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June 17, 2011

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

Re: **"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2012 Rates"**

Dear Administrator Berwick:

The American Association of Orthopaedic Surgeons (AAOS) appreciates the opportunity to comment on the fiscal year (FY) 2012 Inpatient Prospective Payment System (IPPS) proposed rule, entitled "Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2012 Rates," Federal Register Vol. 76, No. 87 (05/05/2011). The AAOS, which represents over 18,000 board-certified orthopaedic surgeons, has been a committed partner to the Centers for Medicare and Medicaid Services (CMS) in patient safety, cultural competency, and the provision of high-quality, affordable healthcare. We commend CMS on its efforts to improve the quality of, and access to, care, while at the same time slowing growth in healthcare spending and we appreciate this opportunity to provide input on hospital-acquired conditions, modification of MS-DRG severity levels, assignment of spinal procedure codes to the spinal fusion MS-DRG, and quality measures.

**Preventable Hospital-Acquired Conditions (HACs)**

The AAOS shares CMS' goal of reforming the provider payment system to recognize and reward high quality care, including withholding payment for preventable hospital-acquired conditions (HACs). However, the selection of HACs should be based on conditions that are truly preventable with adherence to evidence-based practice guidelines. The AAOS is concerned about CMS' proposal (Sec. II. F. 2. b.) to add a new diagnosis code to the HACs that would be subject to the statutorily required quality adjustment in MS-DRG payments for FY 2012. The proposed addition is code 415.13 (saddle embolis of pulmonary artery). Under the proposal, the diagnosis code 415.13 would be subject to the

penalty adjustment when reported along with one of the following musculoskeletal procedure codes: 00.85 through 00.87, 81.51, 81.52, or 81.54. The proposal also assigns 415.13 as a major complication or co-morbidity (MCC) designation which we believe is clinically inaccurate. A saddle embolis is a subcategory of deep vein thrombosis (DVT)/pulmonary embolism (PE).

The AAOS voiced concerns in its comments to prior years' IPPS proposed regulations regarding the inclusion of DVT/PE in HAC provisions. Similarly, the AAOS believes that saddle embolis of pulmonary artery, when reported with the cited orthopaedic procedure codes, is not a condition that is "reasonably preventable." Patients undergoing total knee replacement (TKR) and total hip replacement (THR) in the Medicare population are at the highest risk for developing a DVT/PE. These patients are placed at an increased risk of venous thromboembolism (VTE) purely based on the procedure. The major recognized contributors to VTE formation are decreased blood flow/stasis, tissue damage/inflammation, and the hypercoagulable state of the blood (Virchow's Triad), and in joint replacement all three of these VTE risk factors are present. In addition, joint replacement patients often have additional complicating co-morbid conditions such as obesity, hypercoagulation, rheumatoid arthritis, hemophilia, and cancer, adding to the risk of DVT/PE. Yet, the current structure of the MS-DRG system does not specifically risk-adjust for these conditions for the DRG's related to primary THR (81.51) or primary TKR (81.54).

The AAOS believes that risk adjustment is an indispensable component of an equitable hospital-acquired condition policy. CMS should ensure that the risk factors and complicating conditions are actually on the appropriate complication or comorbidity (CC) or MCC list and should first develop a means for risk-adjusting for the wide variation in patient characteristics prior to fully implementing the HAC policy.

CMS should implement a multi-faceted approach to risk adjustment that takes into account the condition-specific or procedure-specific risk. Risk factors include patient demographic and socioeconomic factors as well as clinical factors that can influence outcome, and risk adjustment should be tied to the specific condition or procedure. CMS should also account for the patient-specific risk factors that affect preventability. Many hospitalized patients have co-morbidities and other patient characteristics that put them at an increased risk of complications. CMS should take these into account in creating a policy that is reasonable and equitable, so as to minimize incentives for limiting access to patients who are at higher risk for complications. The AAOS recognizes the need for better risk adjustment techniques to account for variation in patient health status and urges CMS to work with provider groups in their respective specialties to create viable, effective risk-adjustment tools.

The AAOS is very supportive of CMS' efforts to encourage the adoption of evidence-based treatment guidelines which could improve the quality of care for our patients, and we are currently in the process of revising our guidelines for the prevention of VTE in THR and TKR patients. However, we are still concerned with the presumption that this "hospital-acquired condition" could be "reasonably prevented" through the use of evidence-based guidelines. While evidence-based guidelines can reduce events, CMS selected one of the patient populations at highest risk for DVT/PE, diverging from the concept of "reasonably preventable."

Moreover, the AAOS believes that HAC policy places high-risk patients with co-morbidities which are known to increase the risk of VTE at a disadvantage for access to quality care. As we have stated before, we are concerned that hospitals will incentivize physicians to deselect patients based on their risk factors or co-morbidities. We hope CMS will consider this unintended consequence and focus on implementing appropriate risk adjustment into the policy, especially with a diverse and complex Medicare population.

**Modifications to MS-DRG Severity Levels for MRE MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)**

The AAOS believes that CMS should subdivide the base MS-DRG 470 (Major Joint Replacement or Reattachment of Lower Extremity without MCC) and MS-DRG 469 (Major Joint Replacement or Reattachment of Lower Extremity with MCC) into three severity levels—with MCC, with CC and without CC/MCC. (See Sec. II. G. 5.). The AAOS is concerned that CMS has chosen instead to maintain the two existing severity levels for MS-DRGs 469 and 470. The AAOS believes that adding a third "with CC" designation would allow Medicare to better recognize severity of illness, utilization of resources, and complexity of services. Creating one more subgroup with smaller differences in average costs would give a more accurate picture of the care afforded patients.

In developing the MS-DRGs, two of CMS' goals were to create DRGs that would more accurately reflect the severity of the cases assigned to them and to create groups that would have sufficient volume so that meaningful and stable payment weights could be developed. The intention was that hospitals would be paid more accurately for the costs associated with treating patients who require more resource-intensive treatment. CMS established three different levels of severity into which diagnosis codes were subdivided: Major CCs (MCCs), CCs, and non-CCs. MCCs reflect the highest level of severity and non-CCs reflect the lowest level. Non-CCs are diagnosis codes that do not significantly affect severity of illness and resource use, and therefore, they do not impact DRG assignment. Secondary diagnoses are important to assure that providers are appropriately reimbursed by Medicare, receive credit for the severity of illness of their patients,

accurately demonstrate the risk of mortality of their patients, correctly rate providers in public report cards, and adequately establish the appropriate level of care.

CMS states that it examined FY 2010 MedPAR claims data to determine if it could subdivide the base MS-DRG into three severity levels--with MCC, with CC, and without CC/MCC. CMS then applied the criteria it used in the development of the MS-DRGs included in the FY 2008 IPPS final rule. Those criteria are: a reduction in variance costs of at least 3 percent; at least 5 percent of the patients in the MS-DRG fall within the CC or MCC subgroup; at least 500 cases are in the CC or MCC subgroup; there is at least a 20-percent difference in average costs between subgroups; and there is a $2,000 difference in average costs between subgroups. CMS determined that these cases do not meet the fourth and fifth criterion.

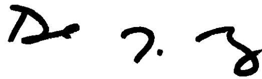
In the statistics provided by CMS, FY 2010 cases “with MCC” number 25,717, cases “with CC” number 179,116, and cases “without CC/MCC” number 220,739. While there would be only approximately $1000 difference in costs between the “without CC/MCC” cases and those “with CC,” there is a difference of approximately $8,000 between the “without CC/MCC’ cases and those “with MCC.” The large number of “with CC” cases that are currently classified as “without CC/MCC,” places an unfair burden on providers who treat these patients and presents a distorted picture of the actual severity level of cases assigned to those providers. The AAOS believes that adding an additional severity level to MS-DRGs 469 and 470 would better identify those conditions that lead to higher severity of illness and resource use relative to the average Medicare patient. Although we understand that CMS’ analysis does not support a 20 percent or $2,000 difference in average costs for “with CC” cases, we believe the high volume of procedures included in these MS-DRGs warrants more careful and precise delineation of the resource intensity of these procedures.

The AAOS agrees with the CMS proposal to keep procedure codes 84.62 and 84.65 for insertion of a cervical or lumbar artificial disc to the MS-DRGs for spinal fusion. Clearly, the insertion of an artificial disc is not the same as a spinal fusion and therefore should not be included in the MS-DRG for spinal fusion.

**Conclusion**

The AAOS is supportive of CMS’ effort to develop a clinically meaningful, effective Inpatient Payment System program, with the overriding goals of improving quality and decreasing the cost of healthcare delivery in the United States. We appreciate this opportunity to provide input on the FY 2012 IPPS proposed rule and look forward to continuing to work with CMS and provide guidance and clinical input on issues related to musculoskeletal care. If you have any questions on the AAOS comments, please do not hesitate to contact our Medical Director, William R. Martin, III, MD, at (202) 546-4430 or martin@aaos.org

Sincerely,



Daniel J. Berry, MD

President, American Association of Orthopaedic Surgeons

cc: Karen L. Hackett, FACHE, CAE, AAOS Chief Executive Officer
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