination

of whether these laws create any barriers to ACOs and, if so, how to address them. If the agencies conclude that there are barriers that can be addressed, we encourage them to do so in a narrow fashion to ensure that consumer protections are not lost in the process. Specifically, if there are continuing compliance questions regarding permissible relationships, the agencies should encourage entities planning on participating in these relationships to take advantage of the regulatory process for seeking new safe harbors to the anti-kickback rule or to seek advance advisory opinions from the OIG. This type of open process allows an appropriate forum for seeking safe harbor protection if desired.

III. Conclusion

We appreciate the opportunity to submit comments and look forward to working with CMS, OIG, the FTC, and others to ensure that ACOs are best able to deliver on their promise of better, more coordinated, and more efficient care for consumers.

Sincerely,

Joseph Miller
General Counsel

Attachment