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Donald M. Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Attn: ACO Legal Issues
Mail Stop C5-15-12
Baltimore, MD 21244-1850

Dear Dr. Berwick:

The American College of Cardiology (ACC) is pleased to submit comments on the legal implications of the development of accountable care organizations (ACOs) and the Medicare Shared Savings Program created under the Affordable Care Act of 2010 (ACA).The ACC is a professional medical society and teaching institution made up of 39,000 cardiovascular professionals from around the world – including 90 percent of practicing cardiologists in the United States and a growing number of registered nurses, clinical nurse specialists, nurse practitioners, physician assistants and clinical pharmacists. We appreciate the opportunity to provide comments on this new and exciting program.

ACO arrangments

Under the ACA, an ACO must meet the following requirements to qualify for the Medicare Shared Savings Program. It must:

- Be accountable for quality, cost and care of Medicare beneficiaries.
- Commit to participating in the program for at least three years.
- Have a formal legal structure to receive and distribute payments for shared savings.
- Include sufficient primary care professionals to treat a minimum of 5,000 Medicare beneficiaries receiving treatment from the ACO.
- Have a leadership and management structure including clinical and administrative systems.
- Define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures and coordinate care through the use of appropriate technologies.
- Demonstrate that it meets patient-centeredness criteria defined by the Department of Health and Human Services (HHS).

There are few, if any, entities in existence that are currently arranged in such a way that would allow them to meet even these broad requirements. Given that, this program should be viewed as an opportunity for innovation and experimentation. Interested individuals and organizations should be given wide latitude to take risks and attempt new ways of providing high-quality care to patients while

experimenting with models for payment. To accomplish this, the regulations need to be open and inclusive, rather than proscriptive and narrowly focused.

The obvious arrangement for an ACO resembles a model similar to today's integrated health systems; however, this is not the only potential model, nor is it necessarily the ideal model. The overwhelming majority of patient care today is provided by physicians practicing in small, independent medical groups. The ACC believes that physicians should be allowed and encouraged to continue practicing in this way. After all, while the practice of medicine is regulated to a great extent, it is still the province of small business, rather than government. Any regulatory changes need to recognize this and encourage these small practices to work together and with others to improve the quality of care they provide. At least initially, physicians may choose to work together to improve care for certain chronic conditions, such as diabetes and congestive heart failure, rather than the full-range of healthcare services as a way of testing these new collaborative payment models. The ACC urges CMS, the FTC and OIG to craft regulations in such a way that these efforts are permitted and encouraged.

One potential concern with the integrated health system model or a model built around a hospital is that all of the power in the relationship is handed to the hospital or institution within the system, simply by virtue of its consolidated nature, as opposed to the disparate and diverse interests of individual private practices. In order to encourage the involvement of private practices in ACOs without implicitly encouraging mergers and the creation of consolidated health systems with substantial market power, regulations should be crafted in such a way that private practices are protected in these arrangements. Private practices are smaller, and thus, generally able to be more nimble than large institutions when it comes to making changes to the way business is conducted and care is provided. They may also be more able to hone in on specific areas of focus than larger organizations, whether it is for the purposes of cost control, efficiency or increased care quality. As the primary advocate of private practice cardiology, the ACC strongly supports the development of arrangements that allow and encourage physicians to work collaboratively to improve the quality of patient care while remaining independent.

The government should foster arrangements that enable private practices to remain independent while simultaneously encouraging collaboration to improve accountability and high-quality care. These arrangements should be based on policies that empower and engage physicians in the process of controlling costs and encouraging quality care. Therapeutic, diagnostic and hospitalization decisions are regularly made by physicians. The level of physician engagement in these discussions will have a significant effect on the success of an ACO. Creating the opportunity for physicians to lead ACOs, despite the more limited financial power of private practices, will be critical.

Creating such arrangements may require permitting individual negotiations for certain components and joint negotiation for others. For instance, one approach might be for practices that form an ACO to independently negotiate for their base payments, while negotiating jointly for a bonus or incentive payment based on shared savings or improvements in care. While such approaches are not permissible currently, the ACC would support changes in the laws and regulations that allow for experimentation in this fashion.

As a general principle, the College believes that any exception to the physician self-referral (Stark) law for incentive payment and cost-sharing programs should be consistent with the analyses of gainsharing arrangements by the HHS Office of Inspector General (OIG) under the Medicare-Medicaid anti-kickback rules and the Civil Monetary Penalty rules against payments from hospitals to physicians that create incentives for reducing services. The OIG has issued

several favorable advisory opinions on gainsharing arrangements that include the following features:

- Measures that promote accountability and transparency;
- Adequate quality controls (e.g. efforts to ensure no decline in quality of care or reduction in service occurs due to implementation of the arrangement); and
- Controls on payments related to self-referrals.

Any new regulations should take these advisory opinion analyses into account.

Additionally, the ACC urges the government not to limit participation in the Medicare Shared Savings Program solely to situations where the entire organization agrees to participate as a whole. Instead, regulations should be crafted in such a way so that individual physicians within an organization can make their own determination as to whether to participate in an ACO. Arrangements requiring participation from all physicians within a practice or hospital will likely significantly limit the number of physicians who can participate. However, the College would support arrangements where only physicians participating in the program are able to share in the incentive or shared savings programs and believe this will provide adequate protection against payments to physicians who do not participate in the program.

Past attempts to create regulations permitting shared savings or incentive programs have included requirements for minimum numbers of physician participants. However, such requirements may prevent smaller practices and hospitals from participating in incentive payment or cost sharing practices and may encourage abusive practices. Larger specialty practices will be able to form pools more easily than smaller groups, and smaller hospitals may not have significant numbers of doctors on staff within a given specialty. Also, a hospital may chose a larger group to participate in a program over a smaller group because of the larger group's importance as a referral source, but the hospital could point to a size requirement as justification for favoring large groups.

As CMS, the FTC and OIG consider this issue, it is important to consider the potential unintended consequences of changes to the regulations. For instance, CMS' incorporation of a new practice expense survey as part of 2010 Medicare physician fee schedule affected the ability of cardiologists to remain in private practice. The ACC anticipates, based on a census of cardiovascular practices, that the 2010 CMS Medicare claims data will reflect a shift in the site of service for cardiovascular services from the physician office to the hospital outpatient setting. This means that there has been an increase to care costs for patients, as well as for the Medicare program.

The role of specialists in an ACO

While it is clear from the ACA requirements for the Medicare Shared Savings Program that Congress intended primary care physicians to play a critical role in ACOs, the role of specialists in an ACO cannot be diminished. To improve the quality of care while decreasing costs will require everyone's participation. In today's medical practice, diseases and conditions not previously traditionally considered the province of specialists, such as congestive heart failure, may in fact now be managed by a specialist, such as a cardiologist. There is ample evidence to demonstrate that the additional education and training that specialists and sub-specialists receive translates into higher quality patient care and better outcomes. Individuals referred to specialists have their conditions or diseases diagnosed more frequently and are more likely to receive the appropriate treatment and follow-up. Thus, it is critical to involve specialists and sub-specialists in any effort aimed at examining care processes and improving outcomes.

It is also evident that any ACO will need to include tracking and accountability for the services that are deemed "ancillary" under the Stark law, but are really critical tools in the arsenal of a diagnostician of high caliber. Thus, CMS will likely need to examine the difficulties faced by medical practices attempting to comply with the in-office ancillary services exception that permits group practices to provide such services, as well as other exceptions to the law that are implicated under potential ACO arrangements. For instance, cardiologists perform a variety of diagnostic imaging services for their own patients, as well as patients referred by primary care physicians. There is evidence to suggest that a higher percentage of inappropriate testing is ordered by primary care physicians than cardiologists. However, under the current system, the primary care physician has no incentive to request a consultation or opinion from a cardiologist before referring the patient for the test, despite the savings to the system and the potential benefits to the patient. An ACO model might provide some incentive to refer the patient to the specialist before or instead of ordering the test. The ACC believes that regulations need to allow for such arrangements.

The importance of evidence-based medicine and quality improvement initiatives

Physicians generally, and cardiovascular specialists in particular, are primarily focused on one goal: providing high quality patient care and delivering the best outcomes possible to those patients. Experience has taught us that the best way to achieve this is to both foster competition among physicians through performance measurement and comparative analysis of that performance and through collaboration and study of care successes and failures. Evidence-based medicine relies on both to develop methods of improving care and for implementation of those new processes. Specialists and specialty societies play a critical role in these initiatives.

Throughout the list of requirements for an ACO, the related goals of providing care that is both high quality and patient-centered are apparent. The ACC believes that both goals are critical to the success of any medical practice. The ACC firmly supports efforts that encourage collaboration among physicians around performance measurement and quality improvement initiatives and believes that commitments to both are critical to the success of any ACO. Even more than the administrative simplification benefits that stem from ACOs, the potential for quality improvement gains is enormous. The ACC believes that it is only through the practice of evidence-based medicine that the quality of care will improve. The development of measures of performance and outcomes is a necessary component of an ACO and determining the quality of care furnished.

However, before performance and outcomes measures can be developed, evidence must be collected and examined. Registries are a critical mechanism for collecting the evidence. From that evidence, the medical specialty societies develop guidelines, appropriate use criteria (AUC), and quality improvement tools. All are critical components for an ACO's efforts to succeed, yet none can be developed by a practice or even an ACO in isolation. It is only with the aggregation of data from a large number and wide variety of sources that enough evidence becomes available to develop generalizable evidence and processes that will assist in the improvement of care and reductions in cost. This is best achieved with the financial support and resources housed within medical specialty societies, such as the ACC.

Data Collection and Registry Reporting

Registries are critical to the development of guidelines, AUCs and quality improvement tools. They collect the data upon which many of the guidelines, AUCs and quality improvement tools

are based. The ACC is well-known for its support of efforts to collect and use patient data to learn about best practices and appropriate care. The College's National Cardiovascular Data Registry (NCDR®) collects data on a wide range of cardiovascular procedures, including:

- Coronary catheterization
- Percutaneous coronary interventions (PCIs)
- Implantable cardiac defibrillators (ICDs)
- Carotid artery revascularization and endarterectomy
- Percutaneous interventions for adult congenital heart disease
- Acute coronary syndromes
- Ambulatory cardiac care

The information contained within NCDR has been used in a variety of ways. For instance, the ACC Foundation (ACCF) and The Society of Thoracic Surgeons (STS) are currently comparing data from the CathPCI and the STS registries to examine the comparative effectiveness of the two forms of coronary revascularization: percutaneous coronary intervention (PCI) and coronary artery bypass graft (CABG) surgery. Lessons learned from this study will be used to affect the care patients receive in the future. The ACCF and the Duke Clinical Research Institute are leading a study of NCDR registry data that will examine post-discharge care patterns and treatment adherence, and evaluate the safety, efficacy and healthcare costs associated with antiplatelet therapy use among contemporary acute myocardial infarction patient populations treated with PCI.

ACOs should be encouraged to participate in specialty society-supported registries as one way of focusing quality improvement efforts. Participants in the NCDR receive feedback reports comparing their performance to that of other participants. These feedback reports allow individual participants to determine the true nature of the care they provide to patients and spur them to improve. The benefit of registry participation over participation in quality reporting programs is that the data collected by registries is generally not based on claims for payment. Registries can also be used to perform longitudinal research, tracking patients over time to determine long-term, as well as short-tern effects and outcomes. Additionally, physicians trust their medical specialty societies to ensure that the data collected is protected and used in an appropriate manner. They also have more faith in the information produced from that data. Given that the success of a registry's quality improvement initiatives hinges on physician participation, the ACC strongly urges that ACOs be required to participate in medical society-sponsored registries where they exist and that the government draft the new regulations in such a way so as to assure participants that such participation does not run afoul of any anti-trust or other federal laws.

Guidelines and related clinical documents

Specialty societies also play an important role in the development of evidence-based guidelines and other clinical documents that are another component in defining evidence-based processes for clinical care. Where registries collect data on performance for analysis, guidelines, clinical competence statements and expert consensus documents make recommendations regarding treatment options, training recommendations and other components of clinical decision-making. For decades, the ACC has been working jointly with the American Heart Association on the development of guidelines that synthesize available evidence to assist physicians in clinical decision-making by recommending a range of generally acceptable approaches for the diagnosis, management or prevention of specific diseases or conditions. Additionally, the College produces clinical competence and expert consensus documents. All of these documents are updated to

reflect new data and findings as appropriate. For example, the clinical competence statement for cardiac imaging with CT and magnetic resonance was updated to reflect new evidence in 2009, while a 1998 expert consensus document on radiation safety and cardiology will be updated in the near future.

Clinical documents developed by specialty societies are critical to the development of evidence-based medicine because of the emphasis on impartiality that they bring to the table. The development of these documents is not funded by industry nor are the documents owned by industry. Members of writing committees are screened for conflicts of interest to ensure an appropriate balance. Members of ACOs should be encouraged to participate in the development of specialty society-led clinical documents and to use them as part of the clinical decision-making process. Any legal impediments to this should be removed.

AUC

As a result of the evidence collected through registries and the analysis synthesis conducted for guidelines, medical specialty societies have also led the development of AUC, critical to the ACO goals of providing high quality, appropriate and patient-centered care. For example, the College has developed AUC for a variety of diagnostic imaging modalities and procedures used by cardiovascular professionals. AUC define "when to do" and "how often to do" a given procedure in the context of scientific evidence, the health care environment, the patient's profile and a physician's judgment. In the case of diagnostic imaging AUC, they serve to assist the physician in clinical decision-making and to protect the patient from unnecessary radiation. Through regulations, ACOs should be encouraged to use specialty society-developed AUC and AUC implementation tools where they exist to assist in the delivery of appropriate care. Any legal barriers to this should be eliminated.

Quality improvement tools

The ACC firmly believes in a patient-centered approach to furnishing medical care. It is essential that patients be involved in the decision-making process regarding their care. The more patients are able and willing to be involved, the more they are able to weigh the risks and benefits. Such involvement is critical to the success of an ACO and its quality improvement efforts. Specialty societies play an important role here, as well.

Based on its expertise developing clinical documents and clinical education materials, the ACC is undertaking new projects designed to provide patient-centered quality improvement tools. For instance, the NCDR Management Board has made the decision to update its goals to include using the registries to learn more about the effects of radiation on patients as a result of cardiovascular procedures tracked through the NCDR. The NCDR CathPCI Registry, which includes information on coronary catheterization and PCIs, has recently begun collecting information on radiation dose. Specifically, CathPCI Registry participants are now required to report either fluoroscopy time to the nearest 0.1 minute and/or fluoroscopy dose to the nearest integer in milligrays for patients undergoing diagnostic cardiac catheterization or PCI. The other registries constituting the NCDR will begin collecting this information in the near future. Additionally, the ACC is also a participant in the Safety of Atrial Fibrillation Ablation Registry Initiative (SAFARI). The current plan for the SAFARI Registry calls for the collection of similar information.

In an effort to help providers of imaging services best use AUC at the point of care and ultimately reduce inappropriate tests, the ACC recently launched "Imaging in FOCUS," a national quality

improvement initiative designed to help physicians self-assess and gain quantitative feedback on their level of appropriate use. The College is also partnering with a nationally recognized information technology vendor to provide an American College of Cardiology Foundation (ACCF)-branded cardiovascular imaging strategies tool to health plans that will integrate computerized physician decision support with AUC education and quality improvement activities. ACOs should be able to use tools such as this one without legal impediment or fear that if one institution within the ACO opts to purchase such a tool, they will face legal difficulties if they work with others to do the same.

Specialty societies can also help drive campaigns around specific disease states or certain components of treatment process. For instance, the Hospital to Home (H2H) national quality improvement initiative, led by the ACC and the Institute for Healthcare Improvement, serves as a national rallying point to reduce cardiovascular-related hospital readmissions and improve the transition from inpatient to outpatient status for individuals hospitalized with cardiovascular disease. Through an online community, quality-minded individuals share information about their successes and failures and learn from each other about methods of improving care to cardiovascular patients transitioning from the hospital. From communities such as this one, the ACC and other specialty societies can gain valuable insights into the clinical environment and create education materials and plans for the entire specialty community that will serve to improve patient care.

Patient education and tools

ACOs are required to adopt a patient-centered approach to furnishing evidence-based medical care. Specialty societies are well-positioned to develop and disseminate such materials. As representatives of physicians, organizations like the ACC have special insight into the difficulties patients face when they are diagnosed with specific diseases or conditions and the decisions they face as treatment plans are developed. The ACC has recently begun to develop such tools and materials. A physician team/patient shared decision- making project is being designed to support appropriate use of medical therapy, PCI, and coronary bypass graft surgery for stable coronary heart disease patients. The College is also launching a national CardioSmart initiative that will build upon the current CardioSmart website and extend beyond the office visit with community events, web-based education, tracking modules and discounts for heart-healthy products. Others will build on the successes of the first two, allowing physicians and patients to work together to make treatment decisions and to improve patient care.

All of these quality initiatives will be for naught, however, if there are legal impediments to unrelated physicians working together to develop quality improvement strategies and initiatives and to specialty societies employing those strategies in a swath of unrelated institutions and practices across the country. Physicians should be rewarded for the role that they play in reducing the costs of care, whether through reductions in inappropriate testing or increased patient compliance as a result of additional time spent on patient education. Unfortunately, today's legal structure prevents them from being financially rewarded for these efforts.

Given the challenges faced by institutions and practices interested in forming ACOs as a method of working together to improve patient care, the ACC urges the government to reduce legal barriers to entry into this arena and to allow organizations to experiment with new models of care delivery. This country is well-known for the ingenuity and entrepreneurial spirit of its inhabitants. The legal structure should provide support and encouragement for these qualities without requiring the loss of independence that attracts many physicians into private practice. The ACC

urges CMS, the FTC and OIG to work together to craft regulations where necessary that preserve private practice.

The College appreciates the opportunity to provide comments on such an important issue. If there are any additional questions or concerns, please contact Lisa P. Goldstein at (202) 375-6527 or via e-mail at lgoldstein@acc.org.

Sincerely,

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