June 25, 2012

Marilyn B. Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1588-P
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals’ Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers,” CMS-1588-P

Dear Ms. Tavenner:

The American Association of Orthopaedic Surgeons (AAOS) appreciates the opportunity to comment on the fiscal year FY2013 Inpatient Prospective Payment System (IPPS) proposed rule, entitled “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals’ Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers,” 77 FR 27870 (05/11/2012). 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 care while maintaining access to care for all Medicare beneficiaries and slowing growth in healthcare spending, and we appreciate this opportunity to provide input on total hip arthroplasty (THA) and total knee arthroplasty (TKA) complication measures and readmission measures, as well as other proposals.

Hospital Inpatient Quality Reporting (IQR) Program
The Hospital Inpatient Quality Reporting (IQR) Program requires hospitals to report specific quality information to avoid a two-percentage-point reduction in that year’s inpatient hospital payment update factor. The AAOS offers the following comments on CMS’ proposals:
Hip Fracture Mortality Rate (IQI-19)
Beginning in FY2015, CMS proposes to remove the three Agency for Healthcare Research and Quality (AHRQ) inpatient quality indicator (IQI) measures, including Hip Fracture Mortality Rate (IQI-19). The AAOS supports removal of these measures.

Hip fractures are common among elderly people, and they are a common cause of functional decline and ill health, which can increase risk of death. The AAOS believes, however, assessments of hospital quality based on short-term mortality may not reflect important improvements in patient outcomes that hospitals may achieve.

The AAOS commends CMS’ efforts to reduce redundancy among the measures in the Hospital IQR Program. Three of the six conditions in the IQI composite measure overlap with measures in the Hospital IQR Program. The proposed removal of these AHRQ IQI measures would eliminate unnecessary redundancy in the Hospital IQR measure set. The AAOS believes that including a large number of in-hospital mortality measures may lead to unintended consequences because the performance on these measures is highly dependent upon hospital discharge patterns. Unintended consequences include patients being discharged sooner than advisable, patients diverted to other hospitals, or patients at the end-of-life being overtreated to avoid in-hospital mortality. Patients on inpatient hospice or palliative care would reflect patient centric care and may have a different mortality rate profile. Moreover, the AAOS believes that mortality measures that are derived from administrative or claims data may not take into account decisions made by the patient, family, and physician, including those to withhold treatment at the end of life.

Safe Surgery Checklist
Beginning with the FY2016 payment determination, CMS proposes to add a yes/no measure of whether the hospital uses a safe surgery checklist during three periods: prior to administration of anesthesia, prior to skin incision, and from the closure of incision prior to the patient leaving the operating room. The proposed measure has been adopted for use in the hospital outpatient and ambulatory surgical center quality reporting programs, but has not been endorsed by the National Quality Forum (NQF) or the Measure Applications Partnership (MAP) because measure specifications are not yet available.

The AAOS supports the use of a safe surgery checklist, but recommends that hospitals and surgeons be afforded the ability to avoid unworkable and disruptive checklist measures. Specifically, we urge CMS to avoid requiring a checklist that prescribes multiple time-outs or surgical pauses, which can be disruptive and unworkable. We urge
CMS to move beyond measuring only utilization of surgical checklists. A more valuable measure of surgical checklists may be an assessment of how they are used.

**Hip/Knee Readmissions**
CMS proposes to add a measure for hip/knee readmission hospital level 30-day, all cause, risk standardized readmission rate (RSRR) following elective total hip arthroplasty (THA) and total knee arthroplasty (TKA) to the Hospital IQR Program. The AAOS commends CMS for focusing on condition-specific readmissions. We believe this is a better approach to providing valuable feedback to hospitals and physicians and improving health care quality than hospital-wide readmissions involving broad cohorts of patients.

Moreover, the AAOS appreciates CMS’ work toward a robust risk-adjustment model for the readmission measure. The AAOS commends CMS for taking into account the condition-specific or procedure-specific risk. The AAOS, however, urges CMS not to expand hospital readmissions reporting unless adequate guidelines exist for future conditions and the associated measures can be properly risk-adjusted. Accordingly, the AAOS does not support the inclusion of the hip/knee readmission measure in the Hospital IQR program.

The AAOS believes that the measure should account for the patient-specific risk factors that are preventable, even though it may be potentially more difficult to implement. The AAOS urges CMS to further develop a means for risk-adjusting for the wide range of variation in patient characteristics prior to fully implementing the policy. The AAOS recommends that CMS capture as many co-morbidities as possible in its risk adjustment methodologies and adequately account for each patient’s unique risk factors. For example, obesity. Obesity places patients at a higher risk for complications, particularly infection, wound breakdown and venous thromboembolism, and the resultant readmissions. Moreover, the AAOS has additional concerns with the lack of inclusion of socio-economic status (SES) as research identifies this and behaviors such as smoking as relevant variables.

The AAOS believes the hip/knee readmission measure could place some high-risk and co-morbid patients at a disadvantage for access to quality care. We are concerned that hospitals will incentivize physicians to deselect patients based on their risk factors or co-morbidities.
The AAOS agrees that hospitals, in collaboration with medical communities, can take actions to improve health care delivery and reduce readmissions by ensuring that patients are clinically ready at discharge, reducing the risk of infection, reconciling medications, and improving communications among providers involved in transition of care. The AAOS recognizes, however, that there are many factors beyond the hospitals’ control that may impact rates of readmission, including the patient’s own behavior. We are committed to patient-centered care, yet we are concerned that our current health care system has a minimal culture of patient activation and accountability.

**Hospital-Wide Readmissions**

CMS proposes to add the hospital-wide all-cause unplanned readmission measure (HWR) (NQF#1789) to the Hospital IQR program. As a general comment, the AAOS supports quality measures that are actionable and help align and coordinate care in all settings by all providers. We support the measurement and reduction of complications and readmissions. However, we have concerns with the ability of the overall performance rate to inform a hospital of its specific needs for quality and patient safety improvement. We understand that measuring quality in the hospital and physician community differs in many ways but we strive and advocate for alignment when possible.

The AAOS urges CMS not to expand hospital readmissions reporting unless adequate guidelines exist for future conditions and the associated measures can be properly risk adjusted. The AAOS does not support the inclusion of the HWR measure in the Hospital IQR program.

**Risk Adjustment**

The AAOS supports the development of clinically relevant quality measures which recognize the importance of measuring both process and outcome. We cannot stress enough the importance of risk-adjustment when outcome measures are publicly reported and/or used in future value-based purchasing programs. Both of these quality tools rely on accurate, valid, and reliable data to inform stakeholders and improve quality. Without risk-adjustment, comparisons are not equitable nor do they drive actionable, effective improvement efforts.

The AAOS appreciates CMS’ efforts to address risk-adjustment for the HWR measure. The AAOS commends CMS in adopting a multi-level approach to risk adjustment, including its use of hierarchical generalized linear models to adjust for differences in hospital case mix and to account for the clustering of patients within a hospital, its regression analyses, its attempt to adjust for case mix differences among hospitals by
risk-adjusting for patients’ co-morbidities, and its risk-adjustment for service mix differences among hospitals.

The goal of risk-adjustment facilitates equitable comparison among providers by accounting for patients’ co-morbidities and co-conditions that increase their risk for complications and further treatment. Risk-adjustment will significantly vary for acute and chronic conditions and among the individual conditions or procedures. The AAOS, however, believes administrative claims may not give the information that is needed to fully and accurately assess hospitals’ performance or to properly characterize readmissions.

The AAOS recommends that CMS capture as many co-morbidities as possible in its risk-adjustment methodologies. Each condition and/or procedure has different associated co-morbidities, co-conditions, and complications. Chronic conditions have associated acute episodes that may be unavoidable and other associated acute episodes that are avoidable. In addition, chronic conditions will have acute episodes that are unrelated to that condition. Accordingly, post-acute care and readmissions will vary in their necessity and preventability based on each specific condition and/or procedure and each patient’s severity, co-morbidities, and treatment plans. The AAOS believes that risk-adjustment must adequately account for each patient’s unique risk factors.

The AAOS has specific concerns with the lack of inclusion of socio-economic status (SES). The AAOS is concerned that while the measure would employ multiple assessment models, which may increase the likelihood of providing actionable information to hospitals, the broad cohorts used would limit whatever utility is provided by those models. We also recommend focusing on condition-specific readmissions as a better approach to providing valuable feedback to hospitals and physicians working to improve health care quality.

The AAOS acknowledges that defining the outcome as all-cause unplanned readmissions rather than readmissions related to the previous hospitalization alleviates some attribution issues. For example, there is no need to determine whether a readmission is related to the previous hospitalization based on the documented cause of readmission. However, accurate attribution should be a critical element of all performance assessment and quality improvement initiatives. Moreover, there is a need to further delineate what is the goal of the measure. In assessing a hospital’s performance, CMS must be cognizant of the potential to mischaracterize the “appropriateness” of hospital admissions or readmissions under the proposed methodology. The AAOS is also concerned that the definitions and methodologies presented may characterize some
readmissions, particularly those for chronically ill patients, as unplanned when in fact they are planned.

Moreover, the AAOS believes the HWR measure places some high-risk and co-morbid patients at a disadvantage for access to quality care. We are concerned that hospitals and physicians will be incentivized to deselect patients based on their risk factors or co-morbidities. We hope CMS will consider these unintended consequences and focus on implementing more nuanced risk adjustment into the policy especially with such a diverse and complex Medicare population.

If patient de-selection occurs, tertiary centers will be further inundated with the most complex high risk patients. The AAOS commends CMS for addressing risk-adjustment in its measure but urges CMS to further develop a means for risk adjusting for the wide range of variation in patient characteristics prior to fully implementing the policy. CMS should take into account for the patient-specific risk factors that affect preventability, even though it may be potentially more difficult to implement.

**Hip/Knee Surgical Complications**

CMS proposes to add one claims-based surgical complication measure that estimates hospital risk-standardized complication rates (RSCRs) associated with primary elective total hip arthroplasty (THA) and total knee arthroplasty (TKA) in patients 65 years and older. The measure uses Medicare claims data to identify complications occurring from the date of index admission to 90-days post date-of-the-index admission. The AAOS agrees that excluding patients from the measure cohort who had a THA or TKA due to a complication of a prior orthopaedic procedure will create a more clinically cohesive measure cohort. The AAOS, however, has some concerns about the proposed measure.

The history of a complication not due to an orthopedic procedure, not present or active at the date of index procedure (history of prior embolus), may still increase the occurrence of complication and risk de-selection of patients otherwise appropriate for orthopedic procedure. While we agree that complications following primary elective THA and/or TKA are important patient outcomes that may reflect quality of care delivered to patients undergoing these procedures, we believe the evidence available on the relationship between healthcare processes and complication outcomes from primary elective THA and/or TKA is limited and not enough is known about determining which complications are attributable to care processes.

**Socioeconomic Status**

The AAOS believes socioeconomic status (SES) should be included in the risk-adjustment models because low SES patients are known to be at higher risk for post-
operative complications and readmissions and not including SES in the models could result in low SES patients being denied much needed quality enhancing treatments like THA and TKA. Socioeconomic status has been shown to play a role in risk of readmission for post-operative complications. SES is usually measured by level of education, income, occupation or a composite of these dimensions. Researchers involved in analyses of risk adjusted outcomes and costs have suggested the need for a SES adjustment for patient populations in addition to traditional risk-adjustment variables.

Hospital Value-Based Purchasing (VBP) Program

Medicare Spending Per Beneficiary

CMS proposes to include a Medicare spending per beneficiary measure for the Hospital VBP program. This controversial measure is designed to monitor how well a hospital reduces costs compared to national averages during the period of three days prior to a patient’s admission and out to 30-days after discharge. As proposed, a hospital’s Medicare spending per beneficiary would start impacting payment rates in FY2015 based on costs reported in claims data beginning in May 2013.

The AAOS is concerned that this efficiency measure has not been fully tested and validated. This measure is not currently NQF-endorsed and was not recommended by the MAP for inclusion in the Hospital VBP. There is significant risk that patients and families, trusting care givers to act in patients’ best interest, would fear care denials to achieve a flawed financial “efficiency” measure. In addition, the 30-day period following discharge may not properly account for downstream cost savings that may result from technologies with higher upfront costs. Accordingly, the AAOS does not support the inclusion of this measure.

ASC Quality Reporting Program

The AAOS commends CMS on its efforts to initiate the Ambulatory Surgical Center (ASC) Quality Reporting Program. The AAOS believes that it is important that initial reporting thresholds are low to allow ASCs to become familiar with the program and to address any technical difficulties.

In addition, the AAOS believes that a fair and timely process for reconsideration and appeals is important. The AAOS believes that the process for reconsideration and appeal of payment determination should be initiated before any information or data becomes publicly available. Furthermore, if an ASC has requested reconsideration or an appeal, then the ASC’s information or data should not be made publicly available until CMS has responded in writing to the reconsideration request or appeal. The AAOS also supports CMS’ proposal to not make quality measure data publicly available for a payment determination year and any subsequent payment determination year(s) for which an
ASC is withdrawn from the program. Moreover, the AAOS recommends implementation of a reporting feedback program that periodically updates ASCs on their reporting status and allows ASCs to ascertain whether they are on track to meeting reporting requirements and thresholds and to take corrective actions.

The AAOS urges CMS to take every precaution to ensure the accuracy of the quality data made publicly available. ASCs are small businesses and public posting of inaccurate information creates unnecessary needless patient anxiety and could have devastating economic consequences for an ASC site and employees. The AAOS recommends a phase-in of reporting that includes an initial period of confidential feedback and public reporting of participation only, followed by full public reporting.

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 FY2013 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,

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President, American Association of Orthopaedic Surgeons

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