Charles N. Kahn III
President and CEO

October 27, 2010

The Honorable Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

The Honorable Jon Leibowitz
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

The Honorable Daniel Levinson
Inspector General
330 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Medicare Program; Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-kickback, and Civil Monetary Penalty Laws: CMS 1356-N 75 *Fed. Reg.* 57,039 (Sept. 17, 2010)

Dear Sirs:

The Federation of American Hospitals ("FAH") is the national representative of nearly 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural America, including inpatient rehabilitation, long-term acute care, cancer and psychiatric hospitals. We appreciate the opportunity to provide input to the Federal Trade Commission ("FTC") and the Department of Health & Human Services ("HHS"), including the Centers for Medicare & Medicaid Services ("CMS") and the Office of Inspector General ("OIG"), regarding accountable care organizations ("ACOs"), and implications regarding antitrust, physician self-referral, anti-kickback, and civil monetary penalty issues.

The Patient Protection and Affordable Care Act ("the Act" or "PPACA") focuses on the creation of a new structure, the ACO, to pursue the delivery of high quality, coordinated health care on a more efficient, patient-centered basis. To allow these structures to be pursued quickly, Congress also established a number of requirements which it felt would need to be met to achieve the desired goals. These requirements address the need for a legal structure to receive

and distribute shared savings, but permits ACOs to be formed by a variety of entities in order to provide more coordinated and efficient delivery of health care services. The Act also addresses the requirements with respect to processes to promote evidence-based medicine, data reporting, and care coordination, as well as the need to demonstrate an effort to meet patient-centeredness criteria.

As the FTC, CMS and the OIG (collectively, "the Agencies") have also recognized, there is great potential for a qualifying ACO to enhance the quality and efficiency of care delivery outside of the Medicare and Medicaid populations, and in particular into the commercial market. The issue to be addressed in this context, is whether and how to create a safe harbor so that these qualifying ACOs can also "have some certainty" in their dealings with commercial payers.

What follows are comments by the FAH with respect to this issue, formatted around a number of those issues raised in the Notice of Meeting published on September 17, 2010 and during the ACO Workshop that the FTC, CMS, and OIG conducted on October 5, 2010.

ANTITRUST LAWS

<u>Question 1:</u> Should there be a "statutory requirements" safe-harbor, such that when an ACO meets the integration requirements established by CMS for the Medicare program, and is approved by CMS, the antitrust agencies should refrain from an enforcement action for price fixing if the ACO uses the same organizational structure in dealings with private payers, and instead treat the arrangement as one for review under the rule of reason?

The FAH strongly believes that such a safe harbor is necessary. The absence of such a safe harbor will retard the spread and potential benefits of ACOs, both in Medicare and the commercial market. This will likely result from several factors. First, most providers do not seek to organize themselves solely around participation in the Medicare program. Second, the effort required to build an ACO solely for a Medicare population may be cost prohibitive. Third, the pursuit of the "Triple Aim" goals of the ACO effort should be shared and encouraged into the population as a whole. Specifically, the pursuit of one high level, evidence-based, coordinated care delivery model will help to create consistency in delivery, quality, and processes and avoid unnecessary and costly segmentation.

<u>Question 2:</u> To what extent should the Agencies be prescriptive in establishing requirements over and above those in the Act?

There are many delivery models that provide coordinated, evidence-based care. These models are found in a broad range of organizational structures, from fully integrated systems to clinical affiliation models. The provisions in the Act were designed to indicate what Congress thought the core requirements for such systems should be. To foster innovation and maintain flexibility, there should be fewer, rather than more, prescriptive requirements, as long as the Triple Aim goals are what the ACO is pursuing.

In addition, the Agencies must recognize that some models of accountable care delivery that can satisfy the ACO goals may have a more integrated unitary corporate structure than others (*i.e.* a faculty practice plan and an academic medical center within a single entity), or an enhanced ability to employ physicians (*e.g.*, tax-exempt or governmental providers). The approach to be taken by the Agencies should not tilt the competitive landscape to favor one structure over another, or allow more market power flexibility for one approach over another, such that tax-paying community hospitals with predominantly voluntary medical staffs are disadvantaged in the ability to establish an ACO.

Question 3: Should the shared savings program of the Act be sufficient sharing of financial risk to incentivize a change in practice patterns?

Yes. The requirement with respect to ACO participation has been set at a floor of 5,000 Medicare lives over a three-year period. Coupled with the other requirements for clinical coordination, group structure, leadership and management of clinical processes, and the data requirements, there should be ample sharing of financial risk across the group to address concerns with respect to overall integration and to qualify for safe-harbor treatment. In this context, it is important to remember that the safe harbor would not be designed to automatically eliminate antitrust scrutiny, and that any such scrutiny would be under the rule of reason.

Question 4: Will the ACO requirements be sufficient to change practice patterns sufficiently for a safe harbor based on those requirements? In other words, should there also be a requirement of significant human and monetary capital investment and selective choice of providers to participate in the program?

The requirements articulated by Congress are those which are believed to be sufficient to achieve the goals intended. They include the defined processes with respect to evidence-based medicine, data reporting, and care coordination. These will provide the framework for ensuring a good faith pursuit of the goals. In this context, it will inevitably require a significant "human investment" to participate in the ACO and achieve its objectives. There need not be a capital investment (as Congress itself did not establish one as a priority), as that is not the determinant of meaningful participation in the processes, governance and effort required to achieve the goals. In addition, requiring as a threshold commitment a "significant capital investment" in and of itself, does little to truly measure or promote commitment and participation over the required three-year period. Rather, a requirement of a three-year commitment of participants, a commitment to quality improvement goals and processes, and to providing necessary data, coupled with a meaningful review, and if necessary, disciplinary process, will be far more important to enhancing the chances of success.

Question 5: How should issues related to exclusivity and market share be addressed?

The ACO statutory requirements do not address exclusivity or market share. Exclusivity and the measurement of market share are issues that relate to concerns about market power, rather than successful care delivery. It is also an area where the FTC (and the Department of Justice) has historically supervised the results of an improper use of exclusivity, whether on the part of providers or on the part of payers. We do not think a special requirement should

supersede the existing framework in this area, particularly where exclusivity has not been proven to be critical in achieving the desired results, a view that was reflected by the antitrust panelists on October 5th. We also note that in viewing this issue, again, there should be consideration of the need to maintain a level playing field between systems which have varying degrees of corporate integration and regional market power.

Question 6: What ACO performance metrics should the antitrust agencies examine to determine the competitive effects of an ACO in the market?

An ACO is ultimately a joint undertaking between a participating group of providers. The effects of that effort should be reviewed in light of public policy objectives of the Act, but in a manner consistent with other joint undertakings the agencies currently review in the health care markets. The permissible performance metrics should be familiar and widely used, but not static for purposes of all potential ACO models.

Question 7: What happens if in the short term there are price increases and no measurable quality improvements?

Meeting the PPACA requirements of an ACO do not guarantee success. Rather, it is a commitment to use certain required approaches, in good faith, to pursue the articulated goals. If the systems are in place, and they are functional (subject to CMS monitoring), then the safe harbor should continue in its application for the initial period. At that point, the results can be assessed, and a future determination reached. It is important to be cautious in requiring strict performance results, as this may incentivize behavior which may not lead to the desired effects. Finally, our view is also that if it is determined that the required processes are not being operated in good faith, then there should be an appropriate review process, which may result in a removal of the approval for an ACO, and the elimination of the protection of an ACO safe harbor.

Question 8: Should there be a minimum size for success in the commercial markets?

Consideration must certainly be given to the variety of markets and populations involved. The PPACA's ACO minimum of 5,000 already creates a size benchmark determined to be sufficient. Thus, we do not see a need for an addition benchmark of, for example, 5,000 commercial lives from a single payer to operate an ACO in the commercial market.

Question 9: Are there certain types of ACOs that seem to threaten competition more than others?

While the proper answer may turn on a market-by-market review, as noted above, the FAH is concerned about any framework that would affect a level playing field between all the potential competitors who may wish to form an ACO. Thus, it is important to create the flexibility that will allow an independent medical staff membership to participate on a level basis with a hospital-employed physician base, or a tightly affiliated faculty practice plan.

<u>Question 10:</u> Should measurable improvement standards be set, and if so, should they vary by type of measure—process measure vs. outcome measure vs. patient experience measure?

As we have noted, Congress did not require measurable results to participate in the ACO program. Thus, we discourage setting of mandatory measurable improvement standards. Such standards could stifle the very innovative efforts that the law was designed to incentivize to promote the coordination and efficiency of care delivery. In addition, at this point, it is not known just what the right balance between measures might be, or what all the measures that might be used may achieve. Thus, this part of the program should be given time to develop.

For now, we believe the best approach is to adopt a series of goals or targets, based on national quality standards, and based on the required processes for the first phase of implementation. These should be consistent with those generally used by Medicare in other programs to incentivize enhanced quality, and which are consistent with the commercial marketplace measures now generally in use. To mandate standards, particularly new standards, without cognizance of potential impacts, both local and more widespread, would seem unwise and premature.

In a slightly different vein, during the course of the Workshop session, a question also arose with respect to the need for an electronic health record ("EHR") and participation on a community information or data exchange as a part of the safe harbor requirements. To be fully effective over time, a community should have full EHR capability and data exchange capacity. We note that under a separate law, Congress does not require full EHR implementation until 2015. Therefore, it does not seem appropriate, particularly in this era of scarce resources and economic uncertainty, to impose an EHR requirement for ACOs earlier than Congress has already determined for the remainder of the industry. We also must recognize that in many areas, existing health systems provide the type of coordinate care that policymakers are seeking without this type of information technology overlay, as was reflected by panel participants on October 5th.

PHYSICIAN SELF REFERRAL, ANTI-KICKBACK, AND CIVIL MONETARY PENALTY LAWS

I. Waiver:

- **a. Question: Some have suggested that waiving the application of Stark, Kickback and CMP to distribution of shared savings will positively impact the development of ACOs.**
  - **i. Do you agree/disagree?**
  - **ii. And if HHS agencies decide to exercise waiver authority in that direction, do you have any recommendations on what needs to be stated in the waiver to accomplish these goals?**

To provide a fertile field to develop truly innovative, coordinated care models, the fraud and abuse laws should be waived altogether. Depending on the particular innovative model and participating providers, the fraud and abuse authorities can be, at a minimum, an impediment and, at a maximum, a total barrier to the adoption of ACOs and other innovative care models. These legal authorities were developed to address concerns about the improper incentives related to the traditional methods that Medicare and Medicaid employs to cover and pay for health care services. Through its clinical care innovation sections, PPACA seeks to change the old care delivery paradigm and move toward a more provider-integrated, quality-driven, patient-centered approach. With the new approach to care delivery, the focus of the fraud and abuse authorities must also be shifted to enhance the adoption of new innovative care models.

The laws governing Medicare ACOs and the Medicare and Medicaid Innovation Center provide authority for CMS and OIG to waive Medicare program requirements and fraud and abuse laws. While such waivers have been allowed in demonstration projects before, this seems to be the first time such waivers are available in a permanent program. The FAH agrees with Inspector General Levinson that the OIG's enforcement and oversight authorities should be used judiciously. A few bad actors that take advantage of existing systems should not thwart the goals of ACOs or compromise patient care.

The FAH urges CMS and the OIG to use its waiver authority in a way that promotes a level playing field. If HHS is truly interested in promoting new coordinated care delivery models, then (again) a simple waiver of all fraud and abuse laws should be the policy. However, if only certain fraud and abuse authorities are waived, the waivers should be available to all providers who may wish to implement ACOs. We strongly believe that waivers should not be granted on a case-by-case basis to promote a particular innovation model; judicious use of waivers can still promote a variety of care delivery models and promote innovation. Finally, a level playing field is also a more efficient approach to incentivize a large number of participants in the ACO program.

b. Question: If HHS does exercise its waiver authority related to the shared savings distribution, is it necessary to apply the waiver to other financial relationships within ACO?

i. If so, what should the waiver apply to and why is it necessary?

The scope of protection should go beyond simply the financing arrangement which may apply to the distribution of shared savings. When a program is set up, there is no guarantee that there will actually be any savings to share. Participants who act in good faith in operating ACOs, should be afforded protection for their participation in the care coordination, cost savings, and quality improvement activities within these models and those protections need to be flexible to promote innovation. The extended protections should include, for example, the contribution issues around capitalization of infrastructure and the permissibility of various approaches to ownership and control of the ACO entity.

c. Question: This waiver may also apply to many different types of providers and business arrangements.

i. Can you please talk about the different types of business arrangements that may need the waiver in order to function as an ACO?
1. **Hospital/physician group joint ventures or other affiliations?**
2. **Group Practice?**
    a. **Large vs. Small Group Practice?**
3. **Rural vs. non-rural?**
4. **Other practitioners, such as NPs?**

ii. If the waiver is exercised, should it be structured differently as applied to different types of providers?
1. **Example, will rural and non-rural ACOs be different enough that a waiver should treat them differently?**

iii. Are there state law considerations -- such as corporate practice of medicine rules -- that we should take into account when considering a waiver?

Again, the FAH urges a level playing field and a uniform approach to granting waivers to promote innovation. We believe tailoring specific waivers to specific provider groups will complicate policy in this area, and is likely to lead to uncertainty in the field. If CMS and the OIG were to decide to tailor specific waivers for particular types of providers, those waivers should be available to all providers of that particular type, and not granted on a case-by-case basis. For example, we recognize that Critical Access Hospitals ("CAH") may deserve different treatment than other hospital types, but the waiver available for CAHs should be the same for all CAHs.

Many states have laws that are similar to the federal physician self-referral, anti-kickback, and civil monetary penalty laws. While those laws are not an impediment to Medicare care delivery models, they could easily be barriers to expanding new innovative models to Medicaid and other patient populations. Therefore, CMS and the OIG should consider the impact of their waivers on state laws and how those laws may affect broader implementation of ACOs and other innovative care models.

Regarding corporate practice of medicine, PPACA appears to create a problem as it states only that "hospitals that employ physicians" can participate in ACOs. However, PPACA also provides general authority for HHS to permit any other provider group to participate in ACOs. We urge CMS to use the two grants authorities to permit all hospitals to be eligible to participate in ACOs, whether they employ physicians directly, are in corporate practice of medicine states, or rely solely on a voluntary medical staff model. This is a fair outcome and can be achieved under existing authority.

d. Question: Should the same waiver conditions apply with respect to Stark, AKS, and the CMP or are there different considerations that should be taken into account with respect to the different statutes?

i. Should compliance with a Stark exception be sufficient for purposes of a waiver of Kickback and CMP?

As a general proposition, the same waiver conditions should apply with respect to the referenced fraud and abuse authorities. However, where there are differences in the policies that create two sets of rules (*e.g.*, set in advance requirements), it may be necessary for a waiver to be designed to address the separate authorities in different ways.

II. Safeguards:

a. Question: As ACOs develop, what requirements should be instituted in order to protect patients and focus on giving best care to individuals?

The design of the innovative models and their ability to produce desired outcomes related to quality and cost containment are the best way to foster efficient and effective care for patients. These programmatic goals will help determine whether any particular savings can be shared. However, we do not believe the particular goals surrounding programmatic parameters should be conditions that affect the applicability of a fraud and abuse waiver. As stated above, a program can be established in good faith to achieve those goals, but not actually result in any shared savings. It would be inappropriate for an ACO to lose its fraud and abuse protections simply because the program did not achieve those goals, and for participating providers to be potentially subject to retrospective enforcement actions. Instead, if an ACO is underperforming against its goals, it should lose its ACO status as well as its protections on a prospective basis without risk of retroactive enforcement.

b. Question: Transparency. If CMS requires transparency in ACO governance, ownership, investment, and/or distribution of shared savings, does that protect important interests and assist in providing better care and lowering costs?

i. What concerns do you have with transparency?

Transparency is an important goal that the FAH supports in the context of innovative care models. Outcomes related to those programs should be readily available to the government and patients for oversight purposes. We believe the same is true for ownership and governance structures. However, we do not believe transparency policies should be extended to allow public access to particular financing arrangements or to related proprietary information that could affect the free market with regard to health care delivery. The FAH believes that inherent in the goal of innovation is the entrepreneurial spirit, and that health care providers, like other businesses, should be encouraged to conduct their affairs in an innovative way with basic protections that promote free and fair competition.

c. **Question: What types of monitoring should the government require in order to best serve patients and to ensure that ACOs are improving healthcare quality and efficiency?**
    i. **Self-monitoring (e.g., compliance plan/utilization review) vs. government monitoring.**
    ii. **What role does Health IT and EHRs play?**

We believe the primary method of monitoring should be self-monitoring by ACO participants within prescribed parameters. Hospitals have long operated under utilization review and quality assurance protocols and corporate compliance programs, and those concepts are easily transferrable to an ACO and other innovative care model. We believe a separate survey and certification process is not only unnecessary, but would add redundancy, inefficiency and costs to the ACO equation. We support an approach (similar to existing processes) whereby the ACO provides a filing to CMS with requested information accompanied by an officer certification/attestation that the requirements are met.

Many believe, including the FAH, that health information technology and EHRs will play a critical role in transforming how health care is delivered. However, because we believe in a level playing field, we do not believe that whether a provider or a set of providers are using EHRs as part of their ACO is a necessary protection for patients. As noted by several panelists on October 5th, EHRs are not essential to achieving the desired outcomes of ACOs, and therefore should not be a requirement for a waiver or for separate patient protections. Other policies are driving the adoption of EHRs and there is a very specific timeline for incentive for adoption. Given the cost and administrative burden of implementing these systems, requiring an EHR for an ACO at this stage would likely provide a roadblock to a large volume of participants and discourage innovation.

d. **Question: Are different safeguards necessary or appropriate for different types of ACOs?**
    i. **Rural ACOs?**
    ii. **Group practice only?**
        1. **Large vs Small Group Practice?**
    iii. **Non-physician practitioner?**

The FAH believes in a level playing field, and does not believe that different safeguards are necessary or appropriate for different types of ACOs. However, CAHs may require different safeguards from those of other hospital types, but all CAHs should benefit from any special policies.

e. **Question: What type of governance structure and formal legal structure is optimal for ACOs to achieve success?**
    i. **Is dictating specific terms and requirements of an ACO structure helpful because it provides certainty or harmful because it may increase transaction costs or chill innovation?**

Congress did not dictate a particular type of governance or legal structure, because we presume it did not believe strict parameters in this area would help foster a truly innovative environment. Moreover, at this point, it is difficult to say whether there is an optimal structure. The FAH urges CMS and the OIG to refrain from dictating specific terms and requirements for an ACO structure. Any regulatory policy in this area should reflect the statutory parameters and nothing more. To add a regulatory overlay in this area would likely stifle, not promote innovation.

f. Question: What sort of safeguards might best ensure the cost containment goals of ACOs?

i. Should risk-based arrangements between and among ACO network participants be encouraged?

The statute permits a variety of payment models, but is not overly prescriptive in encouraging one model over another. Risk-based arrangements are an available model, and may likely prove to be a preferred model over time, but we do not believe CMS should encourage or direct one approach over another. Instead, CMS should allow participants to determine what works best for them in individual markets, and structure their ACOs accordingly.

III. The Future

a. Question: For existing ACOs and innovative delivery systems, what is working now under the fraud and abuse laws?

i. How do we build on this?

Under existing fraud and abuse laws, it is easier for hospitals to establish an ACO with employed physicians than it is to do so with members of a voluntary medical staff, due to differences between the employment and personal services exceptions/safe harbors. This reality has allowed truly integrated delivery systems with physician employment models and academic medical centers with faculty practice plans to already advance in this area.

To build on this, community hospitals that operate with predominantly voluntary medical staffs should benefit from changes to the fraud and abuse authorities that would permit them to pursue ACOs as well.

b. Question: Moving beyond CMS shared savings program and demonstrations, what exceptions, safe harbors, or other accommodations may be necessary to encourage innovation?

PPACA's delivery reform provisions go well beyond just ACOs and the demonstrations and pilots that may come out of the Medicare and Medicaid Innovation Center. Therefore, the paradigm for all of the fraud and abuse laws should be transitioned to promote a greater level of coordinated care. For hospitals, this includes necessary alignment with physicians to promote behaviors that will promote the goals of value-based purchasing, avoiding readmissions, and eventually bundling for episodes of care.

We urge CMS and the OIG to revisit their 2008 rulemaking that proposed, but did not finalize, exceptions related to payment incentive arrangements and shared savings programs. While these policy proposals were apparently shelved to see what PPACA would bring, it is now clear that PPACA's waivers to promote innovative care models are narrow in scope, and the legislation does not provide relief with regard to a broader set of arrangements that will also help change the health care delivery model to a more patient-centered, efficient system. Without the ability to create more effective alignment between hospitals and physicians, it will be difficult to achieve the integrated approach that Congress and the President contemplated in the landscape of broad reforms that this historic legislation has enacted.

Last but truly not least, as CMS develops policies promoting innovation and coordination of care, consideration must be given to how the policy allowing patients freedom of choice of providers should be interpreted or modified. For hospitals, whether the issue is ACOs, programs designed to minimize readmissions, bundling for episodes of care, or other coordinated care models, a patient who chooses a provider that is not part of the infrastructure designed by hospitals to coordinate patient care more efficiently will create challenges and reduce efficiencies. While this issue was not directly addressed by the October 5th Workshop, it is an important issue that will need to be addressed by CMS. The FAH looks forward to working with the agency to develop a policy in this area that strikes an appropriate balance between the various policy goals.

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The FAH appreciates the opportunity to provide input on suggested policies to help foster clinical integration, ACOs, and other innovation endeavors. If you have any questions about our comments or need further information, please contact me or Jeff Micklos of my staff at (202) 624-1500.

Sincerely,