June 3, 2011

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1345-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

Re: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, Proposed rule.

Dear Administrator Berwick:

The American College of Radiology (ACR), representing more than 34,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, is pleased to submit comments on the implementation of the mandated Medicare Shared Savings Program through the use of Accountable Care Organizations (ACOs). Following are comments that reflect concerns on the assignment of beneficiaries, the tight linkage of all 65 quality measures to shared savings, the heavy emphasis on patient-centeredness, the linkage of decision support and other efforts into EHR records, and the important role of radiologists in the ACO model.

General Comments

The American College of Radiology (ACR) commends the Centers for Medicare and Medicaid Services (CMS) for its efforts to provide such a detailed rule that lays out the requirements and expectations for eligible groups of providers and suppliers who wish to participate in ACOs. However, the ACR is concerned that the basic premise of this proposed rule is flawed. CMS expects organizations to manage a population of patients that is unknown to them and beyond their control, making it extremely difficult to set up a successful model of integrated patient care. Also, the concept of tying the entire structure to the reporting of quality metrics with the goal of cutting costs while making patients the final arbiter will not work. It appears that shared savings cannot be realized by many groups that would like to participate in the ACO model. As evidenced by the Blue Cross and Blue Shield of Massachusetts (BCBS of MA) model quoted in the rule, a defined population is under a capitated fee for service agreement. If the organization provides care within the cap, the savings realized are paid to that organization. Additionally, quality measures that are met will generate added savings. In this model, the two methods of achieving savings are not dependent upon each other. Conversely, in the ACO proposal, an organization would be required to participate in all 65 quality...
measures in addition to functioning within a budget in order to realize any savings. The return on investment for a contract such as this would be very questionable. One necessary remedy is for the patient satisfaction measures to be decoupled from the quality measures that show shared savings.

Given that there will be some attrition of patient participation, it will be very risky to try to set up an ACO with a size anywhere near the minimum threshold of 5,000 beneficiaries, to say nothing of the economies of scale which would be lost in establishing an operation that small. The amount of investment required, the level of risk, and the stringent reporting requirements would make compliance difficult for a small group and make it highly unlikely to realize any kind of shared savings. In addition, strategies which have been successful for large group practices may not be applicable for smaller groups. CMS should not be overly prescriptive in specifying ACO-related policies, based on the results from the large and initially well developed groups, but should allow the market to experiment and should then analyze the data from a variety of schemes, including those that occur in rural areas, to help determine best practices.

Beneficiary Enrollment

The ACR is concerned that without clear guidance, the ability to categorize and attribute patients to a specific ACO will be problematic. We support the concept that the patients be attributed to an ACO at the beginning of the process so that both the ACO and providers can know whose care and costs are being tracked. We are also cognizant of the historical perspective that patients may change mechanisms of obtaining health care and we support the ability of the patients to have a choice in what physicians and hospitals provide their care. However, if a patient initially attributed to an ACO elects to leave the ACO for care, the care obtained outside of the ACO should not be attributed to the ACO. It is common for Medicare beneficiaries to live part of the year in one state and another part of the year in an entirely different part of the country. How will these patients be assigned? Unfortunately, retrospective attribution is equally problematic. One of the major tenets of healthcare reform is the elimination of fragmented care. Therefore, we believe that CMS cannot design a system where patients choose fragmented care but make the ACOs accountable by misattribution. The rules of attribution should be made clear at the outset and remain consistent throughout the covered period. Providers must have the ability to plan for the care of their beneficiary group and should not have to change this midway through a three-year contract. In addition, the beneficiary group should be educated as to how they can successfully participate and receive quality patient care within an ACO model in order to minimize out-of-network activity.
Patient-centeredness

The ACR believes the patient will likely be the final arbiter of whether they believe their care was “patient-centered” in an ACO. However, we are concerned that the focus given at every level, including types of required measures, board representation, and the ability to go out-of-network at any point creates a conflict in this rule. For the reasons stated, the ACR thinks that restricting demonstration of shared savings to the ACO by requiring them to report the proposed patient-centered measures will not work in achieving future quality improvements and thus savings. The ACR does not deny that the patient’s care giver experience is important, but this information can be gathered in patient satisfaction surveys and the results used to evaluate the ACO providers at the end of the 3-year period when a decision needs to be made to renew their contract. More meaningful measures should be developed that address quality of care as we discuss in our measures section below.

The ACR believes it will be difficult to find beneficiary representation for the ACO Boards. In addition, there is major concern that the beneficiaries have no obligation or commitment to work within the ACO to receive most if not all of their care.

The ACR has several recommendations for patient-centered care as they relate to diagnostic imaging:

1) Radiologists will play a pivotal role in assuring appropriate utilization of services within an ACO. Using Appropriateness Criteria and other measures, radiologists can substantially decrease inappropriate utilization with cost savings to the ACO and decreased radiation dose to the patients.

2) The ACR strongly believes that radiation dose management should be one of the patient-centered quality criteria. Radiation dose management is complex and must be tailored to individual patients. It often requires case-by-case dose optimization. Participation by radiologists in this process is essential.

3) Radiologists are the experts in a number of areas that provide value to patients including the use of contrast and managing which examinations require contrast and which do not.

4) In an ACO practice, radiologists should be integral on the front end of coordinated care. For example, in a number of acute care episodes, radiologists can assist the primary care providers in determining the most efficient route to achieve a specific diagnosis. This process of care is disrupted by regulations such as Medicare’s Ordering Physician Rule. In an ACO environment, these barriers should be removed. Obtaining a diagnosis in the most efficient manner would not only be good for patients but financially beneficial to the ACO. This process could streamline costs and potentially reduce inappropriate referrals to specialists for conditions that could be managed by the primary care providers.
5) To complement the front end consultation, the ACR believes that the use of its appropriateness criteria would be a valuable tool to help the primary care physician select the most appropriate study for the patient the first time around. This tool would be accompanied by access to a consulting radiologist to discuss further options.

The Role of Specialists in an ACO

The ACR supports the maintenance of fee-for-service payments to individual providers under the Affordable Care Act (ACA). In addition, we support the proposal for specialists to be able to share in the savings at a .5% level. Given the value-added elements that radiologists provide as listed above, radiology can definitely contribute to better quality and efficiencies in the ACOs. Radiologists’ involvement in the care team and the services they provide are necessary ingredients of the “glue” that links all patient care.

The ACR also appreciates CMS’s proposal that specialists be allowed to participate in more than one ACO. The ACR believes that the majority of specialists will be contracted partners with ACOs and that only the minority of radiologists will be employed by the ACO sponsor organization(s). Therefore, it will be important for radiologists to be able to contract with hospitals in multiple rural areas, for example, in order to offer proper coverage of radiology services.

EHR Comments

The ACR strongly believes that a robust electronic health record (EHR) is essential for an ACO. True accountable care cannot occur unless all providers caring for the patient have access to medical information including diagnostic imaging in order to eliminate duplicative work, unnecessary utilization of services, and in the case of diagnostic imaging, unnecessary radiation exposure. We believe physicians should incorporate EHRs into their practices. We believe that there should be incentives for developing systems that allow ready transfer of electronic health information, including diagnostic images and reports, between institutions. We also request that decision support systems (as discussed below) be tied into the EHRs.

Despite several mentions of small ACOs or physician group ACOs, the requirement that at least 50 percent of ACO PCPs be meaningful users appears to be well beyond the reach of any organization smaller than a large community hospital. Currently the proposal looks like it is structured for health system based integrated delivery systems. The ACR thinks that it will be difficult for primary care physicians and other specialists to finance the IT, case management and quality reporting requirements. A special loan program could be made available for those practices that need to improve their information technology (IT) structure in order to integrate into an ACO system. Small practices
would face major issues related to access of shared information systems and care management processes owned and provided by the ACO system. In addition, CMS will need to determine where there are major legal and regulatory restrictions that could prevent the necessary sharing of such information or provision of IT hardware or software. There might also be a need for waivers or safe harbors allowing otherwise non-aligned physicians to be provided with such tangible benefits that are necessary to effectively participate in the ACO.

The EHR Incentive Program does not currently provide clinically relevant requirements for non-primary care specialists. It would be difficult to require that all ACO physicians be “meaningful users,” unless the EHR Incentive Program includes specialty-relevant alternative requirements for non-PCPs in the upcoming Stage 2 rulemaking. Therefore, this requires that meaningful use regulations and regulations for ACOs be more closely aligned in order for CMS to achieve its goals of half or full attrition.

**Support for Decision Support**

The ACR appreciates CMS’s discussions in the rule supporting the need for decision support systems to help control utilization. Radiologists play an important role in this process as is currently being tested in CMS’s Appropriateness Criteria Demonstration Project. Radiologists can help drive a decrease in unnecessary imaging, especially through decision support efforts, as well as through improved reporting specificity, developing more cost effective imaging workup and follow up strategies, and service efficiencies.

Decision support systems entail the primary care physician (PCP) deciding that a patient needs an imaging study and then using the ACR’s appropriateness criteria to determine which imaging study is the most appropriate based on the patient’s signs and symptoms. In a fully functioning decision support system, a radiologist is also available as a consultant to help the PCP to make the most accurate decision. This type of process saves the ACO money by eliminating unnecessary tests that might have been ordered, offering the most accurate examination from the start, and also providing education to the PCP on proper selection.

The ACR was the first organization ever to develop appropriateness criteria over 15 years ago and was instrumental in the passing of the legislation that mandated the pilot study. Therefore the ACR is in full support of decision support systems and welcomes the opportunity to be actively involved in decision support in ACOs in the future. We believe that physicians should not be penalized for overutilization but rather rewarded for appropriate utilization.
Legal Structure and Governance

The ACR supports the requirement that "each ACO participant must choose an appropriate representative from within its organization to represent them on the governing body". Radiologists play a major role in patient care and decision support and it is important that they are involved in the decision making process.

ACO Marketing Guidelines

The ACR feels that CMS’s proposal that ALL marketing materials, communications and activities developed or revised be approved by CMS will cause an unnecessary administrative overload and will cause delays. It is also important that communication between patients and caregivers, including the ACO itself, be an extension of patient-physician communication. The ACR recommends that CMS rethink if, how, and where it is appropriate to insert itself into this process and what kind of load it can process with respect to the amount of documents and materials it can review. There needs to be a reasonable turnaround time for ACO participants in order for them to move forward with getting information out to beneficiaries and the public as this new payment model moves into action.

Proposed Quality Measures

Currently CMS is proposing 65 quality measures to be used by primary care. Although this is commendable, it leaves specialty physicians with no way to document their contributions to shared savings and value-added. It is essential that quality measures reflect the realities of medical practice with respect to the deeply integrated relationship between primary care and specialty physicians. The ACR has been working in cooperation with the AMA, CMS and other specialties to develop measures for radiology. However, many more need to be developed. CMS should consider the current lack of measures in radiology and help facilitate expanding the measures in a way that promotes collaboration between hospitals and radiologists and referring physicians and radiologists.

CMS should also consider that some measures will be needed that can be attributed to hospital practice and some measures will be primarily for office-based practices. Measures that would be applicable to office-based practice for radiology might include facility accreditation, the use of ASRT registered technologists, the ability to seamlessly share electronic patient information, including images, and incorporation of utilization management and radiation safety programs. For hospital-based radiologists, hospitals might wish to claim all of the value-based payments and shared savings through utilization management and feedback and radiation safety programs. However, such programs cannot exist without radiologists and the value that these hospital-based providers bring to the organization must be accounted for in the structure of the ACO.
Additionally, hospital based physicians should have metrics for value-based payments which reflect the unique role of hospital-based radiologists including the overall higher acuity of patients’ conditions such as trauma, the provision of 24/7 coverage and the higher consultative role including interpretation of outside studies required by hospital-based physicians. In addition, ACO performance measures should ensure that physicians and hospitals have incentives to work together to achieve the same goals, such as implemented appropriateness criteria-based clinical decision support for imaging orders. Because some subspecialties currently lack measures, and a data collection and reporting system that addresses their scope of practice, reporting requirements should be phased-in to ensure that physicians have the opportunity and resources to participate on a widespread basis.

Participation by providers in data registries should also be incented. Registries have the ability to monitor patient safety and outcomes in a variety of areas. In radiology, these include radiation dose, cancer diagnosis and surveillance, and cardiac diagnosis and vascular therapy.

**Conclusion**

The ACR would like to highlight the major points below that should be considered with regard to how radiologists can best play a role in meeting the three principal goals of better quality care for patients, savings to Medicare, and better physician team coordination.

The radiologist should be involved in the primary care encounter by providing decision support systems (CPOE) and acting as a consultant so that the right exam at the right time is performed.

Radiologists should act as the radiation safety officer with respect to insuring proper equipment calibration (with the medical physicist), proper training for technologists and proper dosage of radiation for patients.

Radiologists should be represented in the governance structure.

Radiologists should more actively manage all radiology services and services lines to help with more efficient and effective patient care.

There should be shared savings for cutting costs and additional shared savings for meeting quality metrics. The current proposed mandate that ties shared saving to all of the measures is too high of a risk and not obtainable.

The focus should be on rewarding appropriate utilization rather than rewarding under-utilization or penalizing overutilization.
Thank you for the opportunity to comment on the proposed rule on accountable care organizations. If you have any questions about our comments please feel free to contact Pam Kassing at 800-227-5463 ext. 4544 or via email at pkassing@acr.org.

Respectfully Submitted,

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Chief Executive Officer