

October 12, 2017

Seema Verma, MPH
Administrator,
Centers for Medicare and Medicaid Services
Attention: CMS-5524-P
P.O. Box 8013
Baltimore, MD 21244-1850
Submitted electronically via <http://www.regulations.gov>

**Subject: (CMS-5524-P)
Medicare Program; Cancellation of Advancing Care Coordination Through Episode
Payment and Cardiac Rehabilitation Incentive Payment Models; Changes to
Comprehensive Care for Joint Replacement Payment Model**

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 specialty societies who agreed to sign-on to this letter, we are pleased to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on **Medicare Program; Cancellation of Advancing Care Coordination Through Episode Payment and Cardiac Rehabilitation Incentive Payment Models; Changes to Comprehensive Care for Joint Replacement Payment Model (CMS-5524-P)** published in the Federal Register [42 CFR Parts 510 and 512]; 82 FR 39310 on August 17, 2017.

We commend CMS for cancelling the flawed Surgical Hip/Femur Fracture Treatment (SHFFT) Model and for making the Comprehensive Care for Joint Replacement (CJR) model partially voluntary. The AAOS is encouraged by your op-ed in the Wall Street Journal published on September 19, 2017 and by the release of a Request for Information (RFI) on the new direction for the Innovation Center. While we will comment via the appropriate vehicle, it is clear that CMS and the Innovation Center under your leadership will review the existing bundled payment models for their effectiveness and impact. As a part of this review, the AAOS would like the Agency to consider the following amendments and issues:

1. Mandatory Participation

We continue to urge CMS to revise the mandatory MSAs in the CJR model and make the whole model voluntary. As AAOS had noted in all previous comments, including 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 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 into a bundled payment system who lack familiarity, experience, or proper infrastructure to support care redesign efforts. 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 the Bundled Payment for Care Improvement [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.

2. Incentivizing Participation: Introduce Physician Leadership

The CJR 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 a bundle. 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 qualifying participants (QP) 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.

3. Risk-bearing

We believe that surgeons should have the ability to directly bear risks to actively participate in the CJR model and this ties in with our comment on establishing surgeons as head, or at least co-head, of the episodes. We agree with you that "providers need the freedom to design and offer new approaches to delivering care." One of the ways to achieve this is to allow surgeons in the CJR model to take charge of their patients' health and health care. CMS should directly contract with surgeons rather than have hospitals as an intermediary. Otherwise, surgeons have limited ability to control the process and outcomes of each episode and are left to the consequences of the lead hospital's decision and the dynamics of the local market.

4. Gainsharing

Given your stated goal to "move toward a system that holds providers accountable for outcomes and allows them to innovate," we suggest that there be no limits to gainsharing amounts. Gainsharing is an important feature in bundled payment programs to promote physician involvement in reducing costs and improving quality. When surgeons coordinate with the hospital to provide efficient, high-quality care that decreases cost, they should be able to fully share in the resulting cost reductions. Specifically, since surgeons are willing to bear risks in the CJR model, we believe that the current gainsharing limit of 50 percent of the total Medicare approved amounts under the Physician Fee Schedule for items and services that are furnished to beneficiaries during episodes should be removed altogether. We agree with the importance of "medically necessary" services – as is highlighted in the MACRA statute – and stress that the well-being of the patient must be the highest priority. Taking this together with regular member and patient education through clinical practice guidelines, appropriate use criteria and patient safety considerations, we believe any concerns about stinting care are unwarranted at this time. Instead, our proposed changes will ensure healthy competition among all participants in the model and will ultimately provide better quality of care and reduce the costs of health care.

5. Clinician Engagement

The AAOS supports the CMS proposal to expand the “Affiliated Practitioner” list to include each physician who is not a CJR collaborator, but who does have a contractual relationship on supporting a participant hospital under the CJR model. This would enable surgeons to achieve QP determination under the QPP. Nevertheless, we strongly urge CMS to introduce physician leadership in the CJR model, which will automatically include them as direct collaborators and enable them to have a financial arrangement in the model.

6. Create Specialty-focused Alternative Payment Models (APMs)

While we will provide information through the appropriate vehicle in response to your RFI on the Innovation Center, we would like to highlight some of our long-standing comments and suggestions on specialty physician focused payment models. We appreciate your support for innovative, value-based care delivery models. As you know, for 2017, CJR Track 1/Certified Electronic Health Record Technology (CEHRT) track is the sole Advanced APM available to our surgeons. Hence, we eagerly await the publication of the Bundled Payment for Care Improvement (BPCI) initiative’s next generation regulations. We hope that the Advanced BPCI model will allow voluntary participation and will provide a new pathway for our surgeons and their patients to join the Advanced APM track of the QPP. Further, the current BPCI program already fulfils the three criteria for an Advanced APM and should be designated as such.

The BPCI models have shown that bundled payments offer a highly effective opportunity to improve patient/beneficiary care and reduce unnecessary and/or wasteful costs. Engagement in BPCI has allowed physicians, hospitals, and providers to develop and implement new patient care pathways, and coordinate care to solve complex patient care challenges. Hence, we are strongly supportive of the BPCI initiative. However, as you think through the new updates on the BPCI models, please consider our concerns regarding the current pricing methodology.

In analysis conducted by one of the largest orthopaedic Awardee Conveners in the BPCI initiative, they have presented details regarding the pricing methodology employed by CMMI to account for various Medicare policy changes, geographic-specific wage changes (Wage Factor Adjustment) and national utilization trends (National Trend Factor or NTF) that occur over time. This pricing methodology is used to make adjustments to historical target prices on a quarterly basis and is critical in determining whether participant physicians will share in the savings with Medicare or reimburse Medicare for costs that exceed the target. This methodology ultimately determines whether the program is successful and can be sustained. For three years, a consistently declining trend in price in the current BPCI models attributable to the NTF, has produced unanticipated and significant negative financial consequences for the physician group practices (PGP) convened under this convener. This pricing trend equates to about 7-8 percent price deflation in unmanaged orthopedic episodes of care, which, based on our information, appears in complete contradiction to Medicare’s national cost trends.

The impact of the declining NTF has a compounding effect on an Episode Initiator's (EI) financial performance. Under the current pricing methodology and resulting NTF calculation, the more success physicians have in managing episodes and reducing cost, the faster the BPCI program moves toward unsustainability. So, despite achieving CMMI's goals for the BPCI initiative on cost and quality, the PGPs convened under this convener have been penalized financially because their care redesign efforts have been outpaced by the downward spiraling NTF.

The damage this has caused successful BPCI participants is quite discouraging – not only to the physicians in these groups that have worked very hard to reduce cost and improve outcomes under a new model of care and reimbursement, but to hundreds of other specialists who have become dubious of the government's ability to develop sustainable APMs. To illustrate further, the convener mentioned above has provided the analysis in the table in Appendix A for three physician group practices that are participating in BPCI under them. All three of these groups, despite driving costs down as much as 36 percent and achieving high quality outcomes, had to exit the initiative because they could not reduce their DRG spend enough to remain ahead of the effect of the declining NTF. See Appendix A for the impact of the NTF on three PGPs in BPCI Model 2.

Under this scenario, it will not be financially viable for many other participants to remain in the BPCI program given the continuing investment each EI has to maintain. As we can see from the above example, already some of the best performers in the BPCI program have decided to leave. Moreover, this BPCI convener's projection is only one example of the number of defections that have occurred and will continue to occur in the initiative without intervention. This is likely to taint future bundled and alternative payment models developed by CMS.

Hence, we propose that CMS and the Innovation Center consider the following options to address the current flaws in BPCI's pricing.

First, to address concerns with data transparency and accuracy in the current BPCI initiative, CMS should provide (to conveners that have been significantly impacted by the declining NTF and who request it) the actual data used to calculate the NTF for DRGs so impacted.

Second, to address pricing methodology concerns, the following actions should be undertaken:

1. elimination of the NTF or the placement of tighter limits on NTF changes,
2. complete exclusion of managed episodes from the NTF calculation,
3. elimination of the wage adjustment factor, and
4. reselection of episodes to enter into Phase 2 for the remainder of BPCI.

Further, to help ensure the long-term stability and physician engagement in the next generation BPCI program, we strongly urge CMS to implement the following methodology changes in the pricing model:

- **Prospective Targets** – Prospective targets, distributed before the performance period begins, are essential for EIs to plan and predict their ability to succeed in the program.
- **Regional Pricing Targets** – Adopting regional pricing targets will allow high performers to be attracted to and retained within the program.
- **Elimination of the Wage Factor** – The Wage Factor is inherently unfair to some EIs and does not accurately reflect that actual price changes of the underlying costs.
- **Elimination of the National Trend Factor** – The NTF has been fraught with issues and is one of the main drivers of unsustainability of the program. Removing the NTF and replacing it with a more reasonable approach to measuring utilization changes is desperately needed.
- **Implementation of Episodic Risk Adjustments** – Some episodes are inherently riskier than others. Implementing a risk adjustment methodology would allow EIs to more effectively manage their patient population.

The AAOS and our partners believe that taking these steps will make the BPCI program sustainable and viable in the long-term as well as provide a pathway for specialist physicians to participate in Advanced APMs.

7. Expansion of Models 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 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, and in this context, we would urge CMS to reconsider the MSA selection criteria used earlier and expand these models on a voluntary basis 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.

8. Publish Specific Details on Model Implementation

For 2017, CJR Track 1/Certified Electronic Health Record Technology (CEHRT) track is the sole Advanced APM available to our surgeons. This information is available on the QPP website. However, more specific details are missing from this rule. For example, there are no details on the requirements for participating in CJR Track 1 in this rule. Without these important details, participants in the CJR model are left confused and without the ability to take advantage of the new regulations. More specifically, we urge CMS to finalize the CEHRT and nominal risk requirements for participants who are interested in CJR Track 1. This is urgent if these changes are to launch on January 1, 2018.

The AAOS supports your view that the one time opt-in approach to allow for voluntary participation in the CJR model by certain hospitals would be less burdensome than asking them to opt-out. We also support your proposal to solicit applications and secure participants' agreement to participate in models going ahead. This should enable participants to gain greater clarity directly from CMS without the time lag involved in the rule-making process. However, with the change in focus in the new administration we still need more information on the timeline of this communication from CMS and the expected deadlines.

9. 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.

Given these illustrations, we are requesting for separate target pricing for TAR episodes in CJR. In this context, we acknowledge and appreciate the most recent regulation 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. We believe this will enable more hospitals to include TAR in their musculoskeletal service line. This will enable Medicare beneficiaries to receive higher quality care and improve their overall access to TARs.

10. Socio-economic Risk Adjustment

A recent analysis of Medicare claims for patients in Michigan who underwent lower extremity joint replacement (LEJR) procedures in the period 2011–13, 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.¹ Thus, the CJR model needs financial, clinical, and socio-economic risk adjustment. Another important point raised by this study, referenced above, is that the CJR model is 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 the CJR model.

For a complete list of recommended risk variables, please see Appendix A of our comments on the CJR Proposed Rule available online at:

¹ 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.

http://www.aaos.org/uploadedFiles/PreProduction/Advocacy/Federal/Issues/medicare/AAOS_C Y2016_CMS_%20CCJR.pdf

Priority List of Risk Variables

- Body Mass Index (BMI) – The actual height and weight should be recorded. The BMI should not be captured from the administrative data. The height and weight are currently being recorded in many electronic health records (EHR).
- Race/Ethnicity – Race/ethnicity should be a patient-reported variable and may be recorded in the EHR.
- Smoking Status – Smoking status may be reported through administrative data but additional information may be provided from the EHR.
- Age – Age is reported in administrative data.
- Sex – Sex is reported in administrative data.
- Back Pain – Back pain would be a patient-reported variable and recorded in the EHR. It has been noted to influence outcomes of joint replacement patients.
- Pain in Non-operative Lower Extremity Joint – Pain in a non-operative lower extremity joint would be patient-reported variable and recorded in the EHR. It has been noted that pain in other extremities can influence the outcome of a total joint replacement.
- Health Risk Status – The actual comorbidities that should be included need further investigation. Both the Charlson morbidity index and the Elixhauser morbidity measure may identify appropriate comorbid conditions. In order to identify the patient’s comorbid conditions, it is recommended that all inpatient and outpatient diagnosis codes for the prior year be evaluated.
- Depression/Mental Health Status – The Patient-Reported Outcomes Measurement Information System (PROMIS) Global or VR-12 will collect this variable, as well as the administrative data.
- Chronic Narcotic or Pre-operative Narcotic Use – These variables affect patient outcomes and requires additional consideration. The information should be available in the EHR.
- Socioeconomic Status – This variable affects patient outcomes and requires additional consideration. Further evaluation is required regarding how the data could be collected.

Future Desired List of Risk Variables

- Literacy
- Marital Status
- Live-in Home Support
- Family Support Structure
- Home Health Resources

Risk Variables to Not Include

- American Society of Anesthesiologists Physical Status Classification (ASA) Score
- Range of Motion (ROM)
- Mode of Patient Reported Outcome Measure (PROM) Collection

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 complex and lower SES) patients exceeding the hospital's unadjusted target price. This would severely reduce access for Medicare's most vulnerable beneficiaries.

11. Stark Law

As AAOS and several of our partners have noted earlier in our comments to CMS and to the U.S. Congress, the structure of the Stark law has not been updated statutorily for more than two decades, and at this time, it limits the full potential of these innovative health care delivery models. For example, the BPCI and CJR models reveal weaknesses in current Stark law. These kinds of payment models are value-based programs seeking to promote high-quality care and care coordination within individual health care entities and across multiple sites of service. However, the Stark law prohibits payment arrangements that consider the volume or value of referrals or other business generated by the participating parties. Further, the Stark law is a strict liability statute unlike other health care legislation, and therefore, unintentional and technical errors of physicians and their staff may lead to heavy penalties. Such strict liability statutes may discourage physicians from participating in coordinated care models. Indeed, 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.

To address some of these issues, physician referrals in Accountable Care Organizations (ACOs) are theoretically exempt from the Stark law requirements through fraud and abuse waivers. There must be similar exceptions/protections to physicians participating in APMs. CMS should have the regulatory authority to create exceptions under the Stark law for these types of payment arrangements and remove barriers to the development of such arrangements.

Specific recommendations are:

- Expansion of administrative authority to provide exceptions to physician ownership and compensation prohibitions to promote care coordination in MACRA programs. This empowers CMS to provide the same waiver authority to physician practices that was provided to accountable care organizations in the Affordable Care Act.

- Removal of the “value or volume” prohibition in the Stark law so that practices can incentivize physicians to abide by best practices and succeed in the new value-based alternative payment models. This protection would apply to practices that are developing or operating an alternative payment model. Items and services must be subject to fair market value except that they may not take into account volume or value.
- Creation of a more workable standard that only triggers penalties for knowing and willful violations of the law, which is the current standard for civil penalty provisions of the Anti-Kickback Statute Violations of the Stark law with respect to physician ownership interests.

In conclusion, the AAOS appreciates CMS taking this time for additional review of the CJR model and issues 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 more detailed regulations on CJR CEHRT Track/Track 1 as well as the Advanced BPCI model. We hope that CMS will consider our recommendations as new policy choices are considered and adopted via new rulemaking. 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,



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

Cc: David A. Halsey, MD, AAOS First Vice-President
Kristy L. Weber, MD, AAOS Second Vice-President
Thomas E. Arend, Jr., Esq., CAE, CEO, AAOS
William O. Shaffer, MD, Medical Director, AAOS

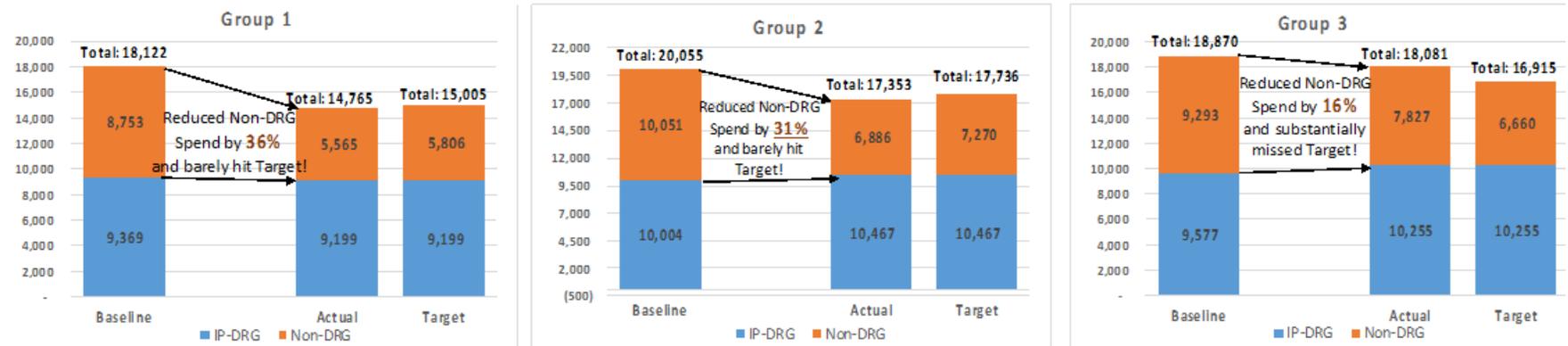
This letter has received sign-on from the following orthopaedic specialty societies:

American Association of Hip and Knee Surgeons (AAHKS)
American Orthopaedic Foot and Ankle Society (AOFAS)
American Orthopaedic Society for Sports Medicine (AOSSM)
American Society for Surgery of the Hand (ASSH)

Arthroscopy Association of North America (AANA)
Cervical Spine Research Society (CSRS)
Limb Lengthening and Reconstruction Society (LLRS)
Musculoskeletal Infection Society (MSIS)
Musculoskeletal Tumor Society (MSTS)
Orthopaedic Rehabilitation Association (ORA)
Ruth Jackson Orthopaedic Society (RJOS)
The Hip Society (HIP)
The Knee Society (KNEE)
North American Spine Society (NASS)

Appendix A

The following depicts the impact of National Trend Factor on three groups in BPCI Model 2 on their ability to manage to the Target Price (DRG 470 Non-Hip Fracture) for Q4 2016:



For Group 1 and Group 2, they **reduced their non-DRG spend by 36% and 31%, respectively, yet barely hit their Targets!**

For Group 3, their implied non-DRG spend has to be **less than \$7,000** just to hit Target, a reduction of 28% compared to baseline.

These are some of the top performing groups in BPCI, **yet all have decided to exit the BPCI program.** Unfortunately, we have other top performing groups that are on the cusp of exiting the program because of the issues with the pricing methodology.