AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

October 1, 2016

Andrew M. Slavitt
Acting Administrator,
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS–5519–P, Mail Stop C4–26–05,
7500 Security Boulevard, Baltimore, MD 21244–1850.

Submitted electronically via http://www.regulations.gov.

Subject: **(CMS–5519–P)**
Medicare Program; Advancing Care Coordination through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR)

Dear Acting Administrator Slavitt:

On behalf of the 18,000 board-certified orthopaedic surgeons who comprise the membership of the American Association of Orthopaedic Surgeons (AAOS) and that of the orthopaedic sub-specialty groups who agreed to sign-on, we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on **Medicare Program; Advancing Care Coordination through Episode Payment Models (EPMs); Cardiac Rehabilitation Incentive Payment Model; and Changes to the Comprehensive Care for Joint Replacement Model (CJR) (CMS–5519–P)** published in the Federal Register [42 CFR Parts 510 and 512] on August 2, 2016.

Per this proposed rule, CMS established the surgical hip/femur fracture treatment excluding lower extremity joint replacement (SHFFT) model to test whether it will reduce Medicare expenditures while preserving the quality of care for beneficiaries. The AAOS has discussed for a long time that while lower extremity joint replacement (LEJR) procedures are common among Medicare beneficiaries, the patient population receiving joint replacements in the Comprehensive Care for Joint Replacement Model (CJR) are distinctly different from the elderly patients with multiple chronic conditions and frailty who will be impacted by the SHFFT model. It is encouraging to note that CMS recognizes this difference via this proposed rule and we applaud you and your colleagues for taking these actions.

It is also encouraging that a track within the Episode Payment Models (EPMs) will allow participants in CJR and SHFFT models to be considered for qualifying Advanced Alternative

Payment Models (APM) participant (QP) determination and thereby receive higher reimbursements under APMs in the Quality Payment Program (QPP). This new pathway is likely to open up opportunities for orthopaedic surgeons to participate in Advanced APMs. In response to the proposal for new Advanced APM models, AAOS has the following comments.

Potential voluntary bundle

As the Center for Medicare and Medicaid Innovation (CMMI) designs new episode demonstrations and we await the Medicare Access and CHIP Reauthorization Act (MACRA, 2015)/Quality Payment Program (QPP) Final Rule, the AAOS would like to put forth recommendations in terms of potential orthopaedic EPMs:

1. A hip fracture bundle with A) a fixation arm and B) an arthroplasty arm *and*
2. A joint arthroplasty bundle

The AAOS is willing to partner with CMMI to develop these EPMs providing clinical and research expertise not only from the Academy but from relevant orthopaedic specialty societies. These models will have voluntary participation and will include clinical services during the anchor hospitalizations, other parallel professional services during the anchor hospitalization period and post-discharge services within the chosen episode length of 30, 60 or 90 days. These EPMs can be hospital or physician group practice led; clinical providers will be paid on a fee-for-service basis and total payments can be made retrospectively against the pre-determined target price for each EPM. We expect these models to begin in 2018 and to meet all requirements for Advanced APMs as defined by the MACRA/QPP Final Rule.

As the AAOS has noted in earlier communication with CMMI, the Academy has been working on developing outcome measures for musculoskeletal care. This is vital work given the focus on reporting outcome measures in the QPP and the lack of outcome measures for our specialties. Many of these guidelines are Level 1 evidence. We are currently developing relevant Clinical Practice Guidelines and Appropriate Use Criteria documents for the hip fracture and joint arthroplasty episodes as priorities. The Patient-reported Outcome Measures (PROMs) on hip fracture procedures should be validated in the next couple of months.

Our other concerns with the proposal

While the AAOS is supportive of the Administration's goal of moving to value-based care and of "The Triple Aim" of healthcare improvement, we continue to have serious concerns on some of the elements of the proposed SHFFT model as below.

- Mandatory participation of ALL hospitals (and in effect their collaborators such as

orthopaedic surgeons) located in any of the 67 Metropolitan Statistical Areas (MSAs), pre-determined by CMS for CJR implementation;
- The immediate and full implementation of the proposal beginning July 1, 2017;
- The lack of designated physician leadership for episodes-of-care;
- The lack of infrastructure support from CMS necessary to properly administer and undertake the proposed changes;
- The absence of risk-adjustment in the program;
- Lack of validated quality measures;
- Absence of necessary exclusion criteria

Mandatory Participation

While it is understandable and convenient that the SHFFT model mirrors the CJR, AAOS continues to have the same concerns on mandatory participation requirement in the selected MSAs that we expressed in response to the CJR Proposed Rule in September 2015. (Our comments on CJR proposals can be found here: http://www.aaos.org/uploadedFiles/PreProduction/Advocacy/Federal/Issues/medicare/AAOS_CY2016_CMS_%20CCJR.pdf). Mandated participation in these models will force many surgeons and facilities who lack familiarity, experience, or proper infrastructure to support care redesign efforts into a bundled payment system. This will not only hamper provider participation in these models, will bias model performance evaluation, lead to inaccurate reimbursements and may negatively affect patient care. On the other hand, voluntary program (such as the BPCI models) that allows surgeons, facilities, and non-surgical providers to tailor their episode-of-care models to their particular patient population would lead to far better patient care as well as more accurate and efficient payments. The two successive annual BPCI evaluation results buttress this point. Hence, we continue to urge CMS to revise the mandatory nature of these demonstration and instead provide greater incentives for providers to voluntarily collaborate as well as develop the infrastructure needed for such collaboration.

Immediate Launch

CMS proposes to start the performance period on July 1, 2017. The AAOS believes that since this rule will not be finalized until early 2017, this is a very short time frame to launch the model. The CJR model had a very short time frame between finalizing the rule (November 2015) and launch of the performance period (April 1, 2016). Consequently, although the CJR model began six months back, many hospitals have not been able to put together the infrastructure and legal resources (including contracts with collaborators) as of yet.

Moreover, there will not be any evaluation data available from the CJR experience by the time of the final rule on the SHFFT model in early 2017. Data, widely and easily available to all participants, will be important for appropriate development of the next iteration.

Lack of Physician Leadership

Based on the CJR model structure, the SHFFT model continues to be a hospital-led initiative. This is problematic on various levels. The AAOS strongly believes this aspect of the rule requires change to designate that physicians – specifically orthopaedic surgeons – be the primary responsible party, or at least be equivalent in status to the acute care hospital leading an EPM. An orthopaedic surgeon is involved in the patient's care throughout the episode of care, from the pre-operative workup, followed by the surgery, to inpatient post-operative care, to the post-operative care provided in rehabilitation facilities, at home, and in the physician's office. No other party in the total episode of care is as involved in all aspects of the patient's care, and no other party is as important to the final patient outcome as the operating surgeon. In addition, we believe an orthopaedic surgeon bears the most risk throughout the episode of care and ultimately has the most insight into the best pathways to improving patient care quality and efficiency and should therefore lead the bundled payment initiative. In the past, CMS has expressed interest in considering episodes for the entire cycle of care for the patient. For example, in the older, sicker patient population SHFFT will impact, post-acute care will become a more important factor. The orthopaedic surgeon can better impact the appropriate use of this resource to optimize value.

CMS has repeatedly asked for feedback from stakeholders (most recently via Regulation No. CMS-1656-P; Title: Hospital Outpatient Prospective Payment - Proposed Rule 2017) on how to redesign the Medicare orthopaedic bundles such that they qualify as Advanced APMs. In response, AAOS has requested for greater risk sharing with orthopaedic surgeons in these models and have also asked for greater clarity on the risk percentage criteria required for QPs in Advanced APMs.

Moreover, physician leadership becomes imperative as the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) gets implemented and attribution algorithms become significant for accurate reimbursement. In response to the CMS request for information on the MACRA Patient Relationship Categories (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Patient-Relationship-Categories-and-Codes.pdf), AAOS commented that the relationships and roles of physician (and non-physician) team members should be defined by the physician coordinating a particular bundle/episode of care. This is because physician-patient relationships are not linear nor do they always exist within a defined timeline, but are oftentimes built on commonality of focus on reaching and maintaining healthcare goals and positive patient outcomes. Thus, specialists may move between acute and continuing relationships with the same patient

depending on the clinical nature of the particular episode of care. Having the hospital in charge of the bundle gives the hospital inappropriate leverage over surgeons and other participants and could allow some hospitals to exclude surgeons and other care providers if those parties don't wish to meet the hospital's terms. In contrast to the current version of the proposed rule, which allows the hospital to choose to enter arrangements with other providers and facilities to share potential savings and risk, our recommendation to explicitly place a surgeon as head, or co-head, of episodes would significantly reduce barriers to achieving high quality patient outcomes. If the primary goal of these innovative demonstrations is to manage resources while improving the quality of care, physicians should be incentivized to lead the episodes to improve efficiency and effectiveness.

Lack of Infrastructure Support

The AAOS has significant concerns, as noted above, that full scale implementation within 60 days of final rule publication is unrealistic. The proposed timing for implementation is further exacerbated by the concurrent MACRA implementation and the end of the grace period for adoption of ICD-10, which will likely demand physician and facility focus over the next several quarters. Infrastructure support is incomplete. The latest publicly available data on meaningful use attestation is at 18% and 48% for physicians and hospitals, respectively (Centers for Disease Control and Prevention, http://www.cdc.gov/nchs/data/databriefs/db143.htm), and EHR vendors have plagued practices with a lack of interoperability and errors in the 2014 Physician Quality Reporting System (PQRS) program. A recently released evaluation (Year 2) of BPCI models (https://innovation.cms.gov/Files/reports/bpci-models2-4-yr2evalrpt.pdf)[1] reported that ninety-three of the 100 providers surveyed by The Lewin Group for this evaluation used some sort of health information exchange capability. Almost all providers in the survey used electronic records, and most supported meaningful use measurements. Thus, voluntary participants in BPCI episodes seem to be ahead of the average providers on information technology infrastructure and meaningful use readiness. Unlike BPCI, CJR and SHFFT are mandatory models, providers who lack such deep resources will not be able to opt out and therefore will face unaffordable costs for participation.

In addition, we are concerned about the impact on small and medium sized practices since most orthopaedic surgeons are part of small practices. It may be more difficult for small physician practices to reach a contract with hospitals leading the CJR and SHFFT episodes. The second annual BPCI evaluation report also found that episode initiators across settings were more likely to be larger, urban facilities, mostly located in areas with higher income populations than other providers of the same type. The report concludes that BPCI participants are more likely to be

[1] The Lewin Group (2016). CMS Bundled Payments for Care Improvement Initiative Models 2-4: Year 2 Evaluation & Monitoring Annual Report. Available: https://innovation.cms.gov/Files/reports/bpci-models2-4-yr2evalrpt.pdf.

resourceful and many of them employ outside consultants to advise on data analysis and infrastructure including health information technology. Again CJR and SHFFT participants, especially the smaller practices, are likely to lack such resources.

The AAOS is encouraged by your recent announcement on the CMS Blog that physicians will be able to select their own pace of participation as MACRA is rolled out, however, we are waiting to see the period for partial data reporting and other partial reporting requirements (to miss the penalty and receive some bonuses) in the MACRA Final Rule this Fall. Physicians would like to fully participate in any opportunity for providing better care and these infrastructural issues are unfortunate barriers in that. We urge CMS to consider similar flexibilities in the implementation of EPMs.

Absence of Risk-adjustment

While defining the SHFFT model as triggered by Medicare Severity-Diagnosis Related Groups (MS-DRGs) 480-482 with separate target pricing than the CJR episodes is a right step in financial risk adjustment, as you are aware these models lack racial/ethnic, socio-economic and patient condition risk stratification. A recent analysis[2] of Medicare claims for patients in Michigan who underwent LEJR in the 2011-13 period, concluded that hospitals treating medically complex patients may be unintentionally penalized without proper risk adjustment. Reconciliation payments were found to be reduced by $827 per episode for each standard-deviation increase in a hospital's patient complexity. This study also estimated that risk adjustment could increase reconciliation payments to some hospitals up to $114,184 annually. Thus, the CJR and SHFFT models need financial, clinical and socio-economic risk adjustment. Another important point raised by this study, referenced above, is that these models are unique in that the target price is calculated as a blend of a particular hospital's historical episode spending and the average spending of other hospitals in the same region with the weight of the regional benchmark increasing over time, this is going to increase the financial disparity for hospitals treating more medically complex patients. The AAOS urges CMS to include important patient characteristics such as age, socio-economic status (SES), marital status, clinical co-morbidities, functional status, etc. apart from the target price stratification in both the CJR and SHFFT models. For a complete list of recommended risk variables, please see Appendix A of our comments on the CJR Proposed Rule available online at: http://www.aaos.org/uploadedFiles/PreProduction/Advocacy/Federal/Issues/medicare/AAOS_CY2016_CMS_%20CCJR.pdf.

[2] Ellimoottil, C., Ryan, A. M., Hou, H., Dupree, J., Hallstrom, B., & Miller, D. C. (2016). Medicare's New Bundled Payment For Joint Replacement May Penalize Hospitals That Treat Medically Complex Patients. *Health Affairs*,*35*(9), 1651-1657.

The existing literature shows racial disparity in utilization of elective joint replacement (41.5 per 10,000 for black patients vs 68.8 per 10,000 for white patients; P<.001)[3] and that minorities are more likely to receive joint replacement at low-volume/low-quality hospitals compared with nonminority patients and may have worse outcomes including higher rates of hospital readmission[4]. Thus, one unintended consequence of the CJR model may be to accentuate racial disparity in joint replacement surgery.[5] An interesting finding of the BPCI Year 2 evaluation[1] is that the shift from more expensive institutional post-acute care (PAC) to home and community based PAC contributed to major reduction in the cost of orthopaedic surgeries. While this finding implies that CJR and SHFFT episodes may encourage hospitals to provide better quality PAC, it must be considered that BPCI participants operate in more affluent areas. On the other hand, lower SES and minority patients may not have adequate support at home or transportation to receive home and community based rehabilitation services.[5] Thus, CJR and SHFFT episodes may not have the same potential for improving the quality of care while reducing costs of care without adequate risk adjustments.

Even moderate risk adjustment using the Hierarchical Condition Category (CMS-HCC) measures (even if not validated for LEJR episodes) will be a good start. The *Health Affairs* study argues that providers that have established risk-sharing contracts with hospitals in the CJR program might refuse to care for more expensive (and probably clinically more complex and with lower SES) patients exceeding the hospital's unadjusted target price. This expected behavior of 'lemon dropping' by providers and bundle leaders eager to reduce costs is likely to reduce access for Medicare's most vulnerable beneficiaries.

Lack of validated outcome measures

The NQF # 1550 calculates hospital-level complication rates following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) with the goal to reduce complication rates. It addresses a priority condition (osteoarthritis) and is expected to lead to reduced morbidity and mortality post THA and TKA. This measure has not been not been vetted for use in hip fractures and if used as a surrogate from the hospital's Total Joint Arthroplasty (TJA) experience will unfairly measure those hospitals with a smaller arthroplasty experience. Likewise the collection of the patient reported outcome measures (PROMs) will be skewed. The Hip disability and Osteoarthritis Outcome Score (HOOS), JR. is a patient-relevant short-form survey

[3] Singh, J. A., Lu, X., Rosenthal, G. E., Ibrahim, S., & Cram, P. (2014). Racial disparities in knee and hip total joint arthroplasty: an 18-year analysis of national Medicare data. *Annals of the Rheumatic Diseases,73*(12),2107-2115. .
[4] Jorgenson, E. S., Richardson, D. M., Thomasson, A. M., Nelson, C. L., & Ibrahim, S. A. (2015). Race, Rehabilitation, and 30-Day Readmission After Elective Total Knee Arthroplasty. *Geriatric Orthopaedic Surgery & Rehabilitation*, *6*(4),303-310.
[5] Ibrahim, S.A., Kim, H., McConnell, K. (2016). The CMS Comprehensive Care Model and Racial Disparity in Joint Replacement. *JAMA.* Published online September 19, 2016. doi:10.1001/jama.2016.12330.

based on the HOOS, focusing specifically on outcomes after THA. The instrument does not have validity for application to hip fractures.

Absence of exclusion criteria

This proposed rule does not discuss the exclusion criteria for the SHFFT model. We recommend that they be the following:

a. Transfers (such that the potential for transfers to offload risk is mitigated)
b. Patients with dementia/Alzheimer's Disease (in these cases there is a potential for significant unintended ethical consequences related to withholding of surgery)
c. Patients already residing in skilled nursing facilities
d. Fractures related to cancer (this exclusion should also be in place in the CJR model)
e. Patients that are admitted with the fracture being secondary to the following conditions (both in etiology and importance) so as to reduce the huge risk for increases in transfers:
    1. Acute Myocardial Infarction/arrhythmia and syncope
    2. Cerebrovascular Accident (CVA)
    3. Severe seizure (especially new onset)
    4. Head injury
    5. Polytrauma

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Thank you for considering our comments on these important matters. We look forward to the MACRA/QPP Final Rule this fall and expect that the regulations will provide us with greater clarity on requirements for physicians participating in these models to become QPs in the Advanced APMs. In addition, we look forward to the Assistant Secretary for Planning and Evaluation's (ASPE) report to Congress on risk adjustment per The Improving Medicare Post-Acute Care Transformation Act (IMPACT, 2014). If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,

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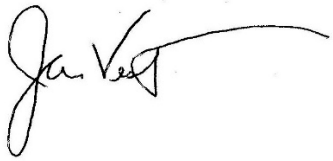

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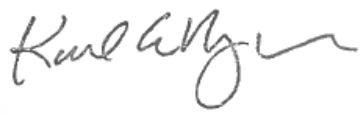

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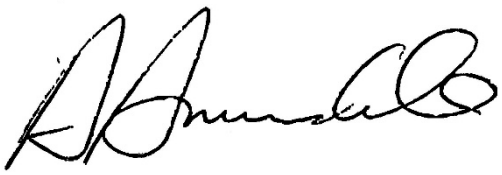

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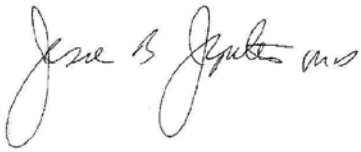

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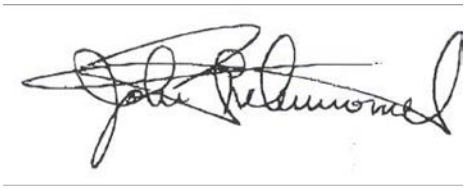

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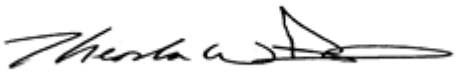

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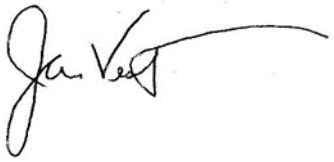

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