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June 6, 2011

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1345-P
PO Box 8013
Baltimore MD 21244-8013

Dear Dr. Berwick:

The American College of Cardiology (ACC) is pleased to offer comments on the notice of proposed rulemaking **Medicare Program: Accountable Care Organizations** as published in the Federal Register on April 7, 2011. This rule is the first implementation of one of the key elements of the landmark Affordable Care Act (ACA) passed by Congress and signed by the President in 2010. We look forward to working with the Department of Health and Human Services (HHS) in implementing this rule and others that intend to improve the quality of care for Medicare patients while also reducing costs.

The American College of Cardiology is transforming cardiovascular care and improving heart health through continuous quality improvement, patient-centered care, payment innovation and professionalism. The College is a 40,000-member nonprofit medical society comprised of physicians, nurses, nurse practitioners, physician assistants, pharmacists and practice managers, and bestows credentials upon cardiovascular specialists who meet its stringent qualifications. The College is a leader in the formulation of health policy, standards and guidelines, and is a staunch supporter of cardiovascular research. The ACC provides professional education and operates national registries for the measurement and improvement of quality care. More information about the association is available online at http://www.cardiosource.org/ACC.

The College has anxiously awaited the release of this proposed rule after participating in the numerous public forums that the Centers for Medicare and Medicaid Services (CMS) held focused on this issue. We are committed to working with CMS to develop new payment models that better reward the provision of quality care. We understand that this new territory is difficult and we appreciate

the many dedicated hours that CMS has committed to this proposal. While we support many of the elements of the proposal, we are concerned that the excessive requirements and the relatively modest bonus opportunities will make it unlikely that many or perhaps any ACOs will take on this endeavor. We are pleased to see the Center for Medicare and Medicaid Innovation (CMMI) has released subsequent program opportunities that may address some of the problems related to this proposed rule. However, the CMMI initiatives may have limited reach, so improving CMS's proposed framework for the ACO program remains a high priority. We provide below detailed comments on the provisions of this proposed rule. We support many elements of the proposed rule including:

- The rigorous approach to quality measurement and reporting;
- Strong patient protections created by the robust quality measurement and reporting requirements;
- Meaningful roles for providers in ACO governance;
- The ability of specialists to work with multiple ACOs.

ACC also has recommendations for significant changes including:

- Increased flexibility for governance and administrative structure;
- Improvements and modifications to some of the proposed quality measures;
- Expanded opportunities for shared savings; and
- Opportunity for a true one-sided model without downside risk for ACOs in the initial three year project period.

Eligibility and Governance

Governance

CMS proposes an extensive operational structure for Medicare ACOs that includes a board of directors, chief executive, medical director, and multiple committees. Overall, we think that this section is too prescriptive in defining the governance structure for these ACO organizations. If CMS intends for there to be a wide variety of ACOs formed in the United States, it should allow for a large number of arrangements. Requiring the exact same governance structure for all ACOs risks creating inefficient bureaucracy which does not improve quality or reduce costs. In addition, there are substantial legal costs associated with forming a new corporation and creating this board of directors. These requirements make it less likely that small ACOs will be able to form, particularly in time to participate in 2012.

If a group of providers believes that it can operate in a structure without a formal board, then CMS should allow for such a possibility. However, if CMS finalizes the proposal to require such structures, we strongly support the requirement that the board be composed of providers within the ACO. If the governance for the ACO is not composed of the providers of the ACO, the important needs of the patient could be forgotten.

Demonstration of Quality Improvement

ACC supports the CMS proposal to require documentation of an ACO's plan to improve quality rather than requiring certain quality improvement techniques. We think this method allows for exploration and should be very helpful in determining what works to reduce costs and improve the quality of care. The ACC has developed many tools that we believe will be used by ACOs to support these efforts.

We think that clinical integration will be a hallmark of a successful ACO. One of the most important parts of clinical integration is the sharing of clinical data, which allows everyone who is caring for the patient to have the same information. One of the most promising ways in which clinical data can be shared is through the use of patient registries. ACC has invested considerably in the creation and dissemination of clinical registries and they are now found in hospitals and physician practices across the country. We think that registries can also provide value in other areas identified by CMS as well. We are only at the beginning of the use and analysis of population level data in healthcare. There is no telling what we can accomplish by encouraging the creation and integration of these clinical data sets with existing claims data.

CMS proposes to require that ACOs include a physician-directed quality assurance and process improvement committee. Many cardiologists already use this model in their own practices and it would be increasingly valuable if used in a larger setting like an ACO. We also think that registry data is valuable in this setting as well. Since hospitals can receive quarterly reports and physicians will be able to access nearly real time reports, they will be able to review their processes in the context of their performance.

CMS also proposes that an ACO "develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of better care for individuals, better health for populations, lower growth in expenditures." ACC was one of the first organizations to write clinical guidelines and has continued to develop and update guidelines for the past thirty years. We recognize that writing the guidelines is only the first step in the quality process and in recent years have developed tools that will allow physicians to implement these guidelines in their clinical practice. Most recently, we have developed a clinical decision support tool called FOCUS that assists physicians in their decision making process in selecting imaging tools. We are also working on the development of a shared decision making tool that should greatly improve the collaboration between physician and patient on the issue of selecting a therapy for coronary artery disease. We think that many ACOs will be able to use these tools to better manage costs and improve quality.

Distribution of Payments

We do not support the proposal that requires the ACO to document how shared savings payments will be distributed among the ACO participants. Since CMS indicates that it is open to

multiple models, it is unclear what value would be gained by revealing this confidential payment information. We encourage broad flexibility in permissible financial arrangements among ACO participants because of the strong quality controls that are in place as part of this ACO proposed rule.

Establishing the 3-year agreement with the Secretary

The ACC opposes the CMS proposal to allow for only a single annual enrollment date for ACOs. CMS expresses concern about patients being assigned to multiple ACOs if it allows for different enrollment dates. We do not believe that enough patients could be assigned to multiple ACOs for this to be a significant issue in identifying the overall collective spending for the more than 5,000 patients assigned to an ACO. Most patients who stay in a geographical area are likely to remain with a single group of primary care physicians. While there is some change in a patient population over a given time, this is more likely related to deaths and relocation. Also, the recent CMS proposal on the pioneer ACO program allows for prospective identification of patients attributed to an ACO. Patients in areas with "pioneer ACOs" and "standard ACOs" could also be counted in both ACOs. Since this issue was not compelling enough to prevent the creation of the pioneer ACO program, we believe it is not compelling enough to mandate a single annual start for ACO operations. CMS should focus on maximizing flexibility so that new ACOs can start as soon as feasible for their operations. This should encourage more ACOs to be created and give more patients access to this new model of care.

In the rule, CMS proposes that it will calculate the savings based on a six month "runoff" of claims data, meaning that the shared savings will not be determined until six months after the first year of participation. There would then be additional processing time before the shared savings could be received and then likely additional time from the receipt of payment by the ACO and the distribution to the ACO participants. One of the biggest reasons that so few physicians have participated in the Physician Quality Reporting System is the long period between participation and the receipt of a bonus incentive payment. By proposing a similar schedule in the ACO rule, CMS risks similarly low participation rates. This issue may be even more acute in this setting due to the substantial upfront costs associated with becoming an ACO. While providers have one year in which to submit claims, CMS notes that more than 98 percent of claims are received within three months of the date of service. For this reason, we think that three months is a more reasonable "runoff" time for the calculation of shared savings. Even a modest three month acceleration in payments should encourage more participants in the ACO program.

CMS expresses concern that ACOs may try to manipulate the shared savings calculation by holding claims for ACO participants beyond this "runoff" period. While we understand this concern, we think that this issue can easily be addressed by monitoring the billing patterns for the ACO participants. If a larger than usual number of claims is received after the "runoff" period, then CMS should be able to investigate. While we doubt that ACO participants would

participate in this kind of trickery, those that did so would experience cash flow delays that would be more problematic than any bonus that they might receive from this program.

Data Sharing

ACC strongly supports the CMS proposal to share claims data on ACO patients with the ACO. Receiving this data will allow ACOs to manage costs in as close to real time as feasible. Most patients in an ACO will receive at least some of their care from providers who are not participants in the ACO and in some cases, ACO patients may receive the majority of their care from providers outside of the ACO, making an understanding of total expenses even more valuable for the ACO. This will be a difficult exercise but will be very important for ongoing population management. We urge CMS to dedicate the necessary resources to ensure that what is proposed in this rule can actually be provided to the ACO. ACO participants will be particularly interested in claims data on individual patients – while aggregate data is helpful in measuring costs, it does not help to identify patterns of inefficient or uncoordinated care for a particular patient. We support the CMS interpretation of the Health Insurance Portability and Accountability Act (HIPAA) privacy provisions that allows this data sharing as part of health care operations, as all patients for whom data will be shared have been patients of the primary care physicians who are ACO participants.

CMS proposes that an ACO must request this data on patients at the time of application to become an ACO and then must document how it will use this data to improve quality and care coordination. We think this data is so important that it should always be shared with ACOs. In some cases, it may not be clear at the time of application how an ACO will best use this external claims data, so it is unclear if CMS will get any meaningful information from requiring this description from ACO applicants. We strongly support the CMS proposal to limit the use of this data to ACO operations and quality improvement activities. ACOs should carefully guard this patient data and ensure it is only used for these purposes.

Proposal to allow beneficiary opt-out of data sharing

The ACC is concerned about the proposal to allow beneficiaries who are seen by ACO primary care providers to opt out of data sharing. While we believe that relatively few patients will opt out, ACOs will not know this until they enter into the program. If an ACO intends to use external data extensively in order manage costs and coordinate care, it will be unable to manage this data in the way it intended.

ACC strongly believes in the rights of patients to control their health information. However, as an organization taking on significant insurance risk, an ACO has as much right to claims information as an insurer. We understand that some patients may still not wish to have their data shared, but we believe patients who opt out should be seen by primary care providers outside of the ACO so that ACOs are not accountable for costs for which they do not have sufficient information. We believe that the sharing of data should be a requirement for patients who wish to be seen by primary care physicians who are part of an ACO.

Assignment of Medicare Fee-For-Service Beneficiaries

CMS proposes that patients will be attributed to an ACO based on primary care services such as office visits provided by physicians in the traditional primary care specialties of family practice and internal medicine. CMS then proposes that any provider of Medicare services such as specialist physicians and hospitals can be included as part of an ACO. We strongly support the allowance for ACOs to include a large group of diverse providers in the ACO. Restricting participation to only primary care physicians could limit the opportunity for an ACO to reasonably reduce costs for their patients as the incentives for other providers would be different than the ACO.

We support the proposal to attribute patients to an ACO based on services provided by physicians in the primary care specialties. Cardiology is a diverse specialty that provides ongoing medical care to patients as well as interventions. Relationships with patients might be brief or go on for many years. For many patients with significant cardiovascular disease, cardiologists serve as the patient's primary physician, directing their overall care, coordinating services provided by other physicians and serving as the first contact for those patients in times of medical need. However, cardiologists also manage patients who may be seen once a year. We believe that the best opportunity for cardiologists to demonstrate value in an ACO system is by effectively managing both acute and chronic cases. The only way to do this is by working with the primary care physicians who have had patients attributed to them.

In some cases, patients who are very sick might not have any visits with a primary care physician in a year. In this case, we believe that CMS should investigate a way to attribute patients to a specialist who is providing the bulk of the care. We think that this will be relatively rare, but could help to capture the costs of patients who have extraordinary needs who often have very high and variable costs.

We strongly support the proposal to allow specialists to be part of more than one ACO. There may be areas of the country that have multiple primary care groups that are interested in forming ACOs, but only a single large cardiology group. In that situation, all of the ACOs in the region could benefit from working with a large specialty practice to improve quality and reduce costs.

The ACO proposal wisely focuses on primary care. However, we want to encourage CMS as it develops future models of ACO or other innovative payment proposals to recognize the important role that specialty care plays in the Medicare environment, particularly for the very sick patients that are the largest consumers of Medicare resources. Specialists like cardiologists can develop strong focused management of patients with diseases as severe as congestive heart failure. Improving the efficiency and quality of care provided to patients with complex chronic conditions holds the greatest promise for achieving both significant savings and improved outcomes. We are concerned that a singular focus on primary care could lead to missed opportunities to demonstrate the value of models such as ACOs. The ACC looks forward to

working with the Center for Medicare and Medicaid Innovation to identify and implement models that focus on patients with such difficult to manage diseases.

Quality and other Reporting Requirements

The ACC supports the CMS proposal of robust quality measurement for ACOs. In a payment model based on shared savings, it is crucial to measure quality to ensure that patients are continuing to receive high quality care. We believe there has been a good faith effort to measure quality for the ACO, but believe that a number of substantial changes must take place in the final rule.

Measures

CMS proposes to use 65 quality measures that are spread across five "domains" for the ACO proposed rule. We were pleased to see that 20 of these quality measures focus on cardiovascular care, recognizing the role of cardiovascular disease as the most expensive and deadly disease for the Medicare program. We support a broad collection of process, structural, and outcomes measures and support the proposal to move as quickly as possible to outcomes measures.

We have specific concerns with a some of the proposed quality measures. Measure 52 is a composite measure composed of five other measures for patients with coronary artery disease. It is measured as an "all or none" measure, meaning that ACOs are not credited for successful performance unless all five elements are met. Given that the individual elements of this composite measure are already included among the 65 quality measures, it seems redundant to include an additional composite measure that is not well established in ambulatory performance measurement.

Seven of the 8 "outcomes" measures in the *care coordination domain* (No. 12-18) are AHRQ Prevention Quality Indicators (PQI) that measure admissions per 100,000 population for various conditions (e.g., CHF, pneumonia, diabetes, dehydration, COPD). According to AHRQ, these PQIs "identify hospital admissions in geographic areas that evidence suggests may have been avoided through access to high-quality outpatient care. These AHRQ PQI measures were developed to identify regional/geographic issues that would assist health planning authorities and have only recently been explored as measurements for providers or groups of providers. When these measures were developed, AHRQ acknowledged their lack of risk adjustment as a flaw but given the intent of the initial measures, determined them to be worthwhile.

Such concerns are even more relevant when these metrics are used to assess and compare the quality of ACOs, who may care for populations with vastly different socioeconomic and demographic characteristics. In fact, ACOs caring for disadvantaged populations may be rendering better care if they preferentially admit some patients with dehydration, pneumonia, or COPD exacerbations, as their outpatient environment and resources may be quite problematic compared with those of more affluent populations.

Given that ACOs already have a significant financial incentive to avoid unnecessary admissions due to the shared savings payment model, we encourage CMS to reevaluate the inclusion of the seven AHRQ PQI measures.

We are concerned with the inclusion of measure #16 used to measure care coordination for congestive heart failure. While coordinating care for patients with CHF is clearly important, there are some technical issues with the measure that caused AHRQ's own clinical panel to express concern about it. The measure may not accurately capture patients with CHF based on the ICD-9 codes that were included as part of the measure. We would urge CMS to remove this measure or closely monitor its implementation to ensure that it captures the intended population.

We are very strongly supportive of the CMS proposal to include measure #23 on Patient Registry Use. Hospitals throughout the country have used ACC's National Cardiovascular Data Registry (NCDR) to measure quality on common cardiac diseases and procedures. Three years ago, we started work on the first cardiovascular outpatient registry, PINNACLE. This registry is a true innovation in the measurement of quality of care in the outpatient setting because it takes data entered into an electronic medical record and then populates the registry with performance measures and other important quality metrics. Use of this registry continues to grow across the country. We believe that the use of registries like Pinnacle will be one of the key drivers of successful participation in the ACO program. We urge CMS to continue to develop programs that will allow for quality measures to be reported directly from registries, rather than requiring an additional data entry step into the group practice reporting option (GPRO) tool.

Scoring

CMS proposes a quality scoring system in which scores on the domains have a minimum attainment level as well as a high performance level. The measures are placed into composites of five domains. It appears from the proposed rule that ACOs that do not meet the minimum attainment level on any of the composite domains will not be eligible for shared savings. However, it is unclear if CMS refers to minimum performance on the composite domains or on the individual measures. We do not support restricting shared savings distribution to an ACO that does not meet minimum performance on only a single measure. The science of performance measurement is too imprecise to believe that there could never be an error or a measurement problem. The composite domains comprise enough measures to prevent these issues so we do support a proposal to prohibit shared savings payment to those who fail to meet the minimum attainment level on any of the domains. ACC believes that ACOs should be able to share in savings as long as they reach minimum attainment level on each of the five domains, even if they do not reach minimum attainment on one of the performance measures contained in that domain.

We do support the CMS proposal to use the first year of the shared savings program to set the quality performance standard at full and accurate reporting. This will be a good opportunity to

gather data before adjusting for performance information and is consistent with other programs that began as pay-for-reporting before moving to pay-for-performance.

We support the CMS proposal to consider ACO participant provider physicians to be successful participants in the PQRS system under the group practice reporting option. The GPRO tool associated with the ACO quality collection is the same tool used for group practice PQRS data collection. Requiring an additional step to measure quality for these participant physicians would be redundant and an unnecessary administrative burden.

Public Reporting

CMS proposes that ACOs publicly report business information related to how shared savings payments were distributed and the total proportion of shared savings reinvested in care coordination. We do not support the inclusion of financial information related to the shared savings in this public report. This information is not relevant to the public for evaluation of the quality of an ACO or its providers and it is unclear to us what value it provides.

The ACC supports the CMS proposal to publicly report on ACO performance measures as long as they align with a focus on the key goal of performance measurement – improving the performance of the provider. In order to support this goal, we recommend that CMS not publicly report measures on ACOs in the first year of participation to be consistent with other pay for reporting and performance programs. In following years, ACOs should have the opportunity to review and comment on their performance measures prior to their release to the public. Creating a feedback loop that first provides quality information to the ACO will best serve the goal of improving performance.

Shared Savings Determination

Models

In the rule, CMS proposes that ACOs will have two options for participating which they refer to as a "one sided" model and a "two sided" model, with the "two sided" model having substantially more risk. Unfortunately, the one sided model is not really "one sided". CMS proposes that those who choose to participate in the one-sided model will be eligible for shared savings in the first two years of the three year ACO agreement, but will be subject to shared risk for increased spending in the third year. The shared risk is structured in a model similar to the shared savings, meaning that the ACOs could be forced to pay thousands of dollars to the government. Since the ACO is responsible for all costs, these payments back to Medicare could be a very substantial portion of an ACO's annual budget. We understand that CMS wanted to limit participation to those who are serious about reducing costs and improving quality, but believe that requiring downside risk for this initial model goes too far.

There are enormous upfront costs to starting an ACO. Creating the documentation of the governance, clinical integration, and other features of the ACO required to even submit an

application will likely cost millions of dollars. The submission of quality measures and additional administrative burden through the three years add even more costs. We believe that ACOs should have the opportunity to participate in a true one-sided model for their first three year contract without any element of downside risk. We believe that this would better encourage participation in the program. We support the creation of a "one sided" risk model that is truly one-sided and a "two-sided" model that is truly "two-sided". The hybrid model that CMS proposes as the "one-sided" model should not be finalized.

Establishing a benchmark

CMS is required to establish an expenditure benchmark which it will use as a comparison point to determine whether there is reduced spending for the patients attributed to the ACO. CMS considers a number of different ways in which to establish this benchmark but proposes to establish the benchmark using the population that would have been attributed to the ACO during the previous three year period. We do not wish to offer any comment on this approach but urge CMS to closely examine its determination of this benchmark on a regular basis as this calculation is crucial in determining shared savings. We are concerned about the exclusive use of claims data to risk adjust the expected increase in spending. We urge CMS to explore alternative methods to gather clinical data to better make these adjustments.

We support the CMS proposal to exclude bonus payments for PQRS, electronic prescribing, meaningful use of electronic health records and other initiatives from the calculation of spending for the ACO. These separate payments are not tied to a specific patient and are intended to achieve another goal of the government. It would be inconsistent to provide this bonus payment for these desired services and then penalize the ACO for higher spending.

Minimum Savings Rate and Sharing Rate

CMS proposes a complex model of minimum savings rate and sharing rate for the one sided model. We agree with the CMS proposal to establish a minimum savings rate that must be attained before savings can be shared. We would not want an ACO that saves money due to random annual variation to gain financially from such random chance. Based on the statistical analysis that CMS performed, two percent seems to be an appropriate minimum savings rate for larger ACOs. However, that two percent threshold might still be a significant barrier to recruitment for ACOs. Additionally, we are unsure if varying the minimum savings rate so substantially based on the size of the ACO would be appropriate – CMS should closely monitor the number of small ACOs that start and determine if the larger minimum savings rate is a significant barrier to entry. If it is, then CMS should lower the minimum savings rate as much as possible to attract ACOs that demonstrate a commitment to quality care and reducing spending.

We are very concerned about the percentage of shared savings that will be available to the ACO, particularly in the one sided model. CMS proposes a model in which an ACO in the one-sided model can keep up to 50 percent of the shared savings depending on their scores on performance measures. However, CMS proposes that those participants not share in "first

dollar" savings. Instead CMS proposes that the ACO be able to share 50% of savings above 2% of the threshold. This means that an ACO is able to demonstrate substantial savings of 5% would only get a bonus of 1.5% of the total target spending. Based on our discussions with members who may consider this option, a bonus of this size is not enough to make the risk worthwhile. CMS appears to have instituted this "net sharing rate" based on additional concern about allowing ACOs to benefit from random fluctuation in costs in a given year. We believe that the establishment of the minimum savings rate is a sufficient step to protect against this random variation. ACC strongly recommends that an ACO be given the opportunity to share in first dollar savings.

The ACC Is very impressed with the level of effort that went into the creation of this proposed rule. Creating an entirely new payment model that encourages both reduced spending and improved quality is an incredibly difficult task. While we have pointed out some of the problems with the proposal in this letter, we wish to reaffirm our commitment to moving Medicare payment towards a system based on quality and outcomes and less on volume. We look forward to working with CMS and others to further refine the ACO model and work on many exciting new models for the coming future. Thank you for the opportunity to comment on this proposed rule. If you have any questions, please contact Brian Whitman, Associate Director of Regulatory Affairs at bwhitman@acc.org or (202) 375-6396.

Sincerely,

David R. Holmes, Jr., M.D., F.A.C.C.
President

Cc: Jack Lewin, M.D. – CEO, ACC