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September 4, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Mail Stop C4-26-05
7500 Security Blvd
Baltimore MD 21244-1850

Dear Ms. Tavenner:

The American College of Cardiology (ACC) is pleased to offer comments on the proposed rule on the *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013* as published in the Federal Register on July 30, 2012.

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>.

2013 is an important year for cardiology because it marks the fourth and final year of implementation of the large payment cuts associated with the integration of data from the American Medical Association (AMA) Physician Practice Information Survey (PPIS) into the practice expense calculations. When CMS proposed to do this in 2009, we warned of the impending dangers to the private practice of cardiology. Our concerns came to be realized as the majority of cardiologists in this country now work for hospitals. For many, this is the best opportunity to provide care, but for some, it was the only way to survive. The results for the entire Medicare system are increased costs without evidence of significantly improved quality or outcomes. We point this out only to remind CMS of the substantial consequences of the decisions within these rules and how important it

The mission of the American College of Cardiology is to advocate for quality cardiovascular care — through education, research promotion, development and application of standards and guidelines — and to influence health care policy.

Is for the Agency to consider all potential reactions to the decisions that are eventually made.

Interest Rate Assumption for Capital Equipment

The ACC understands CMS's desire to utilize an accurate interest rate for capital equipment in practice expense (PE) calculations. The proposal to apply a "sliding scale" interest rate based on the equipment cost, useful life, and a benchmark interest rate allows the PE formula to account for changes in the marketplace. We request that two aspects of the proposal be clarified before it is implemented.

First, we are uncertain whether the Small Business Administration maximum interest rates are the correct benchmark to apply. We are concerned that physicians may not have access to interest rates as low as those presented in the proposal. **We request that Medicare delay this implementation until it can verify that physician practices can obtain loans with interest rates equivalent to the Small Business Administration maximum interest rates.**

Second, the proposal states the interest rate assumption will be updated "through annual PFS rulemaking to account for fluctuations in the Prime rate and/or changes to the SBA's formula to determine maximum allowed interest rates." The proposal does not indicate at what point in time the interest rate sliding scale assumptions will be set for the following year. It could be based on rates and formulas from a single day, an average over the prior quarter, an average over the prior year, or some other mechanism. **We request that CMS clarify the mechanism by which it will select rates and formulas on which to base PE interest.**

Equipment Minutes for Interrogating Device Evaluation Minutes

CMS notes that there are no times for equipment associated with two cardiac device interrogation codes (93294 and 93295). CMS then proposes to correct this error by increasing the equipment time to 10 minutes for the pacemaker follow up system used for analysis in the office. **The ACC supports this proposal and appreciates the CMS correction of this obvious error.**

Potentially Misvalued Codes under the Physician Fee Schedule

Implant and Removal of Patient Activated Cardiac Event Recorder

CMS notes that codes 33282 and 33284, used for the implantation and removal of a patient-activated cardiac event recorder, were nominated for review as potentially misvalued. CMS indicates that these codes were nominated for this category by a member of the public because they are not priced to be performed in the physician office (nonfacility) setting. We agree with CMS that the lack of pricing in a particular setting is not a valid indicator of a potentially misvalued code. We do not believe these services are misvalued. Despite the commenter's request, we did not find a desire or preference within the ACC membership to perform these services in the nonfacility setting.

As such, we do not believe it is appropriate to establish nonfacility inputs at this time. **We recommend that CMS withdraw its proposal to review these codes for revaluation for work and facility practice expense and not request further input from the RUC.** We have shared this recommendation with the RUC through the potentially misvalued code action plan process. We will discuss that action plan further at the October RUC meeting in advance of a decision from CMS in the final rule.

Review of Services with Physician Work and No Listed Physician Time

HCPCS code G0250 used to report physician review, interpretation, and patient management of home INR testing does not have any listed physician time but does have physician work value. The management of these patients does require significant physician work under a limited coverage restriction. **We support the CMS proposal to maintain the assigned work value of 0.18 RVUs and crosswalk the physician time of 5 minutes of intraservice time and 2 minutes of immediate post service time.**

Expanding the Multiple Procedure Payment Reduction Policy

ACC is familiar with CMS's past efforts to reduce payment to reflect typical efficiencies in PE or physician work or both when certain services are provided together. The application of a 25-percent reduction to the technical component (TC) of second and subsequent cardiovascular procedures as presented in the proposed rule appears to be based on flawed assumptions and proposed to be implemented in an unreasonable manner. It is not appropriate to apply a 25-percent reduction of the TC of second and subsequent services provided to the same patient on the same day by the same group physician practice. **The ACC is strongly opposed to the expansion of this multiple procedure payment reduction to cardiovascular services.**

In the rule, CMS evaluates a handful of potentially redundant direct practice expense inputs, primarily clinical labor inputs. However, we found this analysis to be flawed by the assumption that certain clinical labor activities would be performed only once when two or more services are provided to the same patient on the same day by the same group physician practice. Comparing this list of clinical labor activities with the clinical labor activities of two services side-by-side may create the appearance of redundant activities if those activities are in fact performed by the same individual for the same purpose. In reality, many of the services CMS included in Table 12 are supported by different skilled clinical staff. Many of the clinical labor activities CMS considers redundant are in fact performed multiple times, at different times of day, and in different rooms each stocked with unique equipment -even if they happen to take place under the same roof. Furthermore, in group practices, many of the services included in Table 12 are provided by physicians with different sub-specialty expertise.

In the example CMS presents in Table 11, transthoracic echocardiography (93306) is performed the same day as myocardial perfusion single-photon emission computed tomography (SPECT) (78452). In a typical group practice, a different cardiologist provides the professional component of each service. In the same vein, different clinical staff with different specialized training assists

the two different physicians. The patient is greeted and gowned for each service, once by a nurse or a specialized medical technologist for the echocardiography in the echocardiography suite, and separately later in the day by a nuclear medicine technologist in the nuclear imaging suite. In the same fashion, two different rooms of different specialized equipment in two different parts of the facility are prepared for the two unique and different services. Education and consent is separately performed by the appropriate clinical staff for each service. Two very different machines are utilized by two differently credentialed support staff to acquire independent and unrelated important clinical testing data. Different diagnostic forms are completed for the two very different services. The patient is positioned multiple times on different exam tables. Two different rooms are each cleaned. Different quality assurance or regulatory compliance information must be documented. Finally, the two different clinical staff will independently review prior x-ray, lab, echo, and other studies. It is inappropriate for CMS to reduce payments based on perceived redundancies that are not present in reality.

As we mentioned above, many of the services included in Table 12 are provided by different physicians and staff within the same group physician practice. In addition to inappropriately reducing payments for redundancies that do not exist, such a policy punishes physicians for providing efficient, continuous care to their patients. We are concerned that CMS seems intent on creating disincentives for specialists to provide high quality, patient-centered care. At a time when such care coordination efforts are being appropriately rewarded in other portions of the rule, it is counterintuitive to create new fissures in patient care. As we note elsewhere in this letter, we support proposals to reward care coordination, and find the cardiovascular MPPR proposal to be in direct conflict with that initiative.

Our review of the proposal also found a number of technical issues that create additional concerns about the validity of CMS's concept. These technical issues lead us to believe that there was little to no clinical expertise guiding the selection of the services proposed for the MPPR. This is an important proposal that could have significant impact but it appears to not have been well researched for implementation.

Many of the code pair/combinations identified by CMS in Table 12 (code ranges 75600 through 75893, 78414 through 78496, and 93000 through 93990) are not cardiovascular services. It is highly unlikely that these codes would be provided to the same patient on the same day by the same physician. For example, the RUC Database indicates code 93980 for penile vascular study was provided by cardiologists 0.10% of the time to Medicare patients in 2011. We are not recommending removal of these codes from proposed MPPR because their presence produces no impact, making them irrelevant. However, the presence of this code and other codes unrelated to cardiovascular care in Table 12 create doubts about the thoroughness and validity of the analysis underlying the proposal.

Several codes that we would have expected to see in Table 12 were not included. The absence of these codes creates further doubts about the thoroughness and validity of the proposal. These codes are defined with individual global, TC, and PC components. Codes 93005, 93016,

93040, and 93224 represent global services for electrocardiograms, cardiac stress tests, rhythm electrocardiograms, and Holter monitors respectively. Each has a standalone, companion code that also represents the TC. These global codes were not included in the list of services that would be impacted. Since we have not seen any correction notice issued, CMS must have intended to keep these codes separate but has not explained its rationale for doing so. Since CMS has not included these services in the proposed rule and has not issued a correction notice, we believe that CMS has not actually proposed to apply this policy to these services. We believe that expansion to the services in a final rule would violate the Administrative Procedures Act. This is yet another reason that CMS should not finalize this portion of the rule.

Several add-on codes were included in Table 12. This is inconsistent with coding convention since these codes are, by definition, performed with other services. They have already been priced with the intention that certain components of the service are not included. We view inclusion of these codes as further evidence of the shortsightedness of this proposal. Codes 78496, 93320, 93321, 93325 and any other add-on codes should not be included on any MPPR list.

CMS proposes to apply the MPPR to 17 codes related to cardiac device programming, interrogation, and evaluation. Most of these services are used to manage and optimize the function of implanted pacemakers and defibrillators. However, three codes identified by CMS (93293, 93296, 93299) describe the TC for remote interrogation of the devices, meaning that the patient is not even physically present when the service is provided. We fail to see how it is possible for efficiencies to exist in the rare circumstance these services were provided on the same date as a cardiovascular diagnostic service. This inclusion again demonstrates a lack of understanding of how diagnostic services are provided to patients.

We recognize that CMS is desperate to try to identify efficiencies that cause price inequities within the Medicare system. **However, we believe that CMS has seriously erred in this proposal and urge that it not be finalized.**

Hospital, SNF, or CMHC Post Discharge Care Management

Financial pressure on hospitals is leading to shorter and shorter hospital stays which in turn leads to very ill patients being discharged to home. Unfortunately, this has led to a staggeringly high rate of readmissions within 30 days after the initial discharge. Keeping patients well and managing their care requires a strong commitment of the medical team supervised by a physician. Physicians who provide these services are not paid because they are primarily provided outside of a face-to-face visit. CMS recognizes this issue and proposes a new code for transitional care management. **The ACC strongly supports the creation of a new code for transitional care management.** As CMS mentions in the rule, there have been ongoing efforts among medical societies to create similar codes through the normal CPT cycle – while we anticipate that those codes will be made available for use in 2014, we support the CMS efforts to begin to pay for this important work in 2013.

While we support the creation of the code, we believe that CMS has restricted the use of this new code in a way that encourages and rewards fractionated rather than coordinated care. CMS proposes that the physician who billed for the hospital discharge on a patient is prohibited from being paid for these new transitional care management codes on that same patient. CMS proposes this because it believes that the work of hospital discharge includes many of the same work elements as this new code. **The ACC opposes this proposal to not allow a physician to bill for transitional care management and a hospital discharge on the same patient.**

There are two significant problems with the CMS proposal. First, the proposal assumes that the development of a care plan that is part of discharge is the same as the active management of that plan in transitional care management. The fact that this care management is not being provided effectively despite hospital discharges being billed for every hospital discharge is evidence of this already. CMS cites the work description for the hospital discharge codes and notes that the service includes care coordination in the post service period. However, the total post service time associated with 99239, the highest level discharge code, is only 15 minutes, which is primarily composed of completing the discharge records. It is hard to imagine that a physician could meaningfully manage the care of a complex patient for a month in the 5 minutes or so of leftover time with the post service time. For this new code, CMS assumes that more than 47 minutes of total time are spent by the physician on the care coordination over a month. It is hard to understand why CMS would believe that a physician could complete a 47 minute service in 5 minutes. Looking at the work values, the same issue arises. CMS has proposed a work value that is actually crosswalked to the hospital discharge codes. There is no way that a physician should be expected to provide all services associated with the discharge that are related to just getting the patient out of the hospital in addition to all the services associated with care management and receive the same payment.

The second significant problem with the CMS proposal is that it encourages and rewards splitting up responsibilities. The proposal seems in large part to be based on a model in which a hospitalist treats a patient at a hospital and discharges a patient to an unaffiliated community primary care physician. While this model might be common or even dominant in some communities, we are not sure that it is a model that CMS should wish to encourage over all others.

Patients in the hospital following an acute myocardial infarction or with heart failure are likely to be admitted to and discharged from the hospital by a cardiologist. Following the discharge, the best care management can often be provided by a cardiology practice. They often have specialized staff with expertise dealing with the issues that patients with cardiovascular disease often experience leaving the hospital. Because CMS billing rules treat individual physicians within a group as equivalent to the same physician, there is no opportunity for a group to be paid for both the hospital discharge and the transitional care management. This proposed new code is intended to improve care coordination but this proposed limitation could limit coordination and discourage specialists such as cardiologists from providing these services. This limitation would not only adversely affect specialists. Many primary care physicians continue to

operate in a traditional model in which they provide care for their patients who are admitted to the hospital and continue to follow them in the outpatient setting. They also would be prohibited from being paid for this service under this proposal.

We support the CMS proposal to pay for this service only at the conclusion of the 30 days of management. We believe that there is too much risk in billing for a service before the time period has completed for CMS to allow this. Because CMS proposes to pay only the first physician who submits a bill for the coordination of care, allowing billing before the completion of the service could result in a race to submit a bill before the physician even knows what his or her role in providing the service might be.

CMS indicates that it believes that the physician billing for the transitional care management should have an established relationship with the patient. We support this conceptually but would recommend some changes to the proposal. CMS proposes that the physician billing for transitional care management have billed for an E/M either 30 days prior to the discharge or in the 14 days following discharge.

First, as stated above, we believe that transitional care management should be allowed to be billed by the physician that provided the hospital discharge management and that the provision of this hospital service should establish a relationship. Second, we believe that defining a pre-existing relationship as a visit within 30 days prior to the discharge is far too restrictive. A patient with established disease may only be seen by a physician every three to six months. We believe that a physician who provided an E/M service 31 days before a discharge that follows a one week stay in the hospital still has an established relationship with the patient. **We recommend that CMS allow an E/M service provided any time in the 12 months prior to the discharge to be considered evidence of an established relationship.**

The ACC supports the CMS proposal to not require a face-to-face visit as part of this transitional care management. We believe that in many cases it may make clinical sense to see the patient in the office shortly after discharge. However, as CMS notes in the rule, the condition of these patients may be fragile and requiring a face-to-face visit may make it less likely that the transitional care management service will be provided. We believe that a physician and his or her care team can provide a great deal of service without face-to-face contact and support this notion. We recognize that there are issues for CMS to consider regarding patient understanding of billing for services that are not provided face-to-face. However, we believe that there are a number of solutions available to CMS such as allowing active consent by the patient that would be less burdensome than requiring a face-to-face visit.

The ACC believes that CMS may have seriously overestimated the utilization for this service, which results in reduced payments for all other services. CMS has assumed that this service will be provided 10 million times per year, covering more than 80% of all discharges in the Medicare population. Reviewing the service, we do not believe that anywhere close to this percentage of discharges will result in a subsequent transitional care management. Included in these

discharges are patients recovering from surgery using a code with a 90 day global period, patients discharged from hospitals into nursing facilities or rehabilitation units, and patients who may have been relatively healthy outside of whatever acute condition caused their hospitalization. The ACC urges CMS to revise its calculation and project a number that better reflects the actual utilization. **We believe that fewer than half of all discharges will be followed by a bill for transitional care management and urge CMS to update the conversion factor calculation to reflect a lower assumed utilization for transitional care management.**

Primary Care Services Furnished in Advanced Primary Care Practices

The ACC is committed to a strong primary care base in this country. We are pleased to see the commitment of primary care physicians in improving practice and becoming recognized as patient-centered medical homes. We are encouraged to see CMS begin to consider recognizing practices that are operating at a higher level. However, we would like to see CMS broaden this effort so that all physicians have an incentive to provide a higher level of care and be rewarded for these efforts. In addition, we believe that achieving recognition for a practice can only be considered one part of high performance. The baseline for increased pay must be increased performance measured by process and outcomes measures in addition to a structural measure like being recognized as a patient-centered medical home. We comment later in this rule on the extensive value-based modifier proposals and believe that if CMS considers payments for these practices that it be integrated into the value-based modifier.

Non-random complex prepayment medical review

The ACC is concerned by the Agency's proposal to remove all protections for practitioners undergoing non-random prepayment review. While the College acknowledges that the Affordable Care Act (ACA) did remove the explicit statutory authority for the time limitation for contractors to complete the review, it did not remove CMS's general regulatory authority to set program rules and constraints needed to properly administer the Medicare program. This general regulatory authority allows CMS to set definitive standards and requirements for contractors and physicians to meet. **Therefore, the ACC urges CMS to leave 42 CFR 421 Subpart F intact.**

In the event that CMS declines to halt its proposal to remove the time limitation, the ACC urges CMS to set clear benchmarks for removing practitioners from nonrandom prepayment review. The current proposal would remove all tests for determining improvement by practitioners in reducing errors in billing and leave determining how to measure such improvement entirely to the discretion of the Medicare contractors. Accepting that the error rate will never be zero, practitioners need to understand what an acceptable error rate is and what actions need to be taken to achieve such a rate. Without clear standards, practitioners may be faced with meeting a moving target set at the Medicare contractors' whim. Instead, CMS should set a clearly defined standard for practitioners across the country.

Even if the ACC were to concede that CMS did not have the authority to set time limitations, the College still contends that CMS does have the authority to set certain other requirements contained within Subpart F. For instance, 42 CFR 421.505(c)(4) states that Medicare contractors must ensure that claims processing systems must be updated within five business days of a practitioner's removal from non-random prepayment review in order to avoid delaying payment for services. The provision protects practitioners who have worked diligently to reduce their error rate by ensuring that they will be properly removed from non-random prepayment review in an efficient manner. Another provision prevents practitioners from being placed on non-random prepayment review within six months of having been removed from it. This provision protects practitioners from the arbitrary and capricious whims of staff at Medicare contractors who may develop a problematic relationship with practitioners and instead, requires that Medicare contractors only use prepayment review as a tool of last resort for educating practitioners on proper coding and billing practices. After all, practitioners with error rates so high as to require a non-random prepayment review in less than six months of the end of another such review for different services should raise red flags and be considered for a more thorough audit or investigation. The ACC urges CMS to reconsider its proposed removal of 42 CFR 421 Subpart F in its entirety and to only remove such provisions as are either no longer necessary or that it no longer has authority for under its general regulatory authority for the administration of the Medicare program.

Physician Compare Website

The ACC supports the public reporting of physician performance information that leads to the creation of the Physician Compare website. It is important for patients to have the opportunity to learn more about the quality of care that may be provided to them. Because patients and the public come into the process with varying levels of expertise, it is important to ensure that the data that may be included on the Physician Compare website are easily understood, accurate, and consistent across the physician universe.

The ACC is pleased to see that CMS is making efforts to improve the underlying data used in the current directory function of Physician Compare. If the basic data such as which physicians work in a practice and the physical location of the office are inaccurate, it certainly makes the reported quality data seem suspect to many.

In this rule, CMS lays out some provisions of the additional development of the Physician Compare website beyond this enhanced directory function. **The ACC supports the CMS proposal to use the PQRS data as the baseline for public reporting of quality data.** While the PQRS system is far from perfect, it is superior to the currently available alternatives. As in the hospital system, however, we believe that this data may be supplemented substantially by data gathered from a clinical registry. **The ACC does not support the use of administrative claims-based data measures on the Physician Compare website as we do not believe that the measures are accurate and do not truly reflect the quality of care provided.**

One issue that CMS does not discuss in the rule that merits discussion is how measures are displayed for public review. On the Hospital Compare website, some measures are reported with actual statistics and others, particularly outcome measures, are reported as “lower”, “higher”, or “no different than” the national rate. CMS should consider multiple display options as it further develops the Physician Compare website. **The ACC recommends that CMS work with stakeholders including patients and physicians to develop a reporting structure that gives the necessary information to beneficiaries.** Given the large number of measures, reporting structures, and types of physicians, different determinations may need to be made for Physician Compare than for Hospital Compare.

CMS requests comments on the minimum threshold for publicly reporting on measures and proposes that measures may be reported if as few as 20 patients are reported on. While this proposal only refers to the 2013 reporting on participants in the Group Practice Reporting Option (GPRO) that is composed of large practices, it appears that this policy would apply to future expansion of public reporting beyond this initial group. We therefore focus our comments on the future implications of this policy.

This issue of sample size points us to one of the difficulties of public reporting in an environment with multiple reporting mechanisms. A physician may have seen 200 Medicare patients with coronary artery disease but reported a measures group for 20 of them through the claims-based method. Another may have submitted data on all of those patients through a data submission vendor. Because physician practices are able to select the patients that are submitted as part of a measures group, their performance scores may be higher than those who are reporting on 100% of patients. **We believe that CMS should establish a much higher minimum patient sample size for reporting and should also exclude measures reported through measures groups from public reporting.**

CMS proposes to post the names of the physicians who report the PQRS Cardiovascular Prevention measures group on Physician Compare in 2013 in support of the Million Hearts campaign. The ACC is a strong supporter of the Million Hearts effort but we are somewhat confused by this proposal. It is unclear if only this measures group is to be reported, and if so, whether it is given some particular prominence on the website. This measures group is just one of several that measures the quality of care related to cardiovascular disease and we think it would be misleading to a patient to be steered towards a particular physician because he or she reported on this measures group while another reported on heart failure measures. As we have pointed out in previous letters to CMS, a number of the measures contained in this measures group are intended for population levels rather than individual practices and attempts to improve performance in these measures may not always be beneficial to patients. For example, a blood pressure target performance measure does not recognize patients who do not benefit from aggressive treatment to reduce blood pressure if other symptoms are worsened. **The ACC requests that CMS withdraw this proposal.**

CMS proposes to report on patient experience measures as part of Physician Compare in 2014 for groups with more than 25 individuals but to begin reporting on Accountable Care Organization (ACO) patient experience measures in 2013. **The ACC does not support the proposal to publicly report on patient experience measures for ACOs in 2013.** As CMS notes in the rule, this would not allow the ACOs the opportunity to review the data from these surveys confidentially before they were publicly released. The ACC believes that performance improvement should be the primary goal of any public reporting program and believes that groups should be given the opportunity to react and improve based on reviewing the results prior to public reporting on these measures.

The ACC supports the CMS proposal to allow the public reporting of measures that are collected by approved and vetted specialty societies if they are found to be scientifically sound and statistically valid. The ACC is currently working with CMS on the public reporting of measures gathered from two hospital-based registries and we envision a similar program may be appropriate for an ambulatory registry. The ACC, in collaboration with the American Heart Association (AHA), continues to develop measures that we believe are important and relevant in the measurement of the care of cardiovascular disease and many of these maybe appropriate for public reporting. We encourage CMS to develop a clear process by which specialty society measures may be vetted and approved for use in this venue.

The ACC does not support the use of the ambulatory care sensitive condition admission measures as part of Physician Compare. These measures were developed by the Agency for Healthcare Research and Quality (AHRQ) as measures for regional comparisons and have never been reviewed as quality indicators for the much smaller populations attributed to physician groups. These measures are only adjusted for age in a population, not for risk and are not a valid measurement of performance of a physician group. These measures and their attribution methodology are particularly problematic for specialists who care for some of those conditions. Of the seven conditions, two are primarily managed by cardiologists (heart failure and angina) and another is at least partially managed by cardiologists (hypertension). Because of the nature of the specialty, those with particularly difficult disease are more likely to be attributed to cardiologists and also more likely to be admitted into the hospital for this condition. Even in the field of cardiology, there are heart failure specialists who manage the sickest heart failure patients and their attributed admission rate would be even higher. The AHRQ documents detailing the measure do not indicate that poor performance is evidence of poor care but instead poor access to primary care. The use of this measure has the potential to confuse and mislead patients, limit access to care for the sickest patients, and would not be expected to improve care delivered by individual practitioners. We strongly urge CMS to not adopt this measure for Physician Compare.

Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting Program

The Physician Quality Reporting Program (PQRS) is at an important crossroads as it moves from a bonus program into a penalty program. Despite continued efforts to increase participation, only about 25% of physicians participate. Cardiology has a higher participation rate than the national average but still only one-third of cardiologists participated in 2011. We are encouraged by efforts to expand reporting but we are worried that they are not coupled with significant incentives for more robust reporting.

The ACC supports the proposal to redefine the group practice reporting option (GPRO) in 2013 to allow smaller groups to participate. The original GPRO was a remnant of the large group practice demonstration quality reporting – this new definition will allow for measurement at the most appropriate level regardless of the size of the group practice. **We also support the CMS proposal to allow GPRO participants to report through all methods for PQRS including claims, registry, and electronic reporting methods.** The new definition of a GPRO includes many practices that are not multispecialty groups and allowing them to select from the full array of performance measures will allow more groups to participate.

CMS asks for comments on how a practice will identify itself as a GPRO for measurement purposes. We are hopeful that CMS can develop a web-based tool in a timely fashion to allow for members of a group to request to be considered as a group for PQRS purposes. We are afraid that a manual process requiring the mailing of a letter is cumbersome and will likely lead to mistakes being made.

We do not support the CMS proposal to disallow individual PQRS participation for eligible professionals that are part of a GPRO. We believe that CMS should not disadvantage group participants by not giving them opportunities that those reporting as individuals are given. In a group, the failure may be the result of a small group of eligible professionals not reporting properly. We therefore believe that a failed group reporting option should be followed by a determination of individual success. This would remove a potential barrier to groups entering this option.

We believe that CMS should clarify its statement related to the establishment of group size at the time of registration. CMS appears to indicate group size will be fixed for purposes of analysis – meaning that those who join a practice mid-year will not be considered to be part of the group. However, as written, it may appear as though any change in group size would disqualify a practice from participating. Instead, CMS should say that the group would be fixed for analytical purposes but that those physicians who join midyear would be evaluated on an individual basis.

The ACC supports the CMS intention to move towards 12 month PQRS reporting after 2014. The six month reporting periods that have been in existence for many years have provided a great door to practices to begin quality reporting in the middle of the year. As we move into a more meaningful reporting program, however, it is important to have a significant sample size and collect data throughout the year. It may be reasonable to make an exception for physicians

who submit claims using a new Medicare ID number, to encourage reporting despite a change in practice setting from a training program to one's post-training environment.

We support the CMS proposal to continue to allow for PQRS reporting through claims, registry, and direct EHR vendors. We are hopeful that the claims-based submission process can be eliminated in a short time because we believe it is burdensome and less likely to contribute to quality improvement than methods that are directly tied to clinical data. However we recognize that not all physicians are in the position to be able to report through a registry or through electronic data submission. As we discuss later in this comment letter, we are hopeful CMS can continue to encourage robust reporting and move away from claims-based reporting.

The ACC strongly opposes the proposal to make changes to the definition of an EHR data submission vendor for PQRS. Currently, all products that translate electronic medical record data into performance measures may be qualified as data submission vendors. However, CMS proposes to change the definition so that only products that are actually owned by a single EHR vendor could be qualified. Quite simply, this would end the participation of the ACC PINNACLE outpatient registry, a flagship participant since registries were first able to report for PQRS in 2009. This registry was reclassified into a data submission vendor in 2012 because the associated performance measures are calculated by translating data from an electronic health record. This proposal would make it impossible for PINNACLE to continue to qualify because it translates data from multiple EHRs into performance measures. The ability to translate data from multiple EHRs is a significant feature of the program. We would be very disturbed to see the very dedicated PINNACLE participants who have shown a true commitment to quality be required to report through some other method that would almost certainly include less information. CMS should be encouraging participation at the most robust level. **We urge CMS to not finalize this portion of the rule.** We understand that there are many other data submission vendors that submit data from multiple sources so CMS would not only lose the PINNACLE participants but many others as well.

If CMS does need to include a definition in a manual, we urge a change of the definition so that a data submission vendor does not have to be owned by or tied to any single product. We are also concerned that an unintended consequence of this part of the proposed rule would be to concentrate the reporting "market" even more than it already is, resulting in fewer options and higher costs for buyers of these services.

We also oppose the CMS proposal to discontinue qualifying EHR data submission vendors and instead require certification under the Meaningful Use program established by the Office of the National Coordinator for Health Information Technology (ONC) for the 2014 program and beyond. We do not believe that all data submission vendors will wish to go through the process for meaningful use. Instead, we believe that CMS should continue to qualify EHR data submission vendors but allow for those who are certified through ONC to be deemed qualified. We believe this option provides the most flexibility for a large number of products. This greater

flexibility increases the opportunity for more vendors to be able to submit quality data to CMS for the PQRS program.

The ACC supports the proposal to allow physicians to avoid a penalty in 2015 by allowing CMS to calculate measures from administrative claims. However, we are concerned that because this is by far the easiest way to report on PQRS, some physicians may cease active quality reporting and instead opt for this method. We encourage CMS to limit participation in this method as much possible by providing stronger encouragement for active reporting through electronic medical records and registries. CMS appears to have developed this program as an alternative to an exemption from the program that may be appropriate for subspecialists or those with limited applicable measures. We urge CMS to create a method that encourages physicians with appropriate measures to submit as many measures as possible. For those without adequate measures, CMS should develop some kind of alternative method of demonstrating quality improvement activities so that penalties may be avoided.

CMS proposes to continue to allow physicians to report via measures groups but proposes to reduce the threshold for reporting from 30 to 20 patients. The ACC supports the concept of measures groups because they can allow a practice to focus on a specific subset of patients even with very limited reporting. However, reducing the threshold to 20 patients will continue to discourage active reporting. If a physician has fewer than 30 Medicare patients with a particular disease, it does not seem sensible to use that small group of patients as a measure of that physician's quality. **We recommend that CMS maintain a 30 patient threshold for measures group reporting.** We do urge CMS to clarify whether non-Medicare patients may be counted as part of the measures group. They were originally included in measures groups, then removed in later years – in this year's rule there are references to non-Medicare patients being allowed and not allowed.

CMS proposes that practices with greater than 100 eligible professionals be required to report using the GPRO web-based tool. **The ACC does not support the requirement that groups of 100 or greater physicians be required to use the GPRO web-based tool.** With the increasing numbers of cardiologists who are employed by hospitals, many of them are in groups with 100 or more individuals. In many cases they have established reporting methods which have allowed them to best measure quality. While the web-based system may be a superior method to some other methods, it is inferior to registry or electronic data submission reporting in which actual clinical data is being used and in many cases data is being submitted for 100% of patients. In addition, we believe that some groups of this size may not be able to report in this fashion. We believe that while most groups of this size will be multispecialty and include many primary care physicians, we believe that there are some single specialty groups that may not be able to appropriately report using this method.

In reviewing the CMS proposal to allow for claims-based and registry based submission for GPROs, we were confused by the requirements. It appears that each group must report on at least three measures but it is unclear if the groups can choose any measures they desire or if

they must choose measures that are particularly relevant to the practice. We believe that CMS should make some efforts to ensure that groups are reporting on applicable measures that measure quality for the majority of the group, rather than choosing a measure that applies to very few in the practice.

The ACC supports the CMS proposal to establish different criteria for avoiding the PQRS penalty than had been established for receiving a PQRS bonus. Despite all the many mechanisms available for reporting, some physicians may not be able to report without reducing the threshold. As stated previously in this letter, we are concerned that there is not enough emphasis on encouraging reporting. Although a bonus payment is still in place for services provided in 2013 and 2014, it has been reduced to a mere half a percent but the penalties for those same years will be 1.5% and 2% respectively. This means that for many physicians, avoiding the penalty will be of utmost importance. And following 2014, there are no longer any bonus incentives. ACC encourages CMS to establish a plan that will better bridge the program from the bonus to the penalty phase. CMS should consider active reporting to be a significant contributor to the value-based modifier to encourage more reporting. We understand that there are physicians whose practices do not align well with existing performance measures. There should be a process by which those physicians can avoid penalties, but CMS should not gut the requirements of the PQRS program for everyone in the process.

CMS requests comments on the notion that a practice could “game the system” and avoid PQRS penalties by merely changing their tax identification number if they were scheduled to be penalized. Given that there are extensive other costs associated with changing tax ID numbers related to updating contracts and other legal hurdles, we do not believe that is a realistic concern. CMS can certainly monitor this issue to determine if it becomes a problem but we do not believe this issue will arise.

CMS proposes a series of PQRS measures associated with the Million Hearts campaign as “core measures” but it does not appear that this designation has any meaning. While we are supportive of the Million Hearts campaign, we believe there are many appropriate cardiovascular measures and believe this terminology is confusing and misleading, especially because the same term is used in the EHR Meaningful Use program but does have a specific meaning in that context. **The ACC recommends that CMS cease to use the term “core measures” in relation to PQRS unless it uses it to specify something that is substantially different from other measures.**

The ACC supports the CMS proposal to add a structural measure for participation by a physician in a clinical database registry. We are supportive of this measure because we believe it will encourage more physicians to participate in the active reporting and feedback that is part of a clinical registry. However, we do not believe that establishing a structural measure such as this one does nearly enough to encourage the use of these tools. CMS should instead consider providing greater recognition for PQRS measures that are reported through registry or

electronic data submission. We think that a registry is a particularly strong performance improvement tool because it allows physicians the opportunity to benchmark their performance in comparison to their peers. For example, the clinical registries created by the ACC provide reports to hospitals and physicians on a quarterly basis. By the time a physician who submitted claims-based measures knows how he or she compares to other physicians, a registry participant could have already identified and improved upon a performance gap. Establishing a structural measure like this one is only a first step but it is one that we support.

The ACC strongly supports the CMS proposal to add three measures of the appropriate use of cardiac stress imaging to PQRS in 2013. ACC has developed a clinical decision support tool and associated registry called FOCUS to help facilitate collection of the measures. This approach allows physicians to record a rationale for each test referred to the imaging laboratory. These measures have been associated with a decrease in inappropriate ordering by up to 50%. In some locations, the data collection can be used with private payers instead of time-consuming, separate and costly utilization management services. As well, FOCUS participation offers Maintenance of Certification Part IV credit and quality improvement credit for imaging lab accreditation. The PRQS incentive would complement these benefits of participation. As well, several imaging laboratories have developed tracking software that could facilitate data collection for these measures.

The measures are an important step in the evolution of quality measurement to ensure that care is not only high quality but also appropriate for the patient. The measures are an example of how efficiency measures can be clinically oriented and an alternative to more administratively intensive practices such as prior authorization. The creation of these tools and their associated measures are a part of ACC's commitment to wise stewardship of healthcare resources.

The ACC supports the inclusion of NQF measure 1525 used to report anticoagulation therapy for patients with atrial fibrillation or atrial flutter as a PQRS measure starting in 2013. This measure was developed by the ACC in collaboration with the AHA and is an important measure of a large patient population that is actively managed in the outpatient setting. It replaces a measure that is proposed to be retired measuring the use of warfarin for patients with atrial fibrillation.

We support the CMS proposal to remove two cardiovascular measures in the 2013 program that are being replaced by better measures. CMS proposes to no longer include the following measures relevant to cardiovascular disease:

- NQF 82/PQRS 199 Heart Failure: Patient Education
- NQF 17/PQRS 235 Hypertension: Plan of Care

The ACC does not support the CMS proposal to delete NQF 65/PQRS 196 Coronary Artery Disease: Symptom and Activity Assessment in 2013. This measure is a necessary part of another measure that CMS proposes to add for 2013 for CAD Symptom Management. The

denominator for the symptom management measure is determined by those for whom symptoms are assessed.

One issue that is likely to arise in the future is that some of these measures are being substantially revised while retaining their NQF measure number. This means that CMS may need to propose to include these measures again in the future. We are unsure if this will cause significant problem for CMS to take measures in and out of the program but the long endorsement process associated with performance measures may at times orphan a measure before its replacement is fully endorsed and adopted.

The ACC does not support the CMS proposal to include the preventive cardiology composite measure developed by the American Board of Internal Medicine for PQRS in 2014. This measure, composed of eight separate measures, includes a number of elements that are similar to measures developed by ACC/AHA. The composite measure was created as an element of maintenance of certification and we are unsure of the method for how this measure will be composited and how it will be integrated into the overall performance measure composite process.

The ACC supports the proposal to retire the performance measure of Warfarin for Atrial Fibrillation in 2014. This measure was retired as part of the ACC/AHA update of the heart failure performance measures that was released in 2012. We agree with CMS that the use of warfarin no longer necessarily represents the best practice for treatment of atrial fibrillation over other therapies. However, we would also urge CMS to retire this measure for 2013 as a replacement measure for anticoagulation therapy for patients with atrial fibrillation has also been proposed. There is no reason to maintain this out of date measure when an effective replacement is available.

The ACC supports the proposal to include the measures for Coronary Artery Disease (CAD): Symptom Management and Hypertension: Blood Pressure Management in the PQRS program despite these measures not being NQF endorsed. We do support the CMS efforts to use NQF measures if at all possible but the NQF endorsement process has slowed some of the implementation of our measures and we are hopeful that this opportunity will allow the best measures to be used even if they have not been fully reviewed and endorsed by the NQF. The CAD symptom management measure was developed by ACC/AHA and we believe it represents a next generation of measure that is more attuned to what is important to a patient – whether his or her symptoms are being managed.

The ACC is supportive of the proposal to continue to offer measure groups for coronary artery disease, heart failure, ischemic vascular disease, and hypertension. The opportunity to report on measures groups has given some physicians the chance to make an initial limited step into quality reporting and we are hopeful that they will continue on to more robust reporting options. As stated previously, we continue to feel that CMS should provide more recognition of those who report actively on a larger number of patients. The measures group option is a good

start towards quality improvement but can only be a small start. We hope it is maintained as an opportunity to avoid the penalty in the future but do not think it can reasonably become the basis for determination of the value-based modifier given the very small sample size. **We do not support the CMS proposal to remove measure #196 (symptom and activity assessment) from the Coronary Artery Disease measure set and to replace it with #242 (symptom management).** We are supportive of the new measure #142 as it is part of the new ACC/AHA performance measures on coronary artery disease and is also consistent with a movement from measuring the gathering of clinical data to the active management of a clinical problem. However, as stated above, the denominator for the symptom management measure is determined by those for whom symptoms are assessed. In order to properly calculate the new measure, both measures must be maintained. **We encourage CMS to add measure #242 to this measures group but to not remove measure #196.**

As noted above, CMS has proposed to give practices and physicians the opportunity to report on administrative claims instead of reporting on clinical data and avoid the upcoming PQRS penalty in 2015. While we understand why CMS is making this opportunity available, we would like to point out that testing of many of the measures proposed by CMS has identified significant flaws. The measures are a subset of those measures reported back to physicians as part of the Quality and Resource Use Reports (QRURs) that were sent to physicians in four states in the spring of 2012.

CMS proposes to use a measure (NQF 277) that measures the percentage of the population with heart failure that is admitted into the hospital. This same measure was proposed to be used as part of Physician Compare. **The ACC also opposes the inclusion of this measure as an administrative claims measure.** As stated above, this measure was created by AHRQ and intended to be used as a measurement for a geographic area. It was never intended to be used as a measurement of an individual physician or practice. Because of the attribution rules which are associated with these measures, physicians who treat particularly challenging patients, such as those with New York Heart Association Class III and IV heart failure, will be shown to have higher admission rates than those who treat those with less severe heart failure. This has the potential for “gaming” and may limit access to necessary hospital-based care, may significantly skew quality rankings, and result in reporting that is misleading and/or meaningless.

The ACC has concerns with other measures proposed by CMS for inclusion in the administrative claims set. CMS proposes measuring and reporting how often patients are readmitted or seen within 30 days as part of this measures set. While these measures could potentially provide helpful information, we do not believe that the risk adjustment or the attribution models for these particular measures are sound at this point. A patient may be attributed to a physician due to the number of services he or she provided in the year but that physician may not be involved at all in an admission. Some may argue that those who report via this method are not going to be held accountable for their performance, and instead only receive the information for quality improvement purposes. We do not support this notion. We believe that all PQRS measures should give physicians the opportunity to improve their performance. We also expect

that quality improvement (QI) measures may eventually become performance measures with the potential for application of penalties, and therefore do not support methodologically flawed QI measures.

CMS proposes an administrative claims measure of statin therapy for beneficiaries with coronary artery disease (NQF 543). This measure is based on a review of Medicare Part D claims. While ACC strongly believes in the use of statin therapy for these patients, a claims-based measure may be problematic because of the recent availability of generic statin medications. Since many large stores offer free or greatly discounted generic drugs to anyone with a prescription, these claims do not show up in Medicare Part D. This may skew the measure so that physicians treating a large number of patients who seek out these programs will have a lower score on this measure. In addition, some patients choose to use non-prescription products such as red yeast rice (similar to lovastatin) based on a belief that supplements are safer options to use. Other patients who have been tried on statins do not tolerate this class of drugs. **For all of these reasons, the ACC does not support a statin possession measure as part of the administrative claims set.**

Our comments on these particular measures can probably be replicated for many of the administrative claims measures that do not focus on cardiology. These comments serve to further underscore the weaknesses of administrative claims-based measures. These measures are convenient and do not require work on the behalf of anyone other than CMS. But they also do not offer very helpful information. We believe that claims data does offer important information but must be combined with clinical information in order to be meaningful.

E-prescribing

The ACC is pleased that CMS's proposed rule acknowledges that there are efficiencies to be gained from allowing group practices of fewer than 25 eligible professionals to report electronic prescribing jointly. In that same vein, the College supports reducing the threshold reporting requirements for smaller group practices to reflect their smaller size and likely smaller patient population.

Ironically, as CMS makes it easier for group practices to report e-prescribing for the purposes of the E-Prescribing Incentive Program, the Agency continues to refuse to eliminate the hurdles that exist for individuals attempting to both avoid the e-prescribing payment adjustment and participate in the more comprehensive Electronic Health Records (EHR) Incentive Program. Rather than streamlining the process and eliminating administrative burdens on physician practices, CMS is proposing new hardship exemptions for which physicians can apply if they are also participating in the EHR Incentive Program. Given that the information in those exemption requests will be verified based on data within CMS's possession, it seems arbitrary and capricious to require physicians to go through the process of requesting an exemption and waiting to see if their request has been granted. **Instead, the ACC believes that CMS should use the data from the Registration and Attestation System to automatically exempt physicians**

who have either successfully participated in the EHR Incentive Program or have registered their intent to do so by a date certain. By doing so, CMS would eliminate the possibility that physicians who are eligible for the proposed exemptions but who remain unaware of them might be unfairly subject to the e-prescribing payment adjustment.

In the event that CMS declines to simplify the e-prescribing hardship exemption requirements for those attempting to participate in the federal EHR Incentive Program, the ACC would support the adoption of hardship exemption categories that provide some administrative relief to those physicians. While the ACC understands the difficulties CMS faces in determining practice affiliation based on the Registration and Attestation system, the College urges the Agency to develop a less burdensome method for members of physician practices to request exemptions. CMS collects information regarding practice affiliation as part of the Medicare provider enrollment process and should be able to combine this information with Registration and Attestation information for a more streamlined exemption process for members of physician practices.

Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

The ACC prides itself on being an organization at the forefront of the measurement and improvement of quality. For years, we have argued for a fundamental change in the Medicare payment system to better reward high quality performance and incentivize improvement. In this proposed rule, CMS takes the first step in proposing a system that begins to reward value with a payment adjustment in 2015 based on 2013 data. The tenets of these proposals demonstrate how incredibly difficult it is to measure and reward quality and resource use in a large and diverse set of professionals. We support the CMS effort to start small with this effort – there are far too many as yet unknown issues that will have to be identified and resolved. However, we are concerned that CMS has not done enough to move physicians in the direction where they will be able to participate successfully in the near future. We are committed to working with CMS to craft a value-based purchasing program that identifies and recognizes high quality using the best possible measures. If every physician has to be a part of this program by 2017, then there is only a short time to address shortcomings and improve the program.

The ACC supports the CMS proposal to measure physicians at the group level for the purposes of the value-based modifier. We recognize that there has been significant debate about the level at which to determine accountability for quality and costs from as large as a state to as small as a single physician. We believe that a determination at the physician group level provides the right balance in which individual actions can improve quality but at which there is also sufficient data to ensure statistical significance. This does not preclude those groups from performing their own measurement of individual physicians – we believe that this is very important as well, but for accountability purposes, group measurement is most appropriate.

We do believe that in the future, CMS may wish to give the opportunity to physicians who are in smaller groups to band together for accountability purposes. While some may prefer small

groups for business or other reasons, most physicians have a referral base or a group that they commonly work with. As CMS expands the program beyond the initial proposal for large groups, this could lessen difficulties due to small sample sizes for practices with only one physician.

We also support the CMS proposal to limit the value-based modifier program to groups of 25 or more in the first year of implementation. We agree that these groups are in the best position to understand and participate in this kind of program. We would not support efforts to start smaller than this – for example, only starting with participants in the large group practice demonstration. Groups of 25 or more would be expected to include both multi-specialty and single specialty groups and should give CMS a range of experience from which it can build the program over the years. Because CMS proposes that participants have the choice of whether to have payment adjusted under the modifier, they should not be disadvantaged by this proposal.

CMS proposes to base most of the quality score within the program on PQRS measures. We support this proposal because it best aligns the program with clinical quality measures. However, we believe that the PQRS program was developed in the early days of performance measurement and with the expectation that participants would report via claims. We hope that in the future CMS does not limit efforts to those that can be achieved through the PQRS. As we have stated earlier, CMS should do more to encourage active reporting of clinical data, preferably through a registry or an electronic medical record.

The multiple reporting methods are a strong feature of PQRS but create some significant challenges for implementation of the value-based modifier. We believe that there are significant problems when comparing data submitted via claims-based CPT II codes and data gathered from an EMR data submission vendor or a registry. CMS has established different completion standards for registries and claims-based PQRS submissions. Those who participate via registry must report on 80% of eligible patients but those who report via claims must only report on 50%. Those differing standards alone are reason enough to consider the data differently. We believe that registry and EMR data submission reporting is also likely to be more accurate and more consistent than claims-based reporting. **We recommend that when comparing performance scores, CMS score registry and data submission vendors separately from claims-based submissions.**

Scoring those who report via different methods in different ways may solve one problem but creates another – there is a chance that those who report via registry (for example) may have as a group significantly higher performance scores than those who report via another method. We believe that this may be the case as those who have chosen to participate in a registry often show a strong commitment to measuring and improving quality. **In order to address this issue, we recommend that CMS first measure quality based on the reporting method – with more credit given for more robust reporting.** This would provide the incentive to improve and increase reporting that is lacking in the current proposal.

We do have some concerns about the administrative mechanism by which practices will become a part of the value-based purchasing program. First, they must identify as a GPRO for PQRS and register with CMS. Then they must identify their method of reporting through the GPRO. Then, if they wish to participate in quality tiering program, they must indicate this to CMS. **We recommend that CMS integrate the GPRO and quality tiering selection process so that these actions occur seamlessly.** One issue not addressed in the rule is what would happen to a practice with more than 25 physicians that fails to register as a GPRO in the first place. Given the problems with the CMS Provider Enrollment Chain and Ownership System (PECOS) that tracks physician practice information, there may be practices that have far fewer than 25 active eligible professionals but due to orphan records and other incorrect information are considered to have more than 25 eligible professionals. **We urge CMS to actively inform all groups that it considers to be eligible for inclusion in the value-based modifier program before the program begins. We also encourage CMS allow a process by which a practice can demonstrate to CMS that it is smaller than the size required for participation in this program.**

The ACC supports the CMS proposal to allow groups the option of participating in the quality tiering program in the first year of the program. We think that some practices that believe they are high performing will take advantage of this offer but there are too many unknown issues to include all eligible practices in the first year. Even though the penalties are capped at one percent, that one percent may make the difference for many practices between staying open or not. Until CMS has more confidence in the performance measures, the composites, and the cost of care measures, it should not adjust payment for practices that do not volunteer for the opportunity. **We do support the CMS proposal to require PQRS participation to avoid the maximum penalty.** We think this is one proposal in which CMS is doing a good job of encouraging the reporting that must be the backbone of the future program. **We do not support the use of the administrative claims measures for any group that is part of the value-based modifier program.** Giving practices an “out” by allowing CMS to calculate administrative-claims based measures is weak policy. We believe that most if not all practices of this size can report through the various methods available. If there are unusual groups with 25 or more eligible professionals that cannot adequately report on three measures, then CMS should give them an opportunity to identify themselves and demonstrate quality using some kind of other mechanism, rather than having CMS calculate measures that are probably even less relevant to them than the clinical measures which they could not report.

The ACC supports the CMS proposal to set a maximum penalty of one percent for the first year of the value-based modifier program. While many practices may consider a potential one percent loss to be too great a risk to elect to be part of the quality tiering program, some practices will likely consider the risk worth the bigger upside. Without a maximum penalty established, we believe that no practices would risk the chance that their payments could be cut by significant percentages as part of a voluntary program. The low level of interest in the first iteration of the Medicare Shared Savings Program was a direct result of the potential for significant penalties without much opportunity for reward. CMS should closely monitor the

participation in the quality tiering program to ensure that at least some physicians participate. The incentives for participation may have to be adjusted substantially based on the early participation rates.

CMS requests comments on whether hospital-based physicians should be allowed to be assessed based on the performance of their hospitals in the inpatient and outpatient hospital quality reporting programs. Although we would have to review more details, we are supportive of CMS considering this option as a number of physicians may best be measured as a component of a hospital system. We look forward to reviewing potential future proposals on this subject from CMS.

CMS proposes to supplement the PQRS measures with four outcomes measures that it will calculate from claims and include in the performance score for all groups. **The ACC is strongly opposed to the inclusion of these claims-based outcomes measures in the value-based modifier calculation.** Two of the measures proposed by CMS are composites of AHRQ measures reflecting the number of admissions per 1000 attributed patients for a series of acute and chronic conditions. As we have stated in previous portions of this letter, these AHRQ measures are used to measure overall populations – they are not risk adjusted and will continue to show that groups with a large percentage of high risk patients have high rates of admission.

CMS also proposes to use two other measures derived from administrative claims: number of readmissions and number of post discharge visits. As discussed earlier in the section on the administrative claims, these measures will have significant methodological limitations related to attribution. In addition, absent risk adjustment, it is impossible to know if these measures are good reflections of quality care. We strongly urge CMS to not use these measures in any programs at this time. If they are to be used, they should be excluded from payment adjustment until such time that their reliability, validity and feasibility have been confirmed at the physician group practice level, and actionability has been demonstrated.

We understand that CMS is looking for ways to measure outcomes. The ACC and others are working hard to develop outcomes measures that combine the best of clinical and claims data. We are hopeful that these measures can be made available to be used in future years even though they are not ready yet. CMS and others surely understand that it is better to have no measures than to use faulty or untested measures including some of those proposed in this rule.

Proposed Cost Measures

The ACC has been working on quality measurement for many years. Cardiovascular medicine and surgery were among the first specialties to develop performance measures. More than 100 unique performance measures have been developed – many of them in use in Medicare quality improvement programs. We have learned a great deal since the early days of performance measurement, resulting in improved measures and a better process.

Cost measures were introduced much later than other performance measures. There is no history of experience with cost measures in Medicare or other programs. Early attempts to use such measures in the private sector have been crude and inaccurate. The measures that CMS proposes to use present many of the same problems. While we recognize that the ACA requires CMS to consider both quality and cost in applying the value-based modifier, we do not believe that it requires CMS to give these measures equal weight. If the rule is implemented as proposed, we are concerned that there will be very little differentiation across groups on quality measures but extraordinary differences in cost. If we had enough evidence to suggest that these costs were largely under the control of a particular physician group, then it would make sense to adjust the payment significantly based on these costs. However, the measures are based on an attribution methodology that has not been fully tested and include risk adjustment that may be appropriate for very large population but has not been examined in the smaller population of a physician group. We urge CMS to refocus the efforts of the value-based modifier so that the primary focus is on improved quality.

CMS proposes to measure costs per capita for all patients attributed to a group. Two sets of measures are proposed – one measures per capita costs for all patients and the others measure per capita costs for patients with the specific diseases of chronic obstructive pulmonary disease, heart failure, coronary artery disease, and diabetes. We recognize that CMS must select a method to attribute costs to physicians but we do not support this per capita method. We believe episode-based costs would more accurately capture the costs for many physicians, particularly for specialists who may actively manage a patient for only a short period of time. We understand that CMS is making significant progress in the creation of Medicare-specific episode groupers and we believe that these can be helpful in calculating episode costs in the future.

The ACC supports the CMS proposal to standardize costs by removing geographic and other adjustments when calculating cost of care measures. The costs of care related to services depending on the amount of graduate medical education being provided or the percentage of patients with Medicaid has no bearing on what these measures are intended to do. Cost measures are not intended to reward physicians for finding the best bargain for their patients, but instead for serving as a steward of healthcare resources as measured by the number and intensity of those services.

While this price standardization does remove some of the administrative price differences, it does not account for regional differences in spending. **We believe that CMS should establish cost of care measures at both the regional and the national level.** Many people are familiar with the significant regional variation in healthcare spending across the country. Some of this variation is related to the availability of medical care or the culture of the physicians, but much of this variation comes about for other reasons or remains unexplained. We believe that using both regional and national measures is advantageous for two reasons. First, physicians will be less likely to be rewarded just for being in an area where patients seek out less care or punished

for being in an area where they seek a great deal of care. Secondly, it will provide an incentive for those in both high and low cost areas to continue to improve their stewardship of resources.

CMS proposes to adjust the cost of care measures for risk using the Hierarchical Condition Category (HCC) risk adjustment methodology that was developed for the Medicare Advantage program. This risk adjustment methodology examines the claims history of the patients attributed to a physician group and adjusts the expected costs up if certain conditions are noted in claims. We understand that this methodology has worked well in the Medicare Advantage population, but we are concerned that it is not fully tested in the smaller populations of physician groups. Medicare Advantage programs recruit hundreds of thousands or millions of patients and the risk adjustment can serve to ensure that they are not merely targeting the healthiest patients in their recruitment efforts. Even a practice with 25 physicians may only have several hundred Medicare patients depending on the specialty. This leaves that practice much more vulnerable to outlier costs. This would be a fertile topic for a CMS pilot project, prior to implementation.

As we understand the proposed rule, the risk adjustment would be based on claims submitted in the years prior to the performance year being measured. This creates a particular problem when combined with the attribution methodology that assigns patients to the physician group based on the group having provided the plurality of care during the performance year. Patients who acquire conditions or whose disease becomes more acute in a given year are much more likely to be assigned to a specialty provider like a cardiologist during the performance year because he or she may require active management and intervention. However, the risk adjustment for that patient would reflect the claims history for the year before the new condition emerged or the existing condition became worse. For a large population, it is likely that the number of patients who are sicker than predicted would be roughly similar to the number who are healthier than predicted. However, an individual group practice is less likely to see such variations balance out due to the smaller patient population it serves. Specialty practices are disproportionately likely to have patients who are sicker in the performance year than in the risk adjustment year. For example, we can consider two patients who had the same risk score based on 2011 diagnosis codes. Both are hypertensive and have diabetes but no active history of coronary artery disease and have never visited a cardiologist. Both see a primary care physician regularly to manage their diabetes and hypertension. Patient A's 2013 looks very much like 2011 – a number of physician visits and some laboratory codes. He remains attributed to his primary care physician. Patient B, on the other hand, has a heart attack early in the year. He receives a stent in the hospital and is discharged after two days of inpatient care. He continues to see his primary care physician to manage diabetes and hypertension. However, at the end of the year, the primary care practice has billed for four E/M visits but the cardiology practice has billed for five – due to the multiple hospital visits and the outpatient follow-up in the office. When we compare the costs of these two patients who are expected to have equal costs, patient B has far higher costs. But the physician who is assigned responsibility had no knowledge or awareness of patient B before the year and patient B is only

assigned to him as a result of experiencing a serious health condition. If we were to repeat this example over and over, the cardiologist would end up with higher costs for the entire population because of this attribution issue. We offer this example not to indicate that patients seen by cardiologists are sicker, but to demonstrate that the combination of methods that are not intended to be used in this fashion has real problems. If the risk adjustment and the attribution are implemented as we understand it, there would be a significant incentive to avoid complex patients, particularly those with new onset disease. We urge CMS to strongly consider these issues as it moves forward.

While we believe that a multiple attribution or “degree of involvement” methodology similar to that used in the QRUR program may help to alleviate some of this issue, we do not believe that it will solve all of the problems. CMS appears to acknowledge this issue in the discussion of comparison groups – recognizing that it may be more appropriate to only compare groups based on their degree of involvement.

Proposed Composite Scores for the Value-Based Payment Modifier

CMS proposes to composite all quality measures in a two-step fashion, first compositing all measures into one of six domains based on the National Quality Strategy and then compositing those scores into a single quality score. The cost of care measures are also composited and compared against the quality composite to determine the overall score.

The ACC supports the CMS proposal to compare each measure on an individual basis and then calculate a normalized score based on standard deviation. This is the only way to composite such disparate measures. However, we do have some concerns about the proposal to calculate each domain separately. As CMS notes, there are six different domains in the National Quality Strategy and each performance measure is assigned to a different domain. Most of the current performance measures are assigned to the clinical care domain. No measures are placed in the population/community health domain and only a handful are placed in the remaining domains. This means that some measures will count far more than others.

For example, consider a practice that reports on all of the available coronary artery disease, heart failure, hypertension and atrial fibrillation measures for a total of 16 measures. With the exception of a new measure for atrial fibrillation anticoagulation therapy, all of these measures are considered clinical process of care measures. If we say that this practice is performing exceptionally well on the a-fib measure but only average on the other measures, the composite methodology would show this to be an excellent practice. If another practice performed extremely well on all of the heart failure, CAD, and heart failure measures but poorly on the a-fib measure, that practice would be considered to have lower quality than the first, despite the fact that the measures they are performing well on cover a much larger percentage of their patients. **The ACC recommends that all clinical quality measures be composited together without consideration of their classification within domains of the National Quality Strategy.** We believe this classification is generally arbitrary in this case and only leads to problems like

the example above. We only view this as a first step towards a goal of a more sophisticated compositing system that takes into account the importance of the measures to CMS and to Medicare patients.

The ACC strongly supports the CMS proposal to publish previous year's performance rates and standardized scores on each quality measure. Regardless of the final form of the program, this is a necessary step to help physician groups prepare for the implementation of this program and attempt to improve their performance in future years.

The ACC supports the establishment of a minimum case size for the use of a performance measure in the value-based modifier. CMS proposes that this minimum be set at 20 but even that number may be too low in order to avoid statistical anomalies. We urge CMS to craft a program that focuses on reporting as many relevant measures as possible. While there may be a small percentage of physicians with limited measure selection, most physicians should have the opportunity to report on a large number of measures and report on them more than 20 times. CMS should develop incentives for physicians to report on their most important population rather than provide incentives to report as little as possible.

CMS proposes to increase the bonus payment for practices that treat patients with high risk scores based on the HCC methodology. While we support adjustments based on patient severity, we do not support this particular method. First, as discussed above, the attribution and the risk adjustment combination may make it difficult to truly identify which practices are providing care to high risk patients. Secondly, we think that the overall severity issue should be more fully integrated into the value-based modifier. If a practice is able to achieve even average quality scores with an extraordinarily difficult and high-risk population, then that effort should be recognized and rewarded. We recognize that it may not be appropriate to adjust process measures based on risk, but we believe that this adjustment, if properly balanced, could still be useful in the payment adjustment. **We recommend that CMS integrate risk adjustment into the overall value-based modifier.**

The ACC supports the proposal to allow physicians the opportunity to discuss the scores on their feedback reports prior to the implementation of the value-based modifier. We support the proposal to include a value-based payment modifier example in these reports as well so that groups understand how the value-based modifier was calculated and what their payment adjustment is. We are hopeful that CMS will include a value-based payment calculation for all practices of 25 or more, even if they elected not to participate in the initial year. Having this information will be beneficial if they are given the opportunity to elect participation in future years. It is unclear in the rule if CMS also intends to send a "test" value-based modifier score to these same practices in 2013 that would demonstrate what the score would be if the program had been in place in 2014. We ask CMS to provide this information because it would be valuable for practices to understand this information as early as possible.

The dissemination of the physician feedback reports should be the first step in a large scale educational campaign on the implementation of the value-based modifier. However the final program is structured, there is no question that it will be complex and physicians will have many questions. The success of the program depends on physician practices believing in the data and acting on it to improve performance. The program will be a failure if physicians view it as an arbitrary adjustment that is used only to reduce reimbursement. This is such a significant change from anything that CMS has done before that it will require an unprecedented educational effort.

We recognize that we have offered a great deal of criticism of the value-based modifier proposals within this rule. We do not offer these comments in an attempt to derail this program but to improve it. It is incredibly difficult to measure and balance quality and cost and to adjust payments on that basis. We have been fortunate to have many discussions with the CMS staff members working on these efforts. We are impressed that they share our dedication to doing this right. We want to continue to meet with CMS to improve this program so that it accomplishes what Congress intended.

The ACC is very pleased to have the opportunity to offer comments on the myriad proposals that are part of this rule. If you have any questions or wish to discuss these comments further, please contact Brian Whitman, Associate Director of Regulatory Affairs at bwhitman@acc.org or (202) 375-6396.

Sincerely,



William A. Zoghbi, MD, FACC
President