The Association of American Medical Colleges (AAMC) welcomes this opportunity to submit comments on the legal and regulatory issues related to accountable care organizations (ACOs) and other innovative delivery models, including healthcare innovation zones (HIZs), described below. The AAMC represents all 133 accredited U.S. medical schools, nearly 400 major teaching hospitals and health systems, and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 128,000 faculty members, 75,000 medical students, and 110,000 resident physicians.

We very much appreciate that the Federal Trade Commission (FTC), the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General of the Department of Health and Human Services (HHS OIG) are hosting this workshop. This is an important time for the nation’s healthcare system. It is critical that we find ways to improve the health of our population while constraining the unsustainable growth in healthcare costs. Such goals will require a fundamental redesign of both the systems of care delivery and payment for healthcare in the U.S. today.

The current fee-for-service reimbursement model focuses on rewarding volume and encourages care silos that limit operational flexibility in the effective utilization of professional expertise. We must find new models which encourage information sharing, quality improvement, and cost efficiencies while providing Medicare beneficiaries and all other patients with the care they need.

We believe academic medicine can and must play an important role in testing new models of care delivery. In addition to providing opportunities to coordinate and integrate care across the full spectrum of settings, academic medical centers train current and future healthcare providers, and they also conduct the majority of federally funded biomedical and health services research. However, making changes in the healthcare system requires providers to commit significant time and resources. Our member organizations are willing to take on this challenge, but the government needs to be a willing partner in this journey. Understanding and recognizing how current laws can facilitate or impede innovative solutions are critical first steps. These initial steps must include a willingness on the part of the government to exercise its authority to grant waivers of the fraud and abuse laws to HIZs and ACOs that receive approval from CMS. CMS approval should be deemed a sufficient indication that adequate safeguards are in place to ensure that the risk of fraud and abuse is minimal and that Medicare beneficiaries who receive care from the organization will not be harmed; in other words, the arrangement “does not pose a risk of program or patient abuse.” (Social Security Act §1877(b)(4))
Healthcare Innovation Zones (HIZs)

The HIZ, a concept developed by the AAMC, is included as one of the models to be tested by the Center for Medicare and Medicaid Innovation (CMI), as set forth in section 3021 of the Affordable Care Act (ACA). According to § 3021, the purpose of the CMI is “to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles.” The ACA allows for evaluation and testing of numerous care delivery models, including HIZs. Specifically, the ACA permits the CMI to:

“…[establish] comprehensive payments to Healthcare Innovation Zones, consisting of groups of providers that include a teaching hospital, physicians, and other clinical entities, that, through their structure, operations, and joint-activity deliver a full spectrum of integrated and comprehensive health care services to applicable individuals while also incorporating innovative methods for the clinical training of future health care professionals.” (ACA § 3021(b)(2)(xviii))

The goal of HIZs is to demonstrate that coordination of comprehensive care will improve quality while controlling costs, not only for Medicare, but potentially for Medicaid and private payers as well. HIZs present the CMI with tremendous opportunities to study rigorously a range of academic medical center innovations in care delivery and payment reform, thus informing CMS, HHS and others about the impact of system transformation on complex institutions.

In an HIZ, providers will deliver coordinated, quality care that will see more effective utilization of their professional expertise, because there will be a better system for determining how services are provided and by whom. Because they have the tri-partite mission of clinical care, education, and research, teaching hospitals that form HIZs will change the nature of medical education by teaching a new cadre of clinicians how to work effectively in teams and how to lead innovation and change. Anchored in these robust medical education environments, HIZs will create sustainable changes in our nation’s healthcare delivery system by permitting and empowering providers and trainees to become part of continuous quality improvement by learning and integrating important principles, such as evidence-based medicine, into the process of care delivery.

Academic medical centers are ideally suited to develop and test new care delivery and payment models. Through the research conducted in these institutions, information on care outcomes and knowledge of resource costs can be applied in meaningful, real-world instances. Additionally, HIZs will serve as learning laboratories in which the diverse and complementary sciences of healthcare economics, population health, evidence-based medicine, community medicine, medical ethics, cost effectiveness, and quality improvement can be applied and studied first-hand. These types of research, known collectively as implementation science, will evaluate current care delivery practices and promote a culture of innovation, allowing for step-wise process improvements. Through these methods, academic medical centers will reinforce the goals of healthcare reform.

Simply put, AAMC-member teaching hospitals are uniquely positioned to accelerate the transformation of the healthcare system that is envisioned by healthcare reform. Academic medical centers provide an
ideal learning and testing ground for innovative care and payment delivery models. The AAMC looks forward to partnering with the CMI to develop and implement Healthcare Innovation Zones in our nation’s academic medical centers.

Legal and Regulatory Issues Associated with ACOs, HIZs, and Other Innovative Delivery Models

Program Integrity Laws

While many of our member teaching hospitals and faculty physicians are eager to identify and test new ways of delivering healthcare, they also are very concerned that current federal and state laws and regulations may stand in the way of meaningful health system innovations. At the federal level, concerns center on the physician self-referral prohibition (commonly known as the Stark Law), the anti-kickback statute (AKS), the civil monetary penalty (CMP) law, the antitrust statutes, and tax-exempt organization laws. Before healthcare providers, including academic medical centers, invest the considerable resources required to make long-term and large-scale changes to their care delivery systems, they need confirmation that their planned innovations will not be viewed as violations of federal laws.

We appreciate that the ACA modified the CMP statute so that remuneration does not include “any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs” (ACA § 6402). Although this would appear to protect services provided through an HIZ from accusations of violations of the CMP statute, HHS has yet to indicate how it will interpret and apply this provision. This provision also does not apply to either the physician self-referral law or the AKS. More must be done to ensure that innovations such as HIZs and ACOs that reduce costs while maintaining or improving quality do not run afoul of the fraud and abuse and other laws. We appreciate that, in the past, CMS has recognized the unique nature of academic medical centers through the creation of the academic medical center (AMC) exception in the physician self-referral regulations (42 CFR § 355(e)). However, due to the variability of structures in academic medical centers, this exception has not been widely utilized. Moreover, the structures envisioned under HIZs and ACOs will require more flexibility than is available in the AMC or other exceptions as currently drafted.

The AAMC is pleased that the ACA (§ 3021(d)(1)) gives the Secretary authority to waive requirements for models approved under the CMI “as may be necessary solely for purposes of carrying out this section with respect to testing models. . . .” The statute also provides for a similar waiver authority for ACOs (§ 3022(f)). We encourage HHS to use this authority for purposes of the ACO program and CMS-approved pilots and demonstrations. Such waivers are particularly necessary because current exceptions are unlikely to apply because they require arrangements to involve “identifiable services” and require that the arrangement be at “fair market value”. HIZs and ACOs involve the total provision of care covering a wide and variable range of services, depending on the needs of the patient. Even if these services could be valued, placing a fair market value on the savings that accrue from this new system, which may result in compensation to physicians, may be an impossible task. These new models rely on cost-effective choices that will result in improved quality of care—laudable goals that do not fit readily into the health care models envisioned by the current fraud and abuse laws and regulations. CMS oversight within both of these programs should sufficiently safeguard against any risk of fraud and abuse activity. Additionally, HIZs and ACOs are likely to include rigorous monitoring, active and
regular physician participation, and quality measures that are established prior to the start of the demonstration, which will provide additional safeguards and which further support the Secretary’s use of her waiver authority.

The AAMC also is concerned about innovations in healthcare delivery once an HIZ or other demonstration program ends. To be successful, the HIZ and other demonstrations will require integration and alignment among hospitals, physicians and other healthcare providers, and a culture that values outcomes achieved through appropriate care rather than the volume of services that are provided. Such change will not come easily and cannot easily be undone once the demonstration period ends—nor should it be, if the goals of cost containment and quality improvement are to be met and sustained.

The current fraud and abuse laws were written to apply to a healthcare delivery system and payment models that are rapidly becoming outmoded. Although waivers of the fraud and abuse laws during demonstration and pilot projects are helpful, they are only temporary. We need permanent changes to the current laws to ensure that properly designed, nonabusive care delivery innovations can proceed and evolve on an ongoing basis, unimpeded by the fraud and abuse laws. Such changes will require careful thought and must recognize that delivering the highest quality, most cost-effective healthcare requires substantial integration of the many parties within our healthcare system. Existing laws should be revised to target specifically the practices that are most likely to give rise to fraud and abuse within the new healthcare delivery system. As an interim step, CMS and the OIG should consider ways in which the current regulations can be revised or reinterpreted to allow for new models of care, acknowledging that these new models contain checks and balances—such as rigorous tracking of cost and quality measures—that will minimize the likelihood of program and patient abuse.

Tax Exempt Laws

The creation of HIZs and ACOs will raise a myriad tax-related questions, including whether these new entities may qualify for tax-exempt status and whether participation in such an entity will jeopardize a participant’s existing tax-exempt status. We need a coordinated effort among all government agencies with authority to affect ACOs and HIZs—HHS, IRS, and the Department of Justice—to ensure that potential Federal law impediments to ACOs and HIZs are addressed.

The Antitrust Laws

Section 1 of the Sherman Act is most applicable to provider arrangements, because in general, it prohibits “unreasonable” restraints of trade. Although the DOJ and FTC have addressed provider integration through two important documents (FTC/DOJ Statements of Antitrust Policy in Health Care and Antitrust Guidelines for Collaborations Among Competitors), given the severity of antitrust penalties, it is important that these agencies issue guidance that confirms that properly structured, appropriately integrated ACOs and HIZs comply with the antitrust laws.

State Laws

Various state laws may also impede meaningful healthcare delivery system innovation. First, most states have one or more physician self-referral, anti-kickback, or related fraud and abuse laws. Second, state “corporate practice of medicine” (CPOM) laws prohibit the practice of medicine or the
employment of physicians by business corporations. In states with COPM laws, a variety of care models and structures for hospital-physician relationships have been developed to comply with the various state statutes—structures that may not fit easily with the structure or goals of an HIZ or ACO. We urge the Federal government to work with the states to ensure that state laws and regulations do not undo any actions that CMS, FTC, HHS OIG, or other Federal agencies undertake to promote innovation.

**CONCLUSION**

The underlying premise of ACOs, HIZs, and similar innovative models of care delivery is to reduce the fragmentation that exists in the current healthcare which contributes to high costs and questionable quality. Once eliminated, a new, cost-effective, quality-driven system can emerge. A major driver behind the current fragmentation is the fee-for-service system. To succeed under healthcare reform, physicians and hospitals will need to work together.

The task before us is daunting: we must identify, test, and implement provider arrangements that will facilitate high quality care while constraining costs. As a first step, it is imperative that the legal and regulatory systems support and facilitate arrangements that have been approved by CMS. Given the myriad arrangements among physicians, hospitals, and other providers, it is critical that Federal laws provide sufficient flexibility to encourage hospitals, physicians, and other providers to enter into arrangements that will result in high quality, high value, patient-centered care. Otherwise, we will not be able to move our healthcare system into the new future that healthcare reform envisions.