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ATTENTION: **CMS-1403-P**

Dear Mr. Weems:

The American College of Cardiology (ACC) is pleased to offer our comments on the notice of proposed rulemaking (CMS-1403-P) entitled: **“Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule** as published in the *Federal Register* on July 7, 2008 *Federal Register*, 73 Fed. Reg. 38502 (“the Proposed Rule”).

The ACC is a 36,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

Our goal in reviewing proposed Medicare policy changes is to assure access to quality cardiovascular care for Medicare beneficiaries. The College believes that rational, fair physician ownership and payment policies are a critical component of adequate access to care. We offer the following comments in support of that goal. This letter addresses several payment policy, operational, and quality related provisions of the Proposed Rule. Our comments on the Independent Diagnostic Testing Facility and Physician Self-Referral and Anti-Markup Issues are addressed in a separate letter.

A. Resource-Based PE RVUs

Change to PE database inputs for certain cardiac stress tests

The ACC supports CMS’s proposal to revise the direct practice expense inputs for CPT 93025 (Microvolt T-wave alternans for assessment of

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ventricular arrhythmias). Specifically we concur with the following proposed changes:

- Designate the RN as the clinical staff for 93025
- Add specific microvolt T-wave testing equipment
- Assess the service period time of 53 minutes to the exam table and microvolt T-wave equipment.

We also agree that treatment of equipment time should be consistent for 93025, 93015, and 93017. Therefore, the ACC also supports CMS's proposal to revise direct practice expense inputs for 93015 and 93017 by allocating the service period time of 55 minutes to the exam table and stress testing equipment.

CMS has also asked the RUC to review direct practice expense inputs for 93025. The ACC plans to recommend that the RUC support CMS's proposals.

Holter monitor

Transitioning to the new practice expense methodology will result in significant cuts in Medicare payments for Holter monitoring services (CPT 93230, 93224, 93226, and 93232). The Remote Services Provider Group (RSPG) has brought to our attention its concerns about the equipment use time assigned to these codes. The practice expense database currently includes 1440 minutes or 24 hours of use for the Holter monitor. This reflects the amount of time the patient is typically hooked up to the device and ECG activity is recorded. RSPG notes that patients usually do not return the monitor within 24 hours of the service being initiated and that the monitor is, therefore, not immediately available for use by another patient at the end of the 24 hour monitoring period. RSPG indicates that patients typically keep the Holter device for at least 48 hours and has asked that CMS increase the equipment use time to 48 hours.

The ACC believes that increasing the equipment use time as requested by RSPG will provide a more reasonable reflection of the resources required to provide Holter monitoring services. We note that in the Proposed Rule, CMS has proposed changes in equipment use time consistent with the time the equipment is unavailable for use by another patient.

Equipment Time-In-Use As Applied to Cardiac Event Monitoring

The ACC supports CMS's proposal to adjust its formula for calculating the cost per minute for cardiac event monitoring devices used in furnishing services described in CPT Codes 93012 and 93271. CMS currently assumes that cardiac event monitoring devices can be used 525,000 minutes per year and are in use for that total time. Thus, CMS has applied a 100 percent utilization rate rather than the standard 50% utilization in calculating the cost of this equipment. Although it is true that a cardiac event monitoring device is in continuous use during the time a patient uses the device – typically 30 days – a given device is not in continuous use throughout the year. After the prescribed test period is completed, the patient sends the device back to the remote monitoring center for cleaning and servicing prior to the center providing that device to a physician's office for use by another patient. Providers of remote monitoring services have reported to us that

an individual device is used between 5 and 6 times per year. Therefore, CMS's proposal to change the 100 percent utilization assumption to its standard 50 percent utilization rate is reasonable. We also recommend that CMS apply the same 50 percent utilization rate to CPT Code 93068 which is the global code for cardiac event monitoring.

Cardiac catheterization

The Proposed Rule notes that CMS accepted the RUC's recommendation to make no changes to the direct practice expense inputs for CPT 93510. The ACC agrees with the RUC's recommendation. The ACC is an active participant in and strong proponent of the AMA RUC process and we believe that it is successful in establishing fair and reasonable RVUs for the vast majority of CPT codes. In 2007 the ACC worked with the Society for Cardiovascular Angiography and Interventions (SCAI) and COCA to revise direct practice expenses inputs for these services. The RUC provided a very careful evaluation of our recommendations and recommended to CMS direct practice expense inputs consistent with the RUC's standard for practice expense. As a result, the non-facility practice expense RVUs for cardiac catheterization services that were published in the November 2007 Final Rule for the Medicare Physician Fee Schedule represented a substantial increase over the practice expense RVUs CMS initially proposed for these services in June 2006. Nevertheless, non-hospital cardiac catheterization labs still face payment cuts in excess of 30 to 40 percent compared to 2006 payment levels. The ACC remains deeply concerned about the impact of these payment cuts.

We believe there are appropriate actions CMS could take to limit the magnitude of the cuts. First, non-hospital cardiac catheterization labs that are organized as IDTFs are unable to correctly report all the services associated with a diagnostic cardiac catheterization procedure because CMS has not assigned separate professional and technical components to the CPT codes for the injection procedures (93539, 93540, 93542, 93543, 93544, and 93545). The RUC recommended direct practice expense inputs to reflect the clinical staff, medical equipment, and medical supply costs required for these procedures, but providers who bill for cardiac catheterization services as IDTFs are not compensated for these costs. We urge CMS to develop separate professional and technical components for these services for use in 2009. Further, we recommend that, as this series of codes was not previously assigned non-facility practice expense RVUs, there should be no transition. Providers should be able to receive the full value of the newly established RVUs in 2009.

Second, as we have noted in previous comments on this issue, the ACC believes that the deep cuts in practice expense payments for non-hospital cardiac catheterization services result in part from the CMS indirect cost data and methodology. It is our understanding that CMS uses a blend of data from supplemental surveys submitted by cardiology and by the National Coalition of Quality Diagnostic Imaging Services (NCQDIS) to determine the indirect cost portion of the non-facility practice expense RVUs for cardiac catheterization services. We believe that indirect costs for non-hospital cardiac catheterization labs could differ substantially from indirect costs for an average

cardiology practice or a free-standing imaging center. It is highly unlikely that the multi-specialty AMA Physician Practice Information Survey currently underway will yield data that reflect practice costs for non-hospital cardiac catheterization labs.

For this reason, we urge CMS to maintain non-facility practice expense RVUs for cardiac catheterization services at the 2008 level until the agency can implement indirect cost data that is representative of the providers of these services.¹ Holding these procedures harmless from further cuts in reimbursement would allow the non-hospital cardiac catheterization lab community the opportunity to gather indirect cost data consistent with the guidelines CMS previously established for such supplemental data.

C. Malpractice RVUs

The ACC agrees with CMS's decision not to eliminate malpractice RVUs for the technical components of imaging services. While we continue to believe that greater liability risk and costs are associated with the professional component of imaging services, we believe that there are some professional liability costs for providers who perform only the technical component. CMS's plan to gather data on malpractice costs for the technical component of imaging services in conjunction with the update of the malpractice RVUs to be implemented in 2010 is an appropriate strategy for addressing this issue.

E. Coding Issues

In 2008, as a result of the technological changes in MRI scanning, eight new cardiac MRI codes were created and five existing cardiac MRI codes deleted. The new codes are CPT code 75557, 75558, 75559, 75560, 75561, 75562, 75563 and 75564. The deleted codes are 75552, 75553, 75554, 75555 and 75556. However, for the four new cardiac MRI codes that contain the language "with flow/velocity quantification," CMS stated the following in the 2007 Final Physician Fee Schedule Rule:

"...four of the new codes incorporate blood flow measurement, which remains one of the nationally non-covered indications for MRI in the Medicare program. Due to a national non-coverage determination for MRI that provides blood flow measurement, CPT codes 75558, 75560, 75562 and 75564 will not be recognized by the Medicare program..."

These four codes were assigned status indicator of "N" (Non-covered) in Addendum B of the 2008 Final Rule. The Proposed Rule also assigns the status indicator N to these codes.

The ACC continues to disagree with CMS's decision not to cover these four new cardiac MRI codes. Currently, flow quantification and velocity assessment are crucial elements of functional cardiac MRI examinations when determination of valve function is necessary. There is a strong body of evidence supporting the clinical value and

¹ This recommendation applies to the following CPT codes: 93501, 93501-TC, 93508, 93508-TC, 93510, 93510-TC, 93526, 93526-TC, 93539, 93540, 93542, 93543, 93544, 93545, 93555, 93555-TC, 93556, 93556-TC. Professional components for these codes should not be affected.

diagnostic accuracy of flow quantification and velocity assessment. We do not believe that the existing National Coverage Determination (NCD) for flow and velocity measurements should be applied to cardiac MRI. After multiple conversations with Center for Medicare Management and Coverage and Analysis Group staff at CMS, however, we have concluded that the issue can only be resolved through a reconsideration of the current NCD. The ACC is working in cooperation with the Society for Cardiovascular Magnetic Resonance and the American College of Radiology to submit a formal request for reconsideration.

In the meantime, however, current CMS policy designates cardiac MR studies with flow quantification (CPT 75558, 75560, 75562, and 75564) as non-covered services. Therefore, if a physician orders a cardiac MR study with flow, a Medicare beneficiary is liable for the entire charge for the study even though Medicare covers all of the other components of the examination when flow is not included. This is an unreasonable result that Medicare beneficiaries may have difficulty understanding.

The ACC strongly recommends that CMS reconsider this position. Because current payment policy is based on a 1995 analysis of flow measurements that may not have even included an assessment of the accuracy of such measurements for cardiac valvular function, we believe CMS could change its decision regarding coverage of 75558, 75560, 75562 and 75564 without opening a new National Coverage Analysis (NCA) and value these services at the RUC recommended values.

If the agency determines that is not possible, CMS could assign a "not valid for Medicare purposes" status (I) to CPT codes 75558, 75560, 75562 and 75564 and create a HPCS ZZZ code ("G-code") for flow velocity quantification that could be non-covered pending the NCA process. When CMS determines that coverage for flow velocity determinations is appropriate, CPT codes 75558, 75560, 75562 and 75564 could be given active status (A) and the G-code for flow velocity quantification retired.

H. ESRD PROVISIONS

Application of Hospital-Acquired Conditions Payment Policy for IPPS Hospitals to Other Settings

CMS requested comments on the application of the preventable HACs payment provisions for IPPS hospitals to other Medicare payment systems. The ACC is strongly committed to quality improvement and we support the concept of establishing appropriate financial incentives as a tool for achieving quality improvement goals. We recognize that in implementing the Hospital Acquired Conditions (HAC) initiative, CMS is carrying out its statutory obligation under the Deficit Reduction Act (DRA) of 2005. Nevertheless, the College has serious concerns about both the approach to reducing the incidence of preventable hospital acquired conditions mandated by the DRA and the manner in which CMS is implementing its statutory obligations.

The College has a fundamental disagreement with quality improvement strategies that rely on only negative reinforcement, such as non-payment for hospital acquired conditions. We believe the HAC initiative is seriously flawed for a number of reasons:

- Determining and documenting that one of the selected HACs was present on admission is not always possible and creates a burden for hospitals.
- There is no provision for risk adjustment. Some patients are at substantially elevated risk for a number of the HACs.
- Non-payment for HAC could encourage hospitals to avoid patients at higher risk of complications and creates an incentive for a hospital to transfer a patient who develops complications.
- There are no provisions to reinvest savings in the system to further improve quality of care.

The ACC believes that setting ambitious goals can challenge health care providers to achieve quality improvement goals they may not have thought possible. However, those goals must be realistic and reasonably achievable. Moreover, providers need practical tools that help them take steps toward achievement of the goal. In the absence of these elements, the HAC initiative is simply a punitive payment policy, not a concrete strategy for improving the quality of hospital care provided to Medicare beneficiaries.

We urge CMS to halt any expansion of this initiative beyond compliance with the DRA mandate to identify two HACs for non-payment beginning October 1, 2008. Any proposed expansion should be delayed until CMS has conducted a thorough evaluation. For example, CMS should assess the impact of the HAC initiative on the incidence of the selected HACs, the administrative burden placed on providers and CMS, and the accuracy of present on admission (POA) coding. In addition, we urge CMS to develop effective risk adjustment techniques to ensure that providers who care for high risk patients are not unfairly penalized.

The ACC was pleased that CMS did not finalize its proposal included in the proposed rule for the Inpatient Hospital Prospective Payment System to expand the list of HACs. The ACC had opposed this proposal because the proposed HACs did not fulfill the statutory requirement of being reasonably preventable. We believe that these conditions should not be characterized as “never events.” Rather, they are known complications which can be minimized with proper care. These conditions cannot always be prevented, even in the best circumstances. A blanket policy of non-payment for the costs associated with caring for patients who experience such complications during a hospital stay or in any other site of service is unreasonable.

CMS has requested comments on alternative approaches to reducing the occurrence of preventable hospital acquired or healthcare-associated conditions. The ACC recommends that CMS explore alternatives that would use a data-driven approach to establishing benchmark and best practice complication rates for selected HACs. CMS could then set payment rates based on an average complication rate and provide evidence-based tools to help hospitals work toward a best practice complication rate. Those hospitals whose complication rates exceeded the average would bear the costs of treating those

complications, while those with better than average performance would be rewarded. As performance improved over time, payment rates would be adjusted to reflect lower complication rates. Data registries such as the NCDTM CathPCI and ICD Registries would be an excellent source of data on complication rates.

CMS has now requested comments on possible application of the concept underlying the HAC initiative in other settings. The ACC believes that extension of the non-payment strategy for preventable health conditions acquired outside the hospital setting would be extremely problematic, especially in the physician office setting. First, separating the physician work and practice resources solely attributable to an HAC-like preventable condition from other medical conditions managed at an office visit would be difficult. In addition, patient compliance and other factors beyond the physician's control would contribute to the likelihood that a patient would acquire a preventable condition while under a physician's care. The College strongly urges CMS to focus its quality improvement efforts for physicians on encouraging and facilitating the adoption of evidence-based guidelines at the point of care in the ambulatory setting. CMS should not consider expansion of the HAC approach to other care settings until the initiative has been thoroughly evaluated within the IPSS program.

J. Physician and Nonphysician Practitioner (NPP) Enrollment Issues

Effective Date of Medicare Billing Privileges

The ACC does not support CMS's proposal to modify the effective date of Medicare billing privileges for individual and group organization physicians. We recognize that the length of time currently allowed for providers to submit retroactive billing—up to 27 months—may not be ideal for CMS to maintain program integrity. However, the provider enrollment process is fraught with error and delays that make it very difficult for physicians to become enrolled with Medicare on a timely basis. These proposals could make this problem far more acute, as payments that are now delayed would not be made at all.

The Medicare program integrity manual requires that contractors process 80 percent of paper enrollment forms within 60 calendar days and 99 percent within 180 calendar days. However, CMS is aware of the difficulties that physicians have had in Medicare enrollment that are the result of forms not processed within 6 months or returned multiple times due to incomplete or missing information. CMS has stated that more than half of all 855I forms received from physicians are returned due to missing information. CMS should not restrict patient access to Medicare providers by changing effective enrollment dates until the application process itself is improved.

In this proposed rule, CMS notes the impending release of the internet-based Provider Enrollment, Chain and Ownership System (PECOS), which is intended to improve the accuracy and speed of the physician enrollment process. The ACC will examine PECOS

when it becomes fully operational and integrated, and the College hopes PECOS will resolve the current backlog of forms and greatly reduce the error rate for physicians that are completing complex and confusing forms. However, CMS states that PECOS will not be available to many Medicare providers until early 2009, and will not be available nationwide until late 2009, well after the CY 2009 Physician Fee Schedule is finalized. **For this reason, we urge CMS to not implement either option in the Proposed Rule and not propose any changes in enrollment standards until PECOS is available to all practitioners, including those in California, Missouri, and New York.**

Additionally, as CMS has proposed significant changes to independent diagnostic testing facilities (IDTF) regulations, concurrent changes to the physician enrollment period are troubling. The agency proposes that physician practices must enroll as IDTFs for each practice location furnishing diagnostic services, presenting unduly burdensome and time-sensitive bureaucratic requirements. Further, this proposal likely would force providers to close diagnostic facilities rather than enroll multiple locations, creating additional patient access difficulties, including longer wait times for appointments and extended travel distances to receive diagnostic tests. Our detailed comments on this proposal are included in a separate letter.

CMS recognizes that its IDTF proposals will take time to implement and suggests an implementation date of September 30, 2009 for currently enrolled Medicare IDTF suppliers. However, the agency intends newly enrolling suppliers to comply with the rule on January 1, 2009. This is especially troubling, as CMS will not determine which diagnostic services will be included until the Physician Fee Schedule is finalized in late 2008. Combined with the current delays in approving physician Medicare enrollment applications, and inevitable delays in certification, licensing and credentialing of diagnostic facilities and service providers, it will be difficult if not impossible for new diagnostic providers to meet all CMS enrollment requirements on January 1, 2009. It is unclear whether CMS would consider physicians who currently provide diagnostic services in one practice location, but who would be required under the PFS proposed rules to enroll other diagnostic service locations as separate IDTFs, as newly enrolled IDTF providers or existing providers. These proposals threaten Medicare access if practitioners must wait for enrollment approval or risk claims denial or revocation of their billing privileges, especially for a simple change in site of service.

If CMS does not agree with the ACC's recommendation to implement neither proposed change to enrollment standards, the College would prefer the second approach ("Option Two"). As explained in the proposed rule, this option would allow physicians that already serve non-Medicare patients to begin Medicare patient billing on the day they submit an enrollment application that can be processed. This would help to reduce the length of time that Medicare beneficiaries must wait before seeing their physician of choice.

Further, the College believes that most providers who apply for Medicare billing privileges meet most if not all the program's service requirements, even prior to their enrollment approval, thus negating the premise behind the first approach ("Option One")

that providers must meet all Medicare performance standards prior to a contractor conferring billing privileges. This approach would impose unnecessary delays for physicians and NPPs who see Medicare beneficiaries, and may restrict access to care in locations where service providers already are scarce.

Reporting Requirements for Providers and Suppliers

The ACC is concerned about CMS's proposal to require physicians and physician organizations to notify the agency of any adverse legal action within 30 days. Because of the potential for legitimate errors in legal procedures and due process, it is wholly possible that a physician or physician organization may be served incorrectly with legal action. According to the proposed rule, if the physician or physician organization does not comply with CMS's reporting requirement within the 30-day timeframe, their Medicare privileges may be revoked or they may be subject to overpayment penalties. Thus, it may be more prudent for CMS to wait for the adjudication process to be complete prior to imposing punishment on Medicare providers.

K. Computer-Generated Fax Transmissions

In comments submitted for the Calendar Year 2008 Physician Fee Schedule, the College urged CMS to consider focusing on efforts, such as surveys or other quantifiable methods, to identify factors contributing to non-adoption of NCPDP SCRIPT-compliant electronic health record (EHR) systems by providers. ACC continues to believe that widespread adoption of fully interoperable EHR systems has not yet reached the "tipping point" sought by CMS. A 2008 study of ACC members indicates that while 28 percent have a basic EHR system in place, only 6 percent have implemented a fully functional system, which includes electronic prescribing capabilities. Further, CMS stated a national chain pharmacy reportedly estimates it produces approximately 150,000 computer-generated fax prescription refill requests every day. Clearly, neither prescribers nor dispensers are now ready for mandates requiring e-prescription.

The ACC supports CMS's proposal to expand the exemption from SCRIPT standard e-prescribing to include computer-generated prescription refill request transactions. While the ACC agrees that CMS's eventual goal of moving to e-prescriptions is worthwhile, the agency's recognition that additional time for implementation is necessary points to a continued need to conduct studies on barriers to SCRIPT-compliant system adoption. Once these studies are completed, CMS can engage with stakeholders to identify pathways towards more widespread use of electronic systems that include true e-prescribing. The ACC welcomes the opportunity to work with CMS in the future as it periodically reviews e-prescribing requirements.

O. PQRI

The ACC commends CMS for the collaborative efforts undertaken with the physician community to implement and improve the Physicians' Quality Reporting Initiative (PQRI). The College views PQRI as an important first step toward a Medicare physician

payment system that supports and rewards physician efforts to improve the quality of care provided to Medicare beneficiaries. The ACC has been particularly pleased to see the expansion of the PQRI program from its initial limited set of measures reported through the claims process to a more robust list of measures and groups of measures that may be reported through the use of clinical registries and electronic health records (EHRs) in addition to the claims-based reporting. However, the ACC has concerns that the improper implementation of these new measures and methods will not allow CMS to take full advantage of available quality information and multiple reporting paths.

Measure development process and proposed measures for 2009

CMS has proposed a total of 175 measures for inclusion in PQRI for 2009. These measures include several adopted by the AQA. As noted in previous comments, the ACC remains concerned about CMS's implicit acceptance of the AQA as a measure development body. The AQA facilitates incorporation of new measures into the quality reporting system by providing consensus review for implementation of a measure prior to National Quality Forum (NQF) endorsement. The NQF meets the National Technology Transfer and Advancement Act (NTTAA) requirements for a voluntary consensus body and its endorsed quality measures constitute voluntary consensus standards within the meaning of the NTTAA. The AQA utilizes certain essential practices of a voluntary consensus standards body under NTTAA, but does not have a defined organizational structure that meets the requirements of the NTTAA.

The ACC's experience with the AQA has been that implementation policies and processes receive the most attention and input from stakeholders, while performance measure adoption input has been minimal and typically defaults to the specialty developer of the measure. We note that the AQA conditionally adopts a measure on a consensus basis, but withdraws the measure for implementation if the measure is not endorsed by NQF. The ACC is concerned that using measures proposed through an organization like AQA (which was originally established to develop policies and process around implementation of measures endorsed by the NQF and has become an organization that adopts measures contingent on NQF endorsement) sets a precedent for bypassing established methodological vetting processes in order to rush measures to market. The ACC strongly recommends that CMS recognize NQF as the endorser of measures since it is the only organization that currently meets the NTTAA standards as a voluntary consensus body.

With respect to the specific measures proposed for PQRI in 2009, the ACC is concerned that the manner in which the proposed measures are presented in the Proposed Rule substantially limits the opportunity for meaningful public comments. The proposal provides only the measure title, with little supporting information provided. For example, Table 12 includes the proposed measure "Anti-platelet medications at discharge." Without further detail it is impossible to know how this measure relates to measure #6 in Table 11 Coronary Artery Disease (CAD); Oral Antiplatelet Therapy Prescribed for Patients with CAD. Similarly, Table 14 includes a measure titled "Lipid

Screening.” We are unable to determine how this measure relates to the NQF-endorsed lipid screening measure.

In the absence of detailed measure specifications, stakeholders are unable to assess whether CMS plans to implement the measure as it was intended by the measure developer. Seemingly minor changes in coding instructions or numerator and denominator definitions can significantly alter the application of a measure and can undermine its validity. The ACC has documented its concern on more than one occasion about the use of inpatient discharge Evaluation and Management (E/M) codes for measures 5, 6, and 7 in the Physician Quality Reporting Initiative (PQRI). Specifically:

Measure 5: Heart Failure: ACE/ARB for LVSD

Measure 6: CAD: Antiplatelet Therapy

Measure 7: CAD with prior MI: Beta blocker therapy

These measures were initially developed by the ACC and the American Heart Association (AHA) in collaboration with the Physician Consortium for Performance Improvement (PCPI) for use in the office-based practice setting and endorsed by the NQF as National Voluntary Consensus Standards for Ambulatory Care for use in the outpatient context.

Our specific concern centers around the inherent difference in the construct of measures developed for acute episodes of care when the patient has a short term, sometimes severe, clinical problem versus those measures intended for use in the outpatient setting where physicians are dealing with chronic, stable conditions and where measurements are made over timeframes of a year or more. If the measures developed by the ACC/AHA/PCPI and endorsed by the NQF for use in the outpatient setting are implemented for inpatient episodes of care, they will not achieve their intended purpose. The use of ambulatory measures for the inpatient setting introduces significant problems with attribution, time span of measurement, and exclusions, which will undermine the validity of these measures and, in turn, the acceptability of these measures to the practicing community.

To provide some background regarding this concern, we should review the history by which these measures were developed. Over 3 years ago, a multidisciplinary PCPI working group co-led by the ACC and the AHA created an outpatient set of performance measures for coronary artery disease and heart failure using a well-developed methodology. These clinically-sound performance measures quantified, as a set, previously unmeasured dimensions of outpatient care and were designed to assist physicians in measuring and improving the quality of their cardiovascular care.

While we have substantial concerns about the adaptation of clinically-designed performance measures, especially those that are designed for prospective use in the outpatient setting to facilitate quality improvement, to measures based upon administrative data for the purposes of reporting, it appears that only measures 5 through 7 were altered for use in the PQRI. It is not clear why these particular measures were singled out for use in the inpatient setting, especially in light of the challenges associated with this approach.

The ACC respectfully requests that the inpatient discharge codes for measures 5-7 be removed from the PQRI in 2009. We believe that the approach of using inpatient codes for these particular measures undermines their validity.

Measures Groups

The ACC supports the addition of measures groups reported on 30 consecutive patients as an alternative reporting option for participation in the PQRI program. This methodology, which groups a series of measures on patients with the same conditions, may allow CMS and physicians to focus on particular disease states in their practice as well as allow a less burdensome reporting option that could increase participation rates in the initiative. However, the ACC wants to ensure that this reporting option is well-understood by physicians and properly implemented by CMS.

The ACC urges CMS to further clarify which patients would be placed in the denominator for the 30 consecutive patients option. The ACC believes that physicians who wish to participate in this option may be confused if they believe that they must report on 30 consecutive patients that meet the requirements for all of the measures included in the measures group. This is particularly relevant for those measures groups where the individual measure specifications may not apply to every patient that has the condition described by the measure group.

The ACC is also concerned about the CMS proposal to limit the reporting of certain measures to a measures group and not allowing physicians to report on these measures individually. Such a move only serves to limit the participation options for physicians. While the proposed measure group for back pain is unlikely to be used by many cardiologists, the ACC does not believe that CMS should restrict any measures to measure group reporting.

EHR Reporting

The ACC believes that allowing physicians to submit measures data through electronic health records (EHR) systems will be beneficial to coordinated delivery of high-quality health care. The potential benefits of EHR implementation in physician practices are enormous and this additional reporting option could be very attractive for those physicians that have chosen to invest in an EHR. However, the College has several concerns about the CMS proposal to begin EHR-based measures reporting in the 2009 PQRI program. The agency has not yet completed testing of the mechanisms necessary to submit data electronically, nor has it selected measures for which physicians may report quality data. The ACC urges caution in implementing this reporting methodology to ensure that the system is properly structured before implementation. CMS anticipates it will conclude its data submission testing process by December 2008, yet the agency is not certain that the electronic process for reporting quality measures data will be practical or feasible. Should CMS testing extend into 2009, it will adversely impact the ability of electronic records vendors to provide physicians with systems or updates that accurately extract and report data to CMS in the required format. Further,

merely posting the data specifications on the CMS website likely will not afford EHR vendors with adequate time to authenticate and validate their systems in order for physicians to be able to report meaningfully on the required 80 percent of their applicable Medicare patients in order to qualify for the bonus payments. Because of potential time constraints physicians may face in reporting quality data electronically, should CMS move forward with the EHR-based submission of quality measures data, the ACC suggests CMS could allow physicians to report data for 30 consecutive Medicare patients, similar to the claims-based reporting option.

CMS will create a data warehouse for physicians to submit their clinical quality data on the 2009 measures. This warehouse will require authentication and identity management, requiring physicians to obtain or maintain special user accounts. CMS has not provided guidance on how these user accounts will be established, nor how physicians or other users will apply and be accepted to utilize the data warehouse. The ACC urges CMS to issue regulations on how the warehouse will be created and maintained, allowing for public comment and consideration, prior to its adoption and implementation.

CMS anticipates physicians should begin electronic data submission early in 2009, working with their EHR vendors to correct any problems that may occur. It is unclear how physicians are to learn whether their submitted data successfully meets CMS requirements. The ACC encourages CMS to hold Open Door Forums and use other educational means to inform stakeholders on EHR data submission to ensure the agency receives meaningful quality measures data that complies with the privacy requirements of the Health Insurance Portability and Accountability Act (HIPAA) and other requirements. Further, because not all physicians utilize EHR systems certified by the Certification Commission for Healthcare Information Technology (CCHIT), it is imperative that CMS clarify what data elements are necessary for successful electronic measures reporting.

There is uncertainty on which quality measures physicians may report on through the use of EHR systems. Even if an individual measure is included in the 2009 PQRI measure set, it may not be selected for the EHR-based data submission option. CMS may post electronic specifications for measures that ultimately physicians may not be able to report data on through this option, leading to confusion and a potential lack of relevant data for CMS to evaluate the electronic submission process. The ACC suggests that CMS may consider extending testing of EHR-based quality measures data reporting through a pilot program or demonstration project if it would allow for a more effective evaluation of the benefits and challenges of electronic quality data reporting.

Registry Reporting

The ACC was very pleased to see the addition of registry-based reporting for PQRI for the 2008 program and is pleased to see that registry-based reporting will continue to be offered in the 2009 program. The National Cardiovascular Disease Registry (NCDR™) is a suite of registries that allow specialists in cardiovascular medicine to truly measure

their performance to ensure that they are providing the best possible care to their patients. Participation in registries and working with hospitals that participate in registries that are part of NCDR are true symbols of a physician's devotion to quality care. The ACC has endeavored to make such registries available to physicians and hospitals and continues to believe that the use of registries will have a transformative effect on the quality of healthcare provided in the United States. When payers such as CMS recognize the value of such registries and offer payment for participation in them, the utilization of such registries should increase.

The ACC does not believe that CMS use of registries in PQRI matches their full potential. Instead, it appears that CMS is merely utilizing portions of registry data extracted to meet CMS needs as a method to match the agency's claims-based process, rather than taking full advantage of registries' relatively complex data sets. The ACC does not believe that the bar for quality reporting should be lowered for registry data to accommodate the technical limitations of another reporting method. Using the more robust data that is prepared by registries based on measures that are approved by a consensus standards organization would do far more to further the mission of providing quality care to Medicare patients. The ACC recommends that CMS allow registries to submit quality reporting data on all patients, including those not on Medicare, to provide the agency with more meaningful information on patient care.

In the Proposed Rule, CMS states that it intends to allow registries to submit information on Medicare and non-Medicare patients and allow that data to count towards the 30 consecutive patients required under the measures group option. The ACC strongly supports this proposal and believes that this rationale should not be limited to reporting options for measures groups. The ACC recommends that CMS add additional reporting options for registry-based submission that would apply to both individual measure reporting and for measures groups.

Specifically, the ACC recommends a registry-based reporting mechanism for one measures group for all patients that may include but may not be exclusively, non-Medicare patients for the period of January 1, 2009-December 31, 2009, and the period of July 1, 2009-December 31, 2009. The criteria for satisfactory reporting of measures groups from registry-based submissions could be expanded to include the reporting of quality measures results and numerator and denominator data for 100 percent of patients for whom the measures group is applicable. Not only would the recommended additional reporting options further strengthen CMS's desire to assess overall care provided by a professional, but also potentially contribute to CMS's efforts to determine if a minimum patient threshold could be developed for quality reporting within measures groups.

Similar to the ACC recommendation that CMS add additional reporting options for measures groups, the ACC recommends CMS add the same reporting options for the 2009 PQRI registry-based submission reporting options for individual measures. Specifically, the ACC recommends a registry-based reporting mechanism for at least three measures for all patients that may include, but may not be exclusively, non-Medicare patients for the period of January 1, 2009-December 31, 2009, and the period

of July 1, 2009-December 31, 2009. The basic criteria for satisfactory reporting of measures groups from registry-based submissions could be expanded to include the reporting of quality measures results and numerator and denominator data for 100 percent of patients for whom the individual measures are applicable.

The ACC disagrees with the CMS proposal to require registries recognized as part of the “2008 PQRI Establishment of Alternative Reporting Periods and Reporting Criteria” by having met the “Registry Requirements to Quality as an acceptable Registry for Submission of PQRI Data on Behalf of Eligible Professionals Seeking Payment in 2008” to self-nominate again for 2009. The ACC thinks that this proposal, if implemented, will create confusion among professionals trying to evaluate viable options available for meeting PQRI reporting requirements, especially since the criteria have not changed significantly. We do recommend that the criteria listed be expanded to include the requirements necessary to assess the additional reporting options recommended already in this letter by the ACC.

Uses of PQRI Data

The ACC supports efforts toward greater transparency of health care quality information. We believe that efforts should strive to promote improve health care quality while avoiding adverse unintended consequences. The College recognizes the strong interest of payers, policy makers, and patients in knowing more about the quality of care provided by physicians. We therefore have published a Health Policy Statement on Principles for Public Reporting of Physician Performance Data.² We believe that these principles outlined below can serve as effective guidance for CMS and other payers in determining appropriate uses of quality data reported by physicians:

- The driving force behind physician performance measurement and reporting systems should be to promote quality improvement.
- Public reporting programs should be based on performance measures with scientific validity.
- Public reporting programs should be developed in partnership with physicians.
- Every effort should be made to use standardized data elements to assess and report performance and to make the submission process uniform across all public reporting programs.
- Performance reporting should occur at the appropriate level of accountability.
- All public reporting programs should include a formal process for evaluating the impact of the program on the quality and cost of health care including an assessment of unintended consequences.

The full document, including a detailed discussion of each of these principles can be found at <http://content.onlinejacc.org/cgi/content/full/51/20/1993>.

² Drozda JP Jr., Hagan EP, Mirro MJ, Peterson ED, Wright JS. ACCF 2008 health policy statement on principles for public reporting of physician performance data: a report of the American College of Cardiology Foundation Writing Committee to Develop Principles for Public Reporting of Physician Performance Data. J Am Coll Cardiol 2008;51:1993–2001.

CMS has requested comments on possible future uses for PQRI data. We support the agency's commitment to continue to provide confidential feedback reports on PQRI performance to physician participants, without public reporting of performance results at the individual or group level. In general, we believe that it would be premature to release to the public information derived from the PQRI program, even if this information is limited to the names of physicians who participated or successfully reported quality data. Public reporting of such data would neither provide meaningful information to advance quality improvement nor even serve to help Medicare beneficiaries select a physician. For example, what conclusion should a patient draw about the fact that his or her physician successfully reported PQRI data? Conversely, what conclusion will a patient draw if his or her physician is not listed among those that successfully reported?

Public reporting of performance data derived from PQRI may be appropriate at some point in the future, in a different format from the reports currently provided to physicians. At this time, however, we urge CMS to focus efforts on evaluating the impact of PQRI and improving the usefulness of the confidential feedback reports provided to physicians.

III. Potentially Misvalued Services Under the PFS

The ACC is an active participant in and strong supporter of the Relative Value Scale Update Committee (RUC) process. We believe that the collaborative process among the specialty societies, the AMA, and CMS is an example of an excellent public-private partnership. We believe that the best interests of the Medicare program will be served by continuing this partnership.

The College supports the development of rational, equitable payment policies for physician services provided to Medicare beneficiaries. CMS has proposed several strategies for implementing an ongoing review of the RVUs assigned under Medicare's RBRVS. The ACC is committed to working with both CMS and the RUC in these efforts to ensure fair and appropriate values for services for patients with cardiovascular disease. The ACC continues to support the RUC's efforts to identify potentially misvalued services through a series of objective screens and believes that this methodology will serve to address concerns raised about overvalued codes in the Medicare Physician Fee Schedule. We must urge, though, that CMS avoid making the assumption that all services for which utilization has grown rapidly are misvalued or that all services with Harvard-established values should be reexamined. Responding to requests to resurvey and develop new recommendation for work RVUs for existing codes or developing proposals to revise and restructure CPT codes that accurately describe current services imposes a significant burden on specialty societies, the CPT Editorial Panel, and the RUC. In some cases the burden may not be outweighed by improvements in payment accuracy.

Expanding the Multiple Procedure Payment Reduction (MPPR) to Additional Non-Surgical Services

CMS has requested comments on the question of whether the multiple procedure payment reduction should be applied to additional non-surgical services. The ACC urges CMS to proceed with great caution on this issue. The MPPR for surgical procedures reflects the concept of the global surgical package in which relative value units reflect not only the work and practice expense of the surgical procedure itself, but also significant pre- and post-service work, including evaluation and management services. RVUs for non-surgical procedures have been established differently and typically do not include extensive pre- and post- service evaluation and management services. Moreover, RUC recommendations for work RVUs and direct practice expense inputs are based on the typical patient. If the RUC determines that a procedure is typically performed in conjunction with another service, physician time, work RVUs, and direct practice input recommendations reflect the resources needed to perform the service in that situation. The ACC would strongly oppose a broad-based application of the MPPR to non-surgical services.

We appreciate your attention to this letter, and remain eager to assist you and your staff as it considers whether to finalize these proposed changes to the FY 2008 Medicare Physician Fee Schedule rule. If you have any questions, please contact Rebecca Kelly, Director – Regulatory Affairs at 202.375.6398, or by e-mail at rkelly@acc.org.

Sincerely,



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