Association of
American Medical Colleges
2450 N Street, N.W., Washington, D.C. 20037-1127
T 202 828 0400 F 202 828 1125
www.aamc.org

Via Electronic Submission

December 3, 2010

Donald Berwick, MD, MPP
Administrator
Centers for Medicare & Medicaid Services
ATTN: CMS-1345-NC
7500 Security Blvd.
Baltimore, MD 21244-8013

Re: Request for Information Regarding Accountable Care Organizations (ACOs) and Medicare Shared Savings Programs (CMS-1345-NC)

Dear Dr. Berwick:

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's or the Agency's) *Request for Information [(RFI)] Regarding Accountable Care Organizations and the Medicare Shared Savings Program*. 75 *Fed. Reg*. 70165 (November 17, 2010). 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. These institutions and organizations include nearly 80,000 clinical physician faculty, 75,000 medical students, and 110,000 resident physicians. We hope the responses CMS receives from this RFI will help the Agency as it develops the ACO/Shared Savings proposed rule. We look forward to providing more detailed comments in response to the specific proposals that will be included in that rule.

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 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 AAMC and our member teaching hospitals, medical schools, and clinical faculty are committed to changing the way health care is delivered to achieve better care for patients and improved health status for communities. These entities deliver more than one-fifth of U.S. health care, train most physicians and many other health professionals, provide half of continuing medical education, and carry out the majority of federally funded medical and health services research. They can, and must, lead the way in improving quality, lowering cost growth, and enhancing care for patients and communities while incorporating changes into the training curricula for the next generation of health care professionals.

Healthcare innovation zones (HIZs), a model included in the Center for Medicare and Medicaid Innovation (CMMI) created by section 3021 of the Affordable Care Act (ACA), which specifically include teaching hospitals and physicians, are one important way for our members to participate meaningfully in improving quality care and reducing health care costs. At the same time, our members also are considering the other health care delivery initiatives contained in the ACA, including the shared savings (also known as the ACO) program authorized under section 3022 of the ACA.

Hospital and Physician Collaboration

To be successful, HIZs and ACOs 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. 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, the civil monetary penalty (CMP) law, the antitrust statutes, and tax-exempt organization laws. Before healthcare providers, including academic medical centers, (AMCs) 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.

The AAMC is pleased that the ACA gives the Secretary authority to waive the Stark Law as well as the anti-kickback statute and CMP law for purposes of implementing the ACO/Shared Savings Program. We believe CMS and the Department of Health and Human Services (HHS) must exercise their authority for purposes of the ACO program and CMS-approved pilots and demonstrations. The current fraud and abuse laws were written to apply to a healthcare delivery system and payment models that are rapidly becoming outmoded. The new models of care rely on integrated and coordinated care that will result in improved quality for patients—laudable goals that sometimes do not fit easily into the health care models that the current fraud and abuse laws and regulations were crafted to address. CMS oversight of the ACO program 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 program, which will provide additional safeguards to further support the Secretary's use of her waiver authority.

The creation of HIZs and ACOs will raise 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, the Internal Revenue Service, and the Department of Justice (DOJ)—to ensure that potential federal law impediments to ACOs and HIZs are addressed. In addition, while the DOJ and the Federal Trade Commission (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.

We also urge CMS to review and identify other Medicare requirements that could impede providers from optimally coordinating care and delivering it in the most appropriate setting. One example could be to waive the three-day inpatient stay requirement prior to receiving rehabilitative care services.

Given the multiplicity of arrangements among physicians, hospitals, and other providers, it is critical that Federal laws and Medicare regulations and policies provide sufficient flexibility to encourage hospitals, physicians, and other providers to enter into arrangement and make care decisions 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.

Beneficiary Attribution Under ACOs

Accurate patient attribution is essential to creating an effective ACO. The ACA requires that assignment of patients be based on "utilization of primary care services." Two important issues associated with attribution are: the time period in which patients are identified, and how primary care utilization is defined.

The AAMC believes that prospective patient assignment, i.e. assignment before the performance period, is preferable to retrospective assignment. With prospective assignment, ACOs can create systems to actively manage and engage patients. Prospective attribution can also allow providers to understand their ACO population and potentially identify specific interventions and programs based on the characteristics and health status of their ACO participants. The ACO also would have the opportunity to review the patient list and ensure the accuracy of the assignment methodology. In addition, a prospective assignment provides the opportunity for Medicare beneficiaries to be informed of their inclusion in an ACO and understand the advantages of being in the program.[1] Finally, certain payment models, such as capitation or partial capitation, require prospective assignment in order for the ACO and CMS to accurately determine payment levels based on the ACO population.

If CMS elects to use a retrospective patient assignment, then the Agency should consider providing the ACO with a list of "potential" ACO patients prior to the beginning of the performance period. While this list likely would not be the final population used for ACO performance evaluation, it would provide some guidance to the ACO about the types of patients

[1] In the proposed rule CMS should specify how beneficiaries will be informed about the ACO program, including assignment determinations. In addition, the proposed rule should clarify the response in the Preliminary Question and Answer document posted on the CMS web site stating that "assignment will be invisible to the beneficiary."

that will be evaluated for cost savings and quality improvement. It also could help the ACO determine whether to implement specific programs to manage particular patient populations.

The ACA gives CMS the authority to determine an "appropriate method" for assigning beneficiaries to the ACO based on "their utilization of primary care services." Many physician specialists, including teaching physicians, manage the overall care for complex patients with chronic conditions. ACOs that appropriately manage these patients can improve care and achieve substantial savings. We urge that in the proposed rule CMS develop an option for considering visits to specialists as primary care for certain beneficiaries with chronic conditions if the specialists are appropriately responsible for the majority of a patient's care.

Finally, as CMS develops the proposed attribution methodology, we urge you to keep in mind that many patients seen by AMC teaching physicians are referred by other physicians for episodic specialized care. To ensure that all physicians that "touch the patient" have an incentive to provide high value care, CMS may want to consider an attribution methodology that takes into account the care provided in these situations.

On a related issue, many of our teaching hospitals and physicians treat Medicare patients who are part of clinical trials. To ensure Medicare beneficiaries' access to the best and most advanced care, CMS issued a national coverage decision in 2000 that allows Medicare payment for the routine costs of care for beneficiaries enrolled in these trials. As CMS develops the proposed rule, we urge you to ensure that the program does not contain any disincentives that will cause ACOs to discourage Medicare beneficiaries from participating in these trials.

Patient and Caregiver Experience of Care

The Agency for Healthcare Research and Quality (AHRQ) has spent significant time and resources in developing and testing a suite of consumer assessment of care surveys known as "CAHPS." The hospital-specific survey tool, HCAHPS, currently is part of the Medicare hospital inpatient quality reporting program to measure patient experience of care. The ambulatory and clinician/group versions of the CAHPS tools (A-CAHPS and CG-CAHPS, respectively), as well as survey tools developed by other entities, have yet to be implemented and validated on a national basis.

Ideally, the ACO program should have a single tool that would measure patient experience across the care continuum. In the short term, while we have some concerns about HCAHPS, because it has been part of Hospital Compare for several years and institutions use the results to identify areas for improvement, we believe it is an appropriate tool to measure ACO patient and caregiver experience of care in the inpatient setting.

Quality Measures

Because quality improvement is a central tenet of the ACO/Shared Savings Program, identifying appropriate quality measures is key to determining those ACOs that are truly successful in

improving the health of Medicare patients. We believe the quality measures included in any quality reporting program, including the ACO program, must meet the following requirements:

- Endorsed by the National Quality Forum (and Hospital Quality Alliance, if applicable),
- Field tested for reliability and validity,
- Appropriately risk-adjusted,
- Actionable and within the control of the provider to change, and
- Have an impact on the care being delivered and ultimately the health and safety of the population served.

The risk adjustment requirement is particularly important given the patient populations served by teaching hospitals and faculty physicians, which often are the sickest and most complex. In addition, AMCs often serve as safety net providers in their communities and treat a large number of disadvantaged patients who often do not have the appropriate support systems to help them manage their care.

Ultimately, the best quality measures for an ACO are those that extend across the care continuum to include physician and hospital care. Many ACOs may utilize provider teams to care for their patients. The majority of the current quality measures are focused on individual provider silos and are unable to measure care beyond a particular setting. Such measures are unable to account for, and measure, care provided by a group of providers rather. Significant work will need to be done in developing appropriate ACO measures, establishing the technological capabilities at CMS to receive the performance data and identifying ways in which data from hospitals, physicians, and other providers can be combined and reported back to the ACO to effectively, and comprehensively, manage its patient population.

Because comprehensive quality measures are not yet available, we recognize that in the short term CMS will need to rely on other types of quality measures for the ACO/Shared Savings Program. At the same time, it is important for CMS to recognize that implementing systems for the collection of new performance measures within an institution or physician practice requires significant resources in both time and money. In order to allow for the greatest participation in the ACO/Shared Savings Program and not overly burden providers, the AAMC strongly recommends that the initial performance measures be a small set derived from those already being collected.

As CMS begins the process of identifying proposed quality measures for the ACO/Shared Savings Program, the Agency should take into consideration other “value-based” payment programs that require quality measures and ensure that all of these programs are developed in a comprehensive and aligned manner.

Patient-Centeredness Criteria

To be successful, an ACO will need to be "patient centered." However, we are unaware of a clear definition for this term and how it could be measured, particularly across providers. While communication and access are likely key components of a thoughtful definition, we recognize the difficulty CMS has in developing a definition that is at the same time adequate and capable of measurement. The AAMC urges CMS in the proposed rule to provide the goals it seeks to achieve through these measures and identify various options of meeting those goals. Whatever definition is ultimately chosen, it is imperative that it be clear, consistent, and associated with relevant metrics.

Payment Models

The payment methodology employed by Medicare will be a critical determinant in whether the ACO/Shared Savings Program will achieve the goal of cost savings. It also will strongly influence the level and types of changes made by health care providers. Given the importance of this decision by CMS, as well as the heterogeneity across health care providers, including the types of patients served, the markets where they are located, and their own organizational structures, we think it is preferable for the Agency to implement and test a wide variety of payment methodologies. CMS should implement and test this variety of payment models either under the ACO/Shared Saving Program or as part of the list of innovative programs to be tested by the CMMI.

While we recognize that the current fee-for-service (FFS) methodology may be a necessary "starting point" for many providers, we believe that CMS should also permit methodologies that allow providers to assume some level of performance risk, which could increase over time. Such methodologies would reduce and ultimately remove the potential incentives to increase service volume associated with the FFS.

As with quality measures, it also is important that ACO payments be risk-adjusted to reflect the costs associated with treating more complex and economically disadvantaged patients. These individuals often require resources not needed by other patients (as well as non-medical support services), resulting in higher costs for their care, a potential disadvantage to providers who treat them. An adequate risk adjustment methodology is critical to ensuring that ACOs that include teaching hospitals are not unfairly penalized and that other ACOs are not incentivized to avoid these patients or the institutions and professionals that treat them. Given the difficulty of identifying the ideal risk adjustment methodology, it may be necessary to incorporate an "outlier" type of mechanism into the payment methodology.

A large percentage of the services provided at academic medical centers are delivered as tertiary, quaternary, or specialty referral care. A patient may be transferred to or seek care at an AMC because the care needed is not available in a patient's neighborhood/region. Since many of these referral patients receive primary or longitudinal care back in their community, we encourage CMS to test ACO payment models that incorporate shared attribution. In such a model, the

percent of savings generated by an academic medical center should be commensurate with and reflected in the amount of savings credited to an academic medical center that participates in an ACO.[2]

The ACA specifies that to determine savings under the shared savings program the Secretary establish a historical benchmark for each ACO based on Medicare expenditures for parts A and B services. Whatever payment methodology is ultimately proposed, we believe it must not include Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. This action is necessary to prevent an erosion of support for academic medical centers' tripartite mission of education, research, and clinical care, to ensure a level playing field for teaching hospitals, and to eliminate incentives for ACOs to reduce Medicare beneficiary access to teaching hospitals solely because of these important policy payments. Inclusion of DGME and IME payments would present a significant risk that Medicare beneficiary admissions would be transferred from teaching to non-teaching hospitals in order to produce "artificial" shared savings that would essentially be only the DGME and IME payments "saved" by receiving care at a non-teaching versus a teaching hospital.

Such a result is undesirable for a number of reasons:

- It would create an unlevel playing field for teaching hospitals and could compromise Medicare beneficiary access to teaching hospital care and safety net providers,
- It intermingles payments for clinical care services and policy payments that support missions of teaching hospitals and safety net providers that other hospitals do not undertake,
- It has the potential to seriously compromise academic medical centers' tripartite mission of education, research and clinical care by reducing the IME and DGME payments that are critical to sustaining these missions, and
- It undermines the goal of ACOs, which is to change care delivery, not to "cherry pick" among beneficiaries and hospitals.

We believe CMS must address these concerns in the forthcoming shared savings proposed rule. Section 3022 of the ACA specifies that ACO benchmarks "shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate" [emphasis added]. We believe CMS can and must use this general authority to remove DGME and IME payments from the ACO benchmark calculations and from subsequent determinations of shared savings. This would level the playing field and make it much less likely that the ACO concept would reduce Medicare beneficiary access to AMCs.

Finally, it is important to recognize that in order to be successful, ACOs will need to incur additional costs to make infrastructure and organizational changes that will be necessary to achieve improved quality and reduced costs over the long term. This is particularly true for

[2] For more information about this methodology, see Wallack and Tomkins, "Realigning Incentives in Fee-For-Service Medicare" Health Affairs Volume 22, Number 4 (July/August, 2003).

academic medical centers that will need to infuse additional resources into their clinical educational activities as they train future physicians and other health care providers to lead and deliver care in a more value-driven, team-based environment. We urge CMS and the CMMI to provide additional support for these vitally important activities. Additional funds will also be necessary to fund the care delivery and clinical outcomes research that will occur at these institutions and ultimately diffused across the entire health care system.

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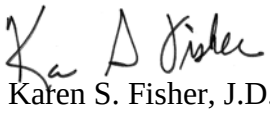
We very much appreciate the efforts that CMS has made to engage the provider community for input on the ACO/Shared Savings Program as well as the CMMI. We look forward to a continued dialogue throughout the rulemaking process to ensure that the efforts of both CMS and providers result in better value care for Medicare beneficiaries and all patients.

If you have any questions about what has been written, please do not hesitate to contact me at (202) 862-6140 or kfisher@aamc.org.

Sincerely,



Karen S. Fisher, J.D.
Senior Policy Counsel

cc: Jonathan D. Blum, CMS
Jennifer Faerberg, AAMC
Mark Lyles, MD, AAMC
Mary Patton Wheatley, AAMC
Ivy Baer, JD, AAMC