AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

February 21, 2018

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Re: Bundled Payment for Care Improvement (BPCI) Advanced Request for Application dated January 9, 2018.

Dear Administrator Verma:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS) as well as the orthopaedic specialty societies and state societies who agreed to sign on, we would like to share input on the Center for Medicare and Medicaid Innovation's (Innovation Center) recent announcement of the Bundled Payment for Care Improvement (BPCI) Advanced (henceforth BPCI Advanced). The AAOS appreciates the initiatives undertaken by the Centers for Medicare and Medicaid Services (CMS) in promoting value-based care including the announcement of this model.

The AAOS has long requested a voluntary payment model that will qualify as an Advanced Alternative Payment Model (APM) under the Quality Payment Program (QPP). We are pleased that BPCI Advanced is a voluntary model that is available nationally, allows for physician leadership and is an Advanced APM. BPCI Advanced includes many orthopaedic procedures which allows opportunities for our surgeons and their patients to participate in musculoskeletal care redesign and improved outcomes. However, we have serious concerns with this model's design and the application requirements that we discuss below.

Precedence of Comprehensive Care for Joint Replacement (CJR) over BPCI Advanced

We understand that CMS decided to provide precedence to CJR over BPCI Advanced in the mandatory CJR metropolitan areas to have adequate sample size for a hospital-led mandatory model evaluation. However, the CJR precedence, as structured currently, will limit the ability of

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the vast majority of independent physicians from participating in BPCI Advanced and thereby the ability of these specialists to participate in an Advanced APM. While physicians will be able to participate in orthopedic episodes outside of Lower Extremity Joint Replacement (LEJR) episodes, LEJR episodes are one of the most common inpatient surgeries for Medicare beneficiaries and a cornerstone procedure for orthopedic participants in the current BPCI initiative.

Independent physicians achieved significant cost reductions while improving outcomes in LEJRs in existing BPCI Model 2. The latest (October 2017) evaluation of the BPCI initiative[1] from The Lewin Group found that LEJR was the only episode within Model 2 that registered a significant decline in average Medicare payments. Specifically, in Model 2 participating hospitals reviewed between October 2013 and September 2015, average cost declines in non-fracture episodes were $1,105 per case without any significant change in quality. Lewin however studied only hospital participants. In comparison, over the 2015 performance period, the physician group practices (PGP) working with the largest BPCI PGP conveners for orthopaedic clinical episodes achieved average CMS claims-based cost savings in elective LEJRs of $3,214, or 15% per episode compared to the 2009-2012 historic baseline period. In addition, significant reductions in post-acute adverse events were achieved with improved quality outcomes. We believe that this high success rate is the reason that BPCI Advanced was developed upon Model 2.

To elucidate further, we have reviewed data from a PGP convener of orthopedic practices in BPCI Classic undertaking LEJR cases at CJR hospitals from Q3 2016 to Q2 2017. The comparison data are between BPCI and CJR cases limited to Medicare Severity Diagnosis Related Groups (MS- DRG) 469 and 470 and done in CJR hospitals. These data consist of 15 PGPs doing 6,340 LEJR episodes in 40 CJR hospitals. Collectively, these PGPs reduced costs by $12.6 million over this time period.

To examine the impact of the BPCI Advanced precedence policy, we reviewed these same PGPs and only the CJR hospitals with positive gains in the current CJR program. We did this so we could compare savings between the two groups based on current performance in their respective programs. In this case, the number of PGPs is reduced to 12 and CJR hospitals to 20. In this hypothetical example, the PGPs would save $4.9 million on 2,635 episodes. Under the current policy for Advanced, all these cases would move to the 20 CJR hospitals and based on

[1] Available: https://downloads.cms.gov/files/cmmi/bpci-models2-4yr3evalrpt.pdf

their current case rate, we estimate the CJR hospitals would save $2.8 million. It appears that given their current performance, these PGPs would outperform the 20 CJR hospitals by a margin of approximately 2:1. These data show that in most of the cases the PGPs significantly outperform the hospitals.

Given the excellent performance of PGPs in BPCI, many orthopedic surgeons are questioning why CMS has found it necessary to structure BPCI Advanced in a way that severely limits a PGP physician's ability to manage all their Medicare patients' care for LEJR episodes. Consequently, all their valuable learning, collaboration, and work to coordinate care (pre-optimizing patients, redesigning care plans, working with post-acute care providers, etc.), which resulted in reduced costs to Medicare and improved outcomes for beneficiaries, will be for naught, as future LEJR episode patients will be managed by CJR hospitals in many markets. Even in markets in which CJR is no longer mandatory, hospitals conducting a significant number of LEJRs will likely opt into CJR to take advantage of their newly acquired precedence over PGP physicians.

Further, this policy of precedence disrupts the physician-patient relationship in the affected geographical areas, as the coordination of the Medicare beneficiary's LEJR care will now fall to the CJR hospital, regardless of the care the beneficiary's physician may have provided previously in BPCI. This is likely to leave beneficiaries that experienced BPCI previously confused as to why their current physician cannot manage their next LEJR.

For the reasons enumerated earlier, we believe CMS will see a significantly lower engagement of PGPs in BPCI Advanced. Hence, we strongly urge CMS to revise the current guideline such that the operating surgeon (PGP-based in BPCI Advanced or hospital-based in CJR or BPCI-Advanced) has precedence over the CJR episode leading hospital. This will be easy since the operating physician already has precedence over acute-care hospitals in BPCI Advanced. This revision will likely increase participation by physician practices along with hospitals in this model. The current BPCI participants should, at the least, be 'grandfathered' into BPCI Advanced rather than be forced to participate in CJR. With over 400,000 Medicare LEJRs performed annually, there are certainly a sufficient number of episodes that can be performed in both CJR and BPCI Advanced models, allowing further evaluation of the effectiveness and efficacy of hospital- and physician-led care models. Most importantly, revising this policy, as suggested, will ensure the continuation of the most important aspect of any care program, that is, maintaining the bond of trust and care that exists between the Medicare beneficiary and their physician.

Complexity of the initial application

The initial application document is 24 pages long and requires significant details on applicant organizations' experience with quality improvement, net payment reconciliation amount parameters, care improvement plan, risk sharing arrangements and beneficiary protections. That is, an extensive application is required before any data can be made available to potential participants. This will be difficult for smaller practices and those with limited data analytics capabilities. Also, this is a narrow timeline to draw up partner contracts and legal counsel review.

We understand that the timeline has been thought through by CMS to allow sufficient time for data availability and target/benchmark pricing calculation through the summer of 2018. However, it is still a significant burden for new applicants to prepare the application in time for the March 12, 2018 deadline. We have followed all the information and stakeholder engagements being conducted by the BPCI Advanced team but have not received adequate clarity on model details. Consequently, it is very difficult (if not impossible) for orthopaedic practices and their potential partners to make a business decision on applying for this model. It should be noted that many of these potential applicants are successful BPCI participants who have demonstrated considerable savings in the existing BPCI models and improved the quality of patient care. Our concern is that new applicants will find it especially difficult and ultimately may decide not to apply. As a result, this model will have lower than expected adoption and may not fulfill the promise of its innovation.

Implications of taking Total Knee Arthroplasty (TKA) out of the Medicare Inpatient-Only List

Although CMS had clearly delineated the requirements of this policy implementation in the 2018 Hospital Outpatient Prospective Payment- Notice of Final Rulemaking (NFRM) with Comment Period (CMS-1678-FC), there are several issues that are arising for participating stakeholders. This has created significant challenges for orthopaedic surgeons, their Medicare patients, and for us in providing adequate member education. The AAOS has also presented these issues on a teleconference on February 5, 2018, with the leadership and staff of the Hospital and Ambulatory Policy Group (HAPG) in the Center for Medicare at CMS. We have also had continuous staff-level communication among AAOS staff and CMS staff at the Center for Medicare and at the Innovation Center on these issues.

Defaulting all TKA procedures to outpatient status: While some hospitals understand the intent of the CMS Final Rule referenced above, a number of hospitals are apparently directing TKA patients to a site of service that is clearly in contradiction to CMS' stated positions as indicated in the agency's responses to the public comments accompanying the final rule. This misinterpretation is likely to impact the CJR, BPCI and BPCI Advanced models despite CMS' expectation that most TKA cases will not be performed in the outpatient setting.

Medicare Advantage plan guidelines: This issue of wrongly defaulting TKA cases to the outpatient setting is especially concerning for surgeons and patients in Medicare Advantage plans across the country. The AAOS has heard several anecdotes from surgeons across teaching hospitals, community hospitals, urban and rural hospitals that Medicare Advantage plans are requiring all TKA procedures to be done in the outpatient setting or otherwise denying claims.

Site of service decisions: The hospital or Medicare Advantage plan directing the site of service decision over the operating surgeon's discretion is also in contradiction to CMS' intent in the final rule. Specifically, CMS points to the beneficiary's physician as the medical professional responsible for determining the care setting in this rule.

Concentration of medically complex patients: Contrary to CMS' expectation, more and more TKA cases are being pushed to the outpatient setting, thereby creating a situation in which most medically complex, high comorbid patients will remain inpatient as they are deemed too high risk not to hospitalize. This change in patient mix has significant implications for BPCI, BPCI Advanced and CJR models.

The AAOS has been running an active member education program and communication on this issue. Based on our understanding of the situation and our discussion with CMS staff, we recommend the following:

1. CMS urgently directs Quality Improvement Organizations (QIOs) to expeditiously address these complaints to protect Medicare beneficiaries from unnecessary risk.

2. CMS formally advises all providers and hospitals that:
    - Removal of TKA from the IPO list does not require the procedure to be performed on an outpatient basis.

- Until the establishment of evidence-based patient selection criteria for inclusion and exclusion of appropriate candidates for an outpatient TKA procedure, the procedure should default to inpatient.
- The patient's operating surgeon, not hospital staff, is responsible for determining the medical necessity of a TKA patient's site of service.

3. Allow a CPT code to trigger a BPCI episode: As removal of TKA from the IPO list rule was not contemplated within the design or historic pricing of BPCI, inclusion of outpatient TKAs in BPCI seems reasonable adjustment considering this radical policy change and the fact that BPCI physicians maybe be financially penalized for making site of care decisions in the spirit of the new policy.

4. In lieu of #3 above, exclude BPCI TKAs from this new policy, e.g. all BPCI TKAs must stay inpatient, until clear and vetted evidenced-based patient selection criteria are established for qualifying Medicare beneficiaries as appropriate candidates for an outpatient TKA.

5. In lieu of #s 3 and 4 above, or other modifications that will limit physician financial risk because of significant changes in patient mix, release BPCI Model 2 PGP participants from all downside risk for lower extremity joint replacements.

6. In the absence of changes to the outpatient TKA policy and to ensure establishment of accurate pricing in BPCI Advanced, TKAs should be removed from baseline pricing in BPCI Advanced.

Lack of clarity and detail in model communication

Expanding on our comment above, CMS should provide timely details on how it will determine benchmark and target pricing. The model was announced on January 9, 2018 and the details on target pricing were not published until February 9, 2018. This is problematic given the tight application window which ends on March 12, 2018. The first 'open door forum' took place on January 30 and emails to the email id dedicated to BPCI Advanced went automatically acknowledged but not responded to. While we understand the complexity involved in launching such a national payment model, timely and easy to use information is highly needed.

It is encouraging to note that the Peer-Adjusted Trend (PAT) factor replaces the National Trend Factor (NTF) in the target price calculations. The AAOS had commented in the past on how the NTF consideration led to a 'race to the bottom' for successful participants in BPCI Classic. However, the current methodology is an overly complicated 20-step model with numerous calculation steps. We are still considering the target pricing methodology document that was published a few days earlier. As you are aware, the regression model specifications are likely to yield differing coefficients and have commensurate drawbacks. We cannot provide feedback on the methodology unless we see the details.

In the FAQs, CMS mentions that target prices will be rebased annually, although it is unclear when the first rebasing will occur. Progressively lower target prices may make it impossible for even efficient participants to continue in the model. We saw some withdrawal of well performing members from existing BPCI models because of a flawed pricing methodology.

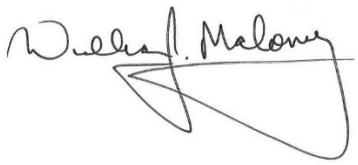
Moreover, semi-annual reconciliation may be an additional barrier for potential participants in the BPCI Advanced Model. We believe that a move from quarterly reconciliation in BPCI to semi-annual in BPCI-Advanced represents a step in the wrong direction and will make it more difficult for clinicians to respond to financial incentives. Also, once participants sign agreements with CMS in August 2018, they are effectively locked into the model until January 2020 when the next window for application opens.

Issues with BPCI as an Advanced APM

Finally, one of our major expectations from BPCI Advanced was that it will qualify as an Advanced APM. While this model fulfils this expectation from the launch date, i.e., October 1, 2018, the performance period begins on January 1, 2019. So just as in 2017, CJR Track 1 (Certified Electronic Health Record Technology/CEHRT Track) is the only Advanced APM for orthopaedic surgeons in 2018. Further, in 2019, Qualifying Participants (QP) in Advanced APMs will either have to receive 50% of their Part B payments or see 35% of their patients through an Advanced APM. It will be extremely difficult for specialists to reach these thresholds and this problem is exacerbated by the issues of BPCI Advanced model design that we have discussed above. We understand that this is a statutory threshold. However, we urge CMS to open up more initiatives such as the All-Payer Advanced APM model option for specialists such that these Advanced APMs are an option for participation in reality.

The CMS staff encouraged feedback and questions on this model. We hope that you will take note of our feedback and work on the revisions that will make the BPCI Advanced a more effective model. 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,



William J. Maloney, MD

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cc: David A. Halsey, MD, AAOS First Vice-President

Kristy L. Weber, MD, AAOS Second Vice-President

Thomas E. Arend, Jr., Esq., CAE, AAOS Chief Executive Officer

William O. Shaffer, MD, AAOS Medical Director

The following orthopaedic specialty and state orthopaedic societies have agreed to sign-on to our comments:

American Association of Hip and Knee Surgeons (AAHKS)

American Orthopaedic Foot and Ankle Society (AOFAS)

American Shoulder and Elbow Surgeons (ASES)

Arthroscopy Association of North America (AANA)

Cervical Spine Research Society (CSRS)

Musculoskeletal Infection Society (MSIS)

Orthopaedic Rehabilitation Association (ORA)

Orthopaedic Trauma Association (OTA)

Ruth Jackson Orthopaedic Society (RJOS)

Scoliosis Research Society (SRS)

Society of Military Orthopaedic Surgeons (SOMOS)

The Hip Society (HIP)

The Knee Society (KNEE)

Alabama Orthopaedic Society

Arkansas Orthopaedic Society

California Orthopaedic Association

Colorado Orthopedic society

Connecticut Orthopaedic Society

Delaware Society of Orthopaedic Surgeons

Eastern Orthopaedic Association

Georgia Orthopaedic Society

Illinois Association of Orthopaedic Surgeons

Iowa Orthopaedic Society

Kansas Orthopedic Sociery

Kentucky Orthopaedic Society

Louisiana Orthopaedic Association

Maryland Orthopaedic Association

Massachusetts Orthopaedic Association

Michigan Orthopaedic Society

Mid-America Orthopaedic Association

Minnesota Orthopaedic Society

Mississippi Orthopaedic Society

Missouri State Orthopaedic Association

Montana Orthopaedic Society

North Dakota Orthopaedic Society

Nevada Orthopaedic Society

New Hampshire Orthopaedic Society

New Mexico Orthopaedic Association

New York State Society of Orthopaedic Surgeons

Ohio Orthopaedic Society

Orthopaedic Society of Oklahoma

Pennsylvania Orthopaedic Society

Sociedad Puertorriqueña de Ortopedia y Traumatologia

Southern Orthopaedic Association

Tennessee Orthopaedic Society

Texas Orthopaedic Association

Utah State Orthopedic Society

Virginia Orthopaedic Society

Washington State Orthopaedic Association

Western Orthopaedic Association