Charles N. Kahn III
President & CEO

December 3, 2010

**BY COURIER AND ELECTRONIC MAIL**

Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-6028-P
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: Medicare Program; Request for Information Regarding Accountable Care Organizations and the Medicare Shared Savings Program [CMS-1345-NC]; 75 *Fed. Reg.* 70,165 (Nov. 17, 2010)

Dear Dr. Berwick:

The Federation of American Hospitals ("FAH") is the national representative of nearly 1,000 investor-owned or managed community hospitals and health systems located 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 comment on the Centers for Medicare & Medicaid Services ("CMS") Request for Information Regarding Accountable Care Organizations and the Medicare Shared Savings Program. ("RFI").

The FAH and its members have been giving considerable thought to ACOs and their potential to promote coordinated health care delivery. From our discussions, a series of basic tenets have emerged as the important themes on the path to ACO creation.

- Hospitals can play a leadership role in developing and operating ACOs.

- Flexible approaches to both organizational and governance structures should be permitted.

- Creation and maintenance of a level playing field for ACOs, one which does not favor one method or approach to, or location of, care delivery over another (*e.g.*, urban versus rural; employment model versus voluntary medical staff model, tax-exempt versus tax-paying hospitals) is what Congress envisioned.

- A variety of payment methods that promote and enhance innovative care delivery models should be permitted.

- New quality performance measures or metrics that extend beyond those required of Medicare providers and practitioners should not be imposed.

- Greater flexibility for ACOs to operate under fraud and abuse laws through new exceptions/safe harbors or the careful, uniform use of the waiver authority for all arrangements to promote and create incentives for care coordination and clinical integration should be implemented.

- ACOs should not be subject to separate accreditation requirements beyond those licensure and accreditation requirements that apply to ACO professionals and providers. ACOs are not designed to be entities subject to health maintenance organization or other insurance-type regulatory requirements.

**Responses to Specific RFI Questions**

1. ***What policies or standards should we consider adopting to ensure that groups of solo and small practice providers have the opportunity to actively participate in the Medicare Shared Savings Program and the ACO models tested by CMMI?***

Hospitals that develop ACOs are likely to want to include solo and small practice physicians in their affiliated ACO. Often, these physicians are part of a hospital's voluntary medical staff, and hospitals will look for creative ways to include their affiliated physicians to better coordinate care. Nearly 80 percent of the nation's primary care physicians are in practices of nine or fewer people, and the majority of those practices have four or fewer physicians. It is likely that these physicians do not have the resources to satisfy all of the ACO requirements nor are they likely to have the financial wherewithal to be able to finance and start their own ACO. So, there is a good chance that they would be interested in partnering with their local community hospital to do so, and hospitals will welcome this opportunity to better serve their communities.

Hospitals, and in particular community hospitals, will inevitably be important leaders in ACO development and care coordination and integration. As the community-based entity often in the middle of the care delivery system in a particular market, a hospital has a keen awareness of the medical needs of the community and the ability - both financially and otherwise – to

develop and support the infrastructure necessary for innovative care delivery models. Hospitals are also likely better suited to attract a comprehensive ACO network that goes beyond the physician practice arena, and includes other important ancillary service providers (such as home health, home infusion therapy, skilled nursing facilities etc.) on which the ultimate success of the ACO will turn.

As the FAH has commented to CMS before, the ACO statute should be interpreted to allow all hospitals to participate in the shared savings/ACO program. The statute specifically permits participation by hospitals that employ physicians. However, hospitals that do not employ doctors and rely upon the voluntary medical staff model should also be encouraged and incentivized to participate in ACOs, as should hospitals that are prohibited from employing physicians under state corporate practice of medicine laws. In our view, it is clear that CMS should make an effort to create a structure that will permit all hospitals, regardless of their employment or physician affiliation model, to participate in ACOs, as the statute also provides broader, general authority to allow participation of other providers as CMS sees fit.

2. ***Many small practices may have limited access to capital or other resources to fund efforts from which shared savings could be generated. What payment models, financing mechanisms or other systems might we consider, either for the Shared Savings Program or as models under CMMI to address this issue? In addition to payment models, what other mechanisms could be created to provide access to capital?***

We agree that solo or small physician practices may have limited access to capital and other resources necessary to fund ACO efforts. The FAH believes that in many cases, hospitals are the likely entities to lead the development of ACOs and may be in the economic position to fund startup and other operational costs in advance of (or even in the absence of) the ACO generating shared savings. From a program integrity standpoint, CMS should expect that the entity that funds the start up of an ACO will have governance control and program accountability.

The need for greater regulatory flexibility was a main topic of discussion during the October 5th Department of Health & Human Services-Federal Trade Commission's Workshop. The FAH's comment letter submitted after that Workshop addressed these issues in depth. Generally, the FAH believes that while greater regulatory flexibility is needed, any new policies should create a level playing field and not advantage one type of model over another.

To summarize our position, the FAH urges CMS and the Office of Inspector General ("OIG") to issue a final rule that promulgates reasonable exceptions and safe harbors for both shared savings and payment incentive programs. (CMS and the OIG issued proposals back in 2008, but that rulemaking was never finalized and should be revisited now in light of the shared savings/ACO program, and the continued need for relief in this area.) CMS and the OIG should also consider whether the electronic health record and e-prescribing exceptions and safe harbors should be expanded to better foster the exchange of information technology and sharing of data among ACO participants.

During the October Workshop, the FTC announced that it was planning to develop an antitrust safe harbor for shared savings/ACO programs. We also urge CMS to consider whether a similar approach would work best with regard to developing a physician self-referral exception that would permit ACOs that comply with the statutory mandates to also be protected from the self-referral ban.

Also, the statute gives HHS broad authority to waive provisions of Title XVIII and certain provisions of Title XI of the Social Security Act. If the Secretary, through CMS and the OIG, wishes to exercise this waiver authority, we strongly urge that waivers that are granted be available for all ACOs and uniformly applied to ensure a level playing field.

Finally, CMS will likely need to use its waiver authority to provide greater flexibility with regard to Medicare post-acute care policies that will hinder the ability of post-acute providers to participate fully in ACOs. Our members have identified a number of existing policies that will create significant burdens for post-acute providers attempting to participate in a coordinated or integrated care delivery arrangement, whether it be for ACOs or under future episode of care bundling policies. We look forward to working further with the agency to identify and resolve problematic areas.

3. ***The process of attributing beneficiaries to an ACO is important to ensure that expenditures, as well as any savings achieved by the ACO, are appropriately calculated and that quality performance is accurately measured. Having a seamless attribution process will also help ACOs focus their efforts to deliver better care and promote better health. Some argue that it is necessary to attribute beneficiaries before the start of a performance period, so the ACO can target care coordination strategies to those beneficiaries whose cost and quality information will be used to assess the ACO's performance; others argue the attribution should occur at the end of the performance period to ensure the ACO is held accountable for care provided to beneficiaries who are aligned to it based upon services they receive from the ACO during the performance period. How should we balance these two points of view in developing the patient attribution models for the Medicare Shared Savings Program and ACO models tested by CMMI?***

The statute states that the Secretary shall determine the appropriate way for beneficiaries to be assigned to ACOs based upon their utilization of primary care services. The FAH urges CMS to be flexible on how beneficiary assignment may occur. CMS should permit prospective ACOs to bring to the agency a list of at least 5,000 Medicare patients that they wish to be assigned to their ACOs. This list would include existing Medicare patients cared for by those primary care physicians who will participate in the ACO. CMS can then approve the list and/or make additions if necessary.

The FAH believes that for an ACO to be most effective, beneficiary assignment/ attribution must take place before the start of a performance period. Knowing which patients are included from the inception allows the ACO to better target care coordination strategies and implement protocols and practices to pursue the goal of creating savings that can then be shared among participants.

Allowing for retroactive beneficiary assignment does not provide desirable controls for the ACO to manage their populations to create shared savings. Retroactive beneficiary assignment may even create a disincentive for ACOs to form and seek to join the program.

The following points further support our position favoring prospective assignment of patients.

- In order to maximize their care management efforts relative to their assigned patients, ACO providers need to know in advance which of their patients are being attributed to the ACO. Holding ACO providers accountable for cost and quality performance before-the-fact (without them even knowing which patients they are being specifically held accountable for) and then attributing the patient to the ACO after-the-fact would be akin to operating first and then taking a patient's medical history after.

- Providers are better positioned than CMS to determine which of their patients would be appropriate candidates for ACO attribution. For example, they know which ones are "snowbirds" *(i.e.*, not a good ACO fit if the patient resides out of the area half the year), and they know which ones incongruously bounce from provider to provider, irrespective of the ACO physician's recommendations (*i.e.*, not a good ACO fit if the patient is unable or unwilling to follow the physician's advice or remain within the ACO provider network).

- Providers know how many assigned beneficiaries their ACO has the functional capability of accepting, and need to be able to control the inflow of attributed patients. Since CMS does not know these ACO resource/capacity limitations, CMS cannot effectively fulfill that role – only the ACO can.

- In a small community with few physicians and only a single ACO, attribution by CMS might not be a problem (and whether prospectively or retrospectively assigned probably doesn't matter one way or the other, either). However, in larger communities with thousands of physicians and multiple ACOs, it is conceivable that many independent physicians will belong to multiple different ACOs. In turn, CMS is simply not positioned to make the ACO assignment call in these communities.

Perhaps the strongest argument for prospective assignment is that CMS continues to maintain that it intends to make the ACO assignment process "blind" to the Medicare beneficiaries (e.g., no different Medicare ID card, no PCP-as-gatekeeper requirements, no formal ACO selection process by the patient, no limitations on patient self-referrals to non-ACO providers, etc.). So long as that is the case, the ACO needs to be able to control as much of the beneficiary prevention and care delivery process as possible.

Finally, in order to preserve the integrity of the comparative results and maximize the positive effect of the ACO model, if the Medicare paid claims database indicates a pattern that an assigned beneficiary subsequently begins to receive a substantial amount of care outside the ACO network, CMS should establish a process under which that beneficiary can be "disenrolled" from the ACO by CMS either directly or at the request of the ACO.

4. ***How should we assess beneficiary and caregiver experience of care as part of our assessment of ACO performance?***

The Medicare program has significant experience in assessing patient experience of care. The Consumer Assessment of Healthcare Providers and Systems ("CAHPS") survey methodology was developed by the Agency for Healthcare Research and Quality ("AHRQ") working closely with a public-private consortium of organizations. The CAHPS family of surveys is a well-respected and reliable tool used by patients to report on and evaluate their healthcare experiences. The tool has been adapted for use in a variety of settings, is continually reassessed, and has wide acceptance in the health care environment. The FAH recommends using this set of tools to assess beneficiary experience with ACOs.

5. ***PPACA requires us to develop patient-centeredness criteria for assessment of ACOs participating in the Medicare Shared Savings Program. What aspects of patient-centeredness are particularly important for us to consider, and how should we evaluate them?***

The FAH is challenged to respond fully due to the lack of consistent and clear definition of the term "patient-centeredness." The term is used throughout The Patient Protection and Affordable Care Act ("PPACA"), but nowhere is it truly defined. Looking to outside guidance, the National Priority Partnership ("NPP"), which was convened by the National Quality Forum ("NQF"), advocates for the concept of "Patient and Family Engagement" as one of its five priority areas for the Secretary to consider as she develops a National Health Care Quality Strategy and Plan. The NPP's recommendations reflect a multi-stakeholder group approach to reaching consensus around common priorities and goals—an approach foundational for shared ownership and shared accountability to result in successful implementation through public-private partnership, and should be considered a good resource for ACO policy.

In its comments to the Secretary, the NPP states that patient-centered care can lead to improvement in better care, better health, and affordability. The NPP suggests that identifying and focusing on patient-centered care involves three basic elements: (1) patient experience of care; (2) patient self-management; and (3) shared decision-making. Requiring ACOs to focus on these three elements would seem to be a reasonable policy.

We encourage CMS to work with the Secretary's office to first define patient-centeredness and then to develop an assessment mechanism. Any program developed to address patient-centeredness should be based on well-recognized, evidence-based and tested metrics. For starters, the CAPHS family of surveys is one way of assessing patient centeredness, as it focuses on several key elements of the patient relationship with physicians and with hospitals. The development and deployment of additional tools, frameworks and measures to address care coordination and transitions are well underway. The FAH urges CMS to look to the NQF-approved measures and frameworks for specific measures to select to measure ACOs.

6. ***In order for an ACO to share in savings under the Medicare Shared Savings Program, it must meet a quality performance standard determined by the Secretary. What quality measures should the Secretary use to determine performance in the Shared Savings Program?***

PPACA provides a significant opportunity for health care providers to better coordinate health care services under its shared savings program through the creation of ACOs. ACOs are intended to change materially the way Medicare beneficiaries receive care through better coordination that promotes high quality and efficient patient care, better population health, and lower cost. Use of NQF endorsed, evidence-based and tested protocols should be a guiding principle in the development of ACO quality performance standards.

In addition, the PPACA in Sec. 3011 through 3014 lays out a well-coordinated national quality infrastructure that establishes a National Strategy for Quality Improvement in Health Care, which is a program for coordination among federal departments and agencies responsible for a wide variety of health programs, development of quality measures and a public-private multi-stakeholder consultative partnership to advise the Secretary on the use of measures in payment and reporting programs. Sec. 3014 establishes a program that will advise the Secretary in advance of rulemaking on the appropriate selection of measures for use in a wide range of public payment programs. While the ACO program is not explicitly included in Sec. 3014, the FAH believes that CMS should use its discretion to employ for ACOs a quality reporting system for which the consultative process would apply. We believe that the ACO quality measures would benefit from the multi-stakeholder input on the use of measures across traditional silos of care. The National Strategy likely will be developed by the National Quality Forum as it is the entity with the current contract under Sec. 1890.

Finally, The FAH recommends starting an ACO quality program with a focused and limited framework that can and should expand over time as new care delivery systems mature. Focusing attention on a set of strong targeted measures will foster a beneficial framework, and the coordination among providers and with patients that will be necessary for ACO to succeed. CMS should determine the appropriate quality measures by selecting them from existing measures that are currently being utilized by provider and practitioners. Building upon use of existing measures will continue to promote evidence-based medicine and high quality care. We believe strongly that new quality measures should not be introduced in the context of ACOs.

7. ***What additional payment models should CMS consider in addition to the model laid out in Section 1899(d), either under the authority provided in 1899(i) or the authority under CMMI? What are the relative advantages and disadvantages of any such alternative payment models?***

The shared savings/ACO program is premised upon the desire for innovation around new care delivery models that provide coordinated care to achieve greater clinical integration. In order to promote innovation and flexibility, CMS should permit various types of fee-for-service and shared risk payment methods, as well as other payment methods that may be brought to the agency by prospective ACOs.

CMS's policy on acceptable payment methods should not be overly proscriptive in either (1) requiring all ACOs to follow one payment model, or (2) prohibiting certain types of payment models from being used by ACOs. Because innovation is the overarching goal, maximum flexibility is appropriate for ACO professionals and providers to develop programs that they think are most likely to be successful in their markets. Based on the particulars of an ACO, CMS can decide which authority the arrangement should operate under.

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The FAH appreciates the opportunity to comment on the RFI. If you have any questions about our comments or need further information, please contact me or Jeff Micklos or Jayne Chambers of my staff at (202) 624-1500.

Sincerely,