



AMERICAN ACADEMY OF  
FAMILY PHYSICIANS  
STRONG MEDICINE FOR AMERICA

February 21, 2011

The Honorable Daniel R. Levinson  
Office of Inspector General  
Congressional and Regulatory Affairs  
Department of Health and Human Services  
Room 5541  
Cohen Building  
330 Independence Avenue SW.  
Washington, DC 20201

Attention: Solicitation of New Safe Harbors and Special Fraud Alerts (OIG-118-N)

Dear Inspector General Levinson:

On behalf of the American Academy of Family Physicians (AAFP), which represents more than 97,600 family physicians and medical students nationwide, I am writing in response to the *Solicitation of New Safe Harbors and Special Fraud Alerts* as published in the December 28, 2010 Federal Register.

As stated in our September 27, 2010 [letter](#) to the Federal Trade Commission, Centers for Medicare & Medicaid Services, and Office of Inspector General, the AAFP urges your office to look carefully at changes to antitrust regulations and to Stark self-referral regulations that will be needed to allow physicians to fully participate in accountable care organizations. The Office of Inspector General must provide explicit exceptions to the anti-kickback rules and Federal Trade Commission to anti-trust laws in organizing accountable care organizations. This will be especially important for physicians in small- and medium-sized practices in Family Medicine as the key components of a Patient Centered Medical Home. To have successful clinical integration and provide quality patient outcomes Federal agencies must address these barriers to clinical and financial integration to assure that accountable care organizations have the opportunity to flourish. We urge the Office of Inspector General to continue to collaborate closely with the Centers for Medicare & Medicaid Services and other agencies so that newly formed accountable care organizations are adequately protected from existing laws that currently restrict the ability of providers to coordinate care and collaborate on payment models.

The AAFP urges HHS and the Office of Inspector General to consider these principles as the Federal Trade Commission, Centers for Medicare & Medicaid Services, and the Office of Inspector General further develop the accountable care organizations concept.

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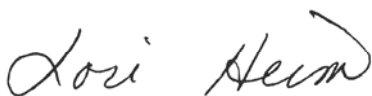
- The core of an Accountable Care Organization is to provide accessible, effective, team-based primary care for the defined population it serves, which includes efforts to deliver care in a culturally competent and responsive manner.
- Should include strong physician leadership, be clinically integrated and operated in a true partnership among physicians and all other participants.
- Physician and patient participation in an Accountable Care Organization should be voluntary. However, if patients are assigned to an Accountable Care Organization they should be encouraged to select a primary care physician.
- Nationally-accepted, validated clinical measures focused on ambulatory and inpatient care should be used to measure performance and augment efficiency and patient experience measures.
- Clinically integrated information systems should provide relevant information at the point of care and assist in care coordination among multiple clinicians and across transitions of care.
- Accountable Care Organization participants will support continuous innovation to identify best practices that provide value to patients.
- Organizational relationships, spending and quality benchmarks, and payment distribution mechanisms need to be clearly defined and agreed to by participants.
- Accountable Care Organization structure and payment systems should be implemented in an incremental manner and monitored to prevent "unintended consequences," such as poor access to physicians or denial of needed care.
- A sufficient number of patients in an Accountable Care Organization is necessary to statistically determine if the care provided and not mere chance resulted in the reported outcomes.
- Primary care physicians and sub-specialists should have the option to participate in multiple Accountable Care Organizations.
- Accountable Care Organizations should purposefully involve and provide incentives for patient engagement in their health and wellness.
- Changes to antitrust regulations and to Stark self-referral regulations need to be explored to allow physicians to fully participate in Accountable Care Organizations especially for physicians in small- and medium-sized practices.

### Payment

- Payment models and incentives must align mutual accountability at all levels, fostered by transparency and focus on disease prevention, care management, and coordination.
- Recognition as an Accountable Care Organization and rewards for its performance should be based on a combination of standards, relative performance, and improvement.
- Payment changes should evolve over time in ways that support the transitional changes in care processes and information systems.
- Primary care practices designated as PCMH's and participating in an Accountable Care Organization should be eligible for payments in both models of care (i.e. fee-for-service, episode/bundled payment, global payment, care management fee, bonuses, shared savings, blended payment, etc.)

The AAFP appreciates the opportunity to provide these comments. If we may be of further assistance in this regard, please contact Robert Bennett, the AAFP Federal Regulatory Manager, at [rbennett@aafp.org](mailto:rbennett@aafp.org).

Sincerely,



Lori J. Heim, MD, FAAFP  
Board Chair