

April 19, 2017

Seema Verma, MPH
Administrator,
Centers for Medicare and Medicaid Services
Attention: CMS-5519-IFC
P.O. Box 8013
Baltimore, MD 21244-8013
Submitted electronically via <http://www.regulations.gov>

**Subject: (CMS–5519–IFC)
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); Delay of Effective Date**

Dear Administrator Verma:

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 subspecialty groups who agreed to sign-on to this letter, we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Interim Final Rule with comment period (IFC) 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); Delay of Effective Date (CMS–5519–IFC)** published in the Federal Register [42 CFR Parts 510 and 512] on March 21, 2017.

We commend CMS for taking additional time to review these models of care for Medicare beneficiaries and sincerely hope that you will take our comments into consideration while making any changes in policy.

Appropriateness of Delay

Per this IFC, CMS delayed the effective and applicability date for the Surgical Hip/Femur Fracture Treatment [excluding lower extremity joint replacement] (SHFFT) model. We support this delay as this is good news for thousands of patients and their health care providers including hospitals, post-acute care providers, surgeons and rehabilitation therapists in the selected metropolitan statistical areas (MSAs) who would, otherwise, have to mandatorily participate in the SHFFT model starting July 1, 2017. We would like to see more time given to all those involved to get ready to launch this important model especially since many of them do not have

the adequate infrastructure and readiness. Thus, we believe that this additional delay in launching the SHFFT model will be beneficial in maintaining good quality of care to all Medicare patients who will be impacted by this model.

It will be informative and efficient to launch the SHFFT model only after we have the first peer-reviewed evaluation of the CJR model. Also, CMS might want to reconsider whether it is meaningful to issue quality incentive payments under SHFFT based on the hospital's composite quality score on the following two measures:

1. Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure (NQF#1550); and
2. Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure (NQF#0166).

Since NQF # 1550 was not validated for hip and femur fracture procedures other than elective lower extremity joint replacements, it may be worthwhile to consider other alternatives until valid and reliable quality measures are developed for the SHFFT model procedures. As you would well appreciate, without appropriate quality metrics, model performance cannot be correctly evaluated in this context.

Further, this IFC delayed the effective date for the specific CJR regulations. As you are aware, the CJR model was launched on April 1, 2016, has already completed its first performance year and the second year is currently underway. The changes to the CJR that were finalized via the January 3, 2017 Final Rule (82 FR 180) would create a separate certified electronic health records technology (CEHRT) track under CJR thereby creating a pathway for this model to qualify as an Advanced Alternative Payment Model (APM) in the Quality Payment Program. With the Bundled Payment for Care Improvement Initiatives (BPCI) models still not qualifying as Advanced APMs, the CEHRT/Advanced APM track in CJR is likely to be the only opportunity for orthopaedic surgeons to participate in Advanced APMs. Delaying the effective date for CJR regulations will not be meaningful for the CJR participants and their patients and may set up this particular model (as well as your Agency's move to value-based care) for failure. Hence, we strongly urge CMS to *not further delay the CJR regulations*.

Model Design

As CMS reviews these EPMS, the AAOS would like the Agency to consider the following amendments and issues:

1. Mandatory Participation

As AAOS had noted in comments in response to both the 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) and to the proposed rule on Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services; Proposed Rule (CMS-5516-P), 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, but will bias model performance evaluation, lead to inaccurate reimbursements and may negatively affect patient care. On the other hand, a voluntary program (such as in 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. Hence, we continue to urge CMS to revise the mandatory nature of these demonstrations and instead provide greater incentives for providers to collaborate as well as develop the infrastructure needed for successful participation.

2. Expansion of CJR and SHFFT to non-MSA areas

The CJR Model is currently under way in 67 geographic areas, defined by Metropolitan Statistical Areas (MSAs) selected by stratified random sampling. The SHFFT Model has been finalized in the same 67 MSAs that are currently participating in the CJR Model. MSAs are counties associated with a core urban area that has a population of at least 50,000. Eligible MSAs, which were used for MSA selection in the CJR Model, must have had at least 400 eligible (not included in the BPCI initiative) CJR cases between July 2013 and June 2014. The AAOS applauds CMS' desire to encourage widespread provider engagement in value-based care models like CJR and SHFFT and in this context, we would urge CMS to reconsider the MSA selection criteria used earlier and expand these models under the Advanced BPCI model. The current BPCI initiative is already a nation-wide program without MSA restrictions or eligible case thresholds. This design has enabled the expansion of care redesign for elective and trauma cases well beyond the limits of only major metropolitan areas. BPCI is a proven model for expanding care for both physician groups and hospitals in large and small markets and as such, it is a model that can be built upon and expanded even further in the model's next iteration.

3. Separate Pricing for Primary and Revision Total Ankle Arthroplasty in CJR

As you are aware, Total Ankle Arthroplasty (TAA) is included in MS-DRGs 469/470. There is increasing evidence, which we would be happy to provide upon request, that the outcomes for TAA are at least equivalent to ankle arthrodesis and are preferable for some patients. Our concern is that grouping TAA with Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) with respect to MS-DRG payments and CJR, as well as grouping primary and revision

TAA together, may make TAA financially non-viable for many hospitals. This may lead these institutions to limit physicians from performing TAA, particularly on patients with higher comorbidities. This in turn would restrict patient access to what may be their best treatment option with respect to pain relief and functional activity.

Per the 2015 MedPar database, the standardized cost mean for primary TAA was \$5,657 more than for all cases in MS-DRG 469 and \$13,471 more in MS-DRG 470. The difference for revision TAA as compared to primary TKA and THA is likely higher. There are multiple potential reasons for this cost differential. Implant costs using more recently developed designs (as compared to hip and knee implants) are one reason.

Also, TAA is a fundamentally different operative procedure than TKA or THA in several important ways:

- The ankle region typically has poorer circulation and thinner soft tissue coverage than the hip and knee leading to a higher risk of wound complications and infection that may be more challenging and expensive to treat.
- Successful TAA often requires addressing concurrent ankle ligamentous instability, foot deformity, and muscle imbalance.
- When compared to THA and TKA patients, TAA patients are more likely to have post-operative cast immobilization and weight-bearing restrictions, often up to 6 weeks. This limitation in weight-bearing reduces independence in walking and can lead to longer inpatient stays, higher rates of placement in and length of stay at extended care facilities, and the need for offloading devices such as wheelchairs and rolling scooters. This is particularly relevant to the ongoing inclusion of TAA in the CJR initiative as the post-operative care differences will affect the costs under CJR.

In this context, we acknowledge and appreciate the most recent proposal (CMS-1677-P) to reassign the following TAR procedure codes from MS-DRG 470 to MS-DRG 469, even if there is no MCC (Major Complications and/or Comorbidity) reported: 0SRF0J9; 0SRF0JA; 0SRF0JZ; 0SRG0J9; 0SRG0JA; and 0SRG0JZ for FY 2018.

4. 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 model 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.

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. 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.

5. Stark Law Waivers

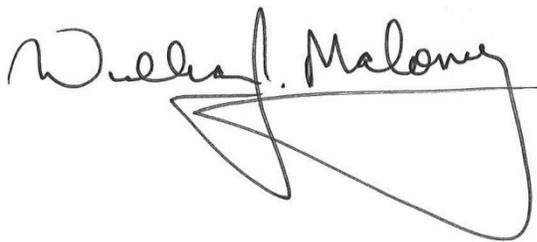
As AAOS and several of our partners have noted earlier in our comments to CMS and to the US Congress, the structure of the Stark Law has not been updated statutorily for more than two decades and at this time, limits the full potential of these innovative health care delivery models. The two issues that we would like to emphasize are the importance of protecting the In-Office Ancillary Services Exception (IOASE), which allows for an integrated continuum of care, and the need to lift the physician-owned hospital (POH) ban on expansion and new construction, which increases access to quality care.

The BPCI and CJR models reveal weaknesses in current Stark Law which is structured to have some control over the volume of referred services. The Stark Law is a liability statute unlike other health care legislation and therefore, unintentional and technical errors of physicians and

their staff may lead to heavy penalties. Such liability statutes are not encouraging of physicians to participate in coordinated care models. The costs of compliance and disclosures required per the Stark Law can be prohibitive for small and medium-sized physician practices participating in these models. physician referrals in Accountable Care Organizations (ACOs) are theoretically exempt from the Stark Law requirements through fraud and abuse waivers. There should be similar exceptions/protections to physicians participating in APMs.

In conclusion, the AAOS appreciates CMS taking this time for additional review of these models that impact the cost and quality of care received by Medicare beneficiaries. As noted above, we sincerely hope that the Agency will not further delay CJR qualifying as an Advanced APM and will consider our recommendations as new policy choices are considered and adopted via new rule-making. Please do not hesitate to get in touch with AAOS Medical Director, William O. Shaffer, MD, at shaffer@aaos.org if you have any further questions or comments. Thank you,

Sincerely,

A handwritten signature in black ink that reads "William J. Maloney". The signature is written in a cursive style and is positioned above a large, stylized, abstract graphic element that resembles a signature flourish or a large, irregular shape.

William J. Maloney, MD
President, American Academy of Orthopaedic Surgeons (AAOS)

This letter has received sign-on from the following orthopaedic societies:

American Alliance of Orthopaedic Executives (AAOE)
American Association of Hip and Knee Surgeons (AAHKS)
American Orthopaedic Society for Sports Medicine (AOSSM)
Arthroscopy Association of North America (AANA)
Cervical Spine Research Society (CSRS)
Musculoskeletal Tumor Society (MSTS)
OrthoForum
Orthopaedic Rehabilitation Association (ORA)
Orthopaedic Trauma Association (OTA)
Ruth Jackson Orthopaedic Society (RJOS)
The Hip Society (HIP)

The Knee Society (KNEE)

Cc: Thomas E. Arend, Jr., JD, CAE, CEO, AAOS
William O. Shaffer, MD, Medical Director, AAOS