



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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January 15, 2019

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7500 Security Boulevard
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Adam Boehler
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Re: Bundled Payment for Care Improvement (BPCI) Advanced; Addendum to our letters dated February 22, 2018 and July 5, 2018

Dear Administrator Verma and Director Boehler:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS) and other orthopaedic specialty societies who agreed to sign on to these comments, we would like to share updated comments on the Center for Medicare and Medicaid Innovation's (henceforth "Innovation Center" or "CMMI") Bundled Payment for Care Improvement (BPCI) Advanced (henceforth "BPCI Advanced") model. This is in addition to our letters previously sent on February 22, 2018 and July 5, 2018. 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. We also greatly appreciate that CMS and CMMI leadership and staff are always willing to respond to our questions and requests to present at meetings.

As you are aware, 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. However, we hope that CMMI will soon launch additional Advanced APMs with opportunities for specialists to participate adequately. Although BPCI Advanced allows opportunities for our surgeons and their patients to participate

in musculoskeletal care redesign, we have serious concerns with this model's design (some of which was discussed in previous dialogues).

BPCI Advanced Physician Reimbursement Cap

In BPCI Classic, CMMI instituted an Incentive Payment Cap for physician and non-physician practitioners at 50% of the Part B payments for these episodes. However, this cap did not extend to the physician group practice (PGP) that employed the practitioner. The PGP itself could receive Net Payment Reconciliation Amount (NPRA) savings above the aggregate cap and utilize these savings to offset direct and indirect costs related to participation in BPCI Classic as well as general overhead for the group. In BPCI Advanced CMMI elected to prohibit NPRA savings from flowing to a PGP working under a convening entity, so its physicians could only be reimbursed up to the 50% cap.

Issues:

- The financial methodology in BPCI Classic provided the proper financial incentive for the PGP to take risk and incur costs it otherwise would not have, while maintaining the integrity of proper incentives through the 50% cap for individual physicians.
- This current interpretation of the cap is a strong disincentive for PGPs to participate in at-risk APMs, such as BPCI Advanced, given substantial investments in staff, IT needed for analytics, and other important investments to successfully participate.
- All physician owners in a practice may not be direct participants in BPCI Advanced and thus are ineligible to receive any direct incentive. Yet, they would be responsible for sharing the group's overhead expenses and the risk associated with any losses for participating in the new initiative.
- Moreover, this NPRA sharing limitation does not apply to PGPs choosing to participate directly in BPCI Advanced who do not use a third-party convener. This effectively creates a dual standard for PGP participation and essentially penalizes PGPs (especially smaller PGPs), who choose to work with a convener in a new APM. Most PGPs work with a convening entity as they provide important services and resources to PGPs who otherwise have limited resources to engage in new, risk-bearing episodic care models.

Recommendations:

- *CMMI should reinstate the financial methodology used in BPCI Classic for BPCI Advanced and allow excess NPRA funds to flow to any PGP participating in BPCI Advanced to offset overhead and related costs for participating in the new model.*
- *In addition to the payment cap, gainsharing arrangements should not be limited. The concern that providers will be encouraged to overutilize services under these*

arrangements is largely neutralized in the Advanced APM risk-based reimbursement structure. Gainsharing arrangements that help to control the costs of care while not impairing care quality should be encouraged.

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 policy has created significant challenges for orthopaedic surgeons, their Medicare patients, and for AAOS in providing adequate member education. Since outpatient procedures are covered by Part B, the patient has a copay for each individual hospital service and faces additional rehabilitation and drug costs, which would have otherwise been covered under Part A. This policy change does not affect physician reimbursement – this is solely a patient care concern for our surgeons. Still, we are very concerned about cases getting excluded from the inpatient payment models because of this policy change.

Issues:

- **Widespread confusion among health systems:** To provide some data from the field, the American Association of Hip and Knee Surgeons (AAHKS) did a national survey on this issue and 60% of orthopaedic surgeon respondents reported that their hospitals were required to book all TKAs as outpatient procedures. Another example: one hospital system recently did an evaluation of the first 1,200 Medicare TKA's in 2018 and determined that only three qualified for inpatient status. AAOS and AAHKS also presented these issues to CMS and HHS leadership over the past several months. We appreciate the CMS Center for Clinical Standards and Quality reaching out to us with ideas for designing stakeholder education. However, we are yet to see the final details of that plan from the Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC-QIO). We would like to reiterate our concerns again with this policy change.
- **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 the outpatient setting, which contradicts CMS' rule making. This misinterpretation is likely to impact the Comprehensive Care for Joint Replacement (CJR) and BPCI Advanced models despite CMS' expectation that most TKA cases will not be performed in the outpatient setting.

- Medicare Advantage plan guidelines: The issue of incorrectly defaulting TKA cases to the outpatient setting is especially concerning for surgeons and patients in Medicare Advantage plans across the country. AAOS has heard several anecdotes from surgeons across teaching hospitals, community hospitals, and urban and rural hospitals that Medicare Advantage plans are requiring all TKA procedures to be done in the outpatient setting, or otherwise have their claims be denied.
- 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 Advanced and CJR models.
- Target pricing for outpatient TKAs: The patient population suitable for outpatient TKAs is not comparable to most patients experiencing MS-DRG 470 Clinical Episodes. We are separately sharing with you our recommendations on patient selection criteria for TKAs. Under 10% of patients experiencing an MS-DRG 470 Clinical Episode were discharged to the community without home health or institutional post-acute care services.¹ However, adequate historical data exists to price a clinically-similar episode triggered in the outpatient setting. Based on data from a major convener in the BPCI Classic and Advanced models, approximately one in four clinical episodes under MS-DRG 470 were one-day in length. Since there is no outpatient surgical data to calculate the Target Price, CMS should consider pricing the outpatient total knee arthroplasty Clinical Episode using the historical costs for the patients who:
 - received inpatient total knee arthroplasty;
 - experienced a one-day anchor stay; and
 - did not use institutional post-acute care.
 If CMS believes that the target price should be a fair approximation of the resources needed to care for the patient in an outpatient setting, the agency should substitute the total knee arthroplasty DRG payment for the ASC or HOPD payment.

¹ <http://www.aha.org/content/12/ahaaamcbundlingreport.pdf>

Recommendations:

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:

- *An immediate suspension of Medicare’s 2 Midnight Rule for TKA admission beyond 24 hours, until CMS promulgates guidance on inpatient-outpatient determinations for the procedure.*
- *CMS urgently directs Quality Improvement Organizations (QIOs) to expeditiously address these complaints to protect Medicare beneficiaries from unnecessary risk. In this regard please see attached the final position statement on outpatient TKA approved by AAHKS and AAOS. We had shared an earlier version of this statement with CCSQ staff.*
- *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 or Medicare Advantage plan staff, is responsible for determining the medical necessity of a TKA patient’s site of service.*
- *Allow a CPT code to trigger a BPCI Advanced outpatient episode: As removal of TKA from the IPO list rule was not contemplated within the design or pricing of BPCI Advanced, inclusion of outpatient TKAs in this model seems a reasonable adjustment considering that BPCI physicians may be financially penalized for making site of care decisions in the spirit of the new policy.*
- *Another alternative is to release BPCI Model 2 PGP participants from all downside risk for lower extremity joint replacements.*
- *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.*

In this regard, we would like to bring some additional issues to your notice.

- We are aware that CMS did suspend RAC audits for TKAs for two years. CMS did not, however, suspend other program integrity contractors like MACS and ZPICS. Thus, hospitals are wary of RACs reaching back after the two-year moratorium concludes.
- CMS provided preamble language describing their policy intention was not to shift many procedures to outpatient setting. However, this provides no comfort to compliance experts, since preamble language has not been enforceable in a court of law.
- Moreover, TKAs are the highest volume procedure to come off the IPO list. The Two-Midnight Rule provides for case-by-case exceptions for inpatient stays spanning fewer than two midnights, but the sheer volume of procedures and lack of guidance makes the exception unworkable.
- Patients are denied the resource-intensive interventions in the inpatient setting which are responsible for reducing average length of stay as well as outcomes. Since outpatient procedures are covered by Part B, the patient has a copay for each individual hospital service and faces additional rehabilitation or drug costs which would have otherwise been covered under Part A.

Exit option should be extended beyond March 2019

CMMI launched the BPCI Advanced program under tight deadlines from its announcement in January 2018, to an application deadline of March 12, 2018, and final contract on August 8, 2018. Recognizing the difficulties participants faced with this rapid process, including errors in data that had been supplied by CMS, the agency announced on July 6, 2018 that it will give participants until March 1, 2019 to submit an irrevocable exit option from the model. A participant can either stay in the program, but withdraw patient episodes that began before that date, or the participant can choose to exit the program entirely.

Issue:

This deadline does not allow participants to receive enough feedback on their performance in the program. As of the March 1, 2019 deadline, participants will not know whether they will receive gainsharing payments or will owe money to CMS. The only relatively complete claims data a participant will have at that point is from the first “performance period,” October-December 2018. The second performance period will be January-June, 2019.

Recommendation:

CMS should extend the exit deadline to Fall 2019, when participants will have enough claims data to predict whether they will be successful in the program. By then, current participants will have an analysis of the first two performance periods.

Precedence of CJR over BPCI Advanced

The CJR precedence requirement continues to be a major problem for PGPs that successfully led the Lower Extremity Joint Replacement (LEJR) episodes in BPCI Classic. We have discussed this earlier with you both through written comments and during face-to-face meetings with CMS leadership. 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, without any indication for policy change, we have reiterated (below) several reasons why this may not be a good decision for Medicare beneficiaries and for the success of this innovative payment model. We have also provided accompanying policy suggestions where applicable.

Issues:

- Limits specialty physicians' opportunities to participate in an Advanced APM. BPCI Advanced is the first model that qualifies as an Advanced APM from the launch date (CJR Track 1 qualified as an Advanced APM recently). Hence, this precedence requirement severely limits orthopaedic surgeons from participating in an Advanced APM. While surgeons will be able to participate in orthopaedic episodes outside of LEJR episodes, LEJR episodes are one of the most common inpatient surgeries for Medicare beneficiaries and a cornerstone procedure for orthopaedic participants in the BPCI initiative. We also have anecdotal evidence that hospital systems are buying orthopaedic physician groups in several markets so that they are well-positioned to lead the BPCI Advanced LEJR episodes. This will be a big challenge for precedence on trauma cases.
- Hampers quality of care for Medicare beneficiaries. This issue may arise in two ways in the current design of BPCI Advanced. *First*, by creating a precedence for hospitalists/attending physicians over the operating surgeon in the model, Medicare beneficiary's care decisions are re-directed to a physician whom the patient did not choose in the first place. *Second*, beginning October 1, 2018, since many former existing BPCI Classic PGPs are in CJR markets and must participate in CJR, 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 in vain, thereby weakening one of the key objectives of the Innovation Center's value-based payment models. For example, in Texas (one of the states which has several CJR mandatory MSAs), physicians will have limited leadership opportunities to produce meaningful change in the mandated CJR model. These physicians operate in many

different hospitals and health systems across their geographical area. They are specifically concerned that each hospital's individual CJR programs will create a fractured delivery system for their patients. Since the surgeons in the CJR program hold no downside risk, they are less engaged in making meaningful change occur for the Medicare program. Hence, the quality of care for Texas' Medicare patients who have greatly benefitted from BPCI Model 2's physician-led episodes will be adversely affected. By disrupting the physician-patient relationship, this policy is likely to leave beneficiaries that experienced BPCI previously confused as to why their current physician cannot manage their next LEJR procedure.

- Reduced or no cost savings for the Medicare program. As we have discussed with you earlier, independent physicians achieved significant cost reductions while improving outcomes in LEJR episodes in existing BPCI Model 2. The Lewin Group's August 2018 Performance Year 1 (2016) Evaluation Report of CJR found that average total payments for the 43,801 LEJRs (MS-DRG 469/470) managed by the CJR hospitals declined \$910 more (3.3%) from baseline to the intervention period compared to the hospital control group. Lewin also found no improvement in quality. Additionally, as noted in the Milliman White Paper², less than half of the 799 hospitals participating in CJR over the 2016 review period achieved positive reconciliation. Of the 382 that did succeed in reducing costs, they collectively averaged a reconciliation payment of \$1,133.99 per episode on 33,152 episodes. In contrast, for the 2016 performance year, the PGPs convened under the largest PGP awardee/convenor for orthopaedic episodes in BPCI Classic, Model 2, managed 39,600 LEJRs (MS-DRG 469/470) and the average CMS claims-based costs were reduced 17% or \$4,089 per episode compared to baseline. Adverse outcomes similarly declined across the spectrum of events, including reductions in acute myocardial infarction within seven days by 39%; pulmonary embolisms by 49%; surgical site infections by 38%, and 30-day and 90-day re-admissions by 24% and 25%, respectively. Further, over the three-year period 2014 to 2016, these 57 PGPs produced total net savings to Medicare of \$114 million after reconciliation payments to the groups and CMMI's 2% discount per episode. These savings are even more impressive given that only a handful of groups participated in 2014 and many had not entered the risk bearing phase until mid-2015.

In light of the strong performance of these PGPs in BPCI Classic compared to CJR hospitals it is difficult to understand a CMS policy that restricts many PGP physicians from managing their Medicare patients' LEJR episodes through the changes in BPCI Advanced precedence policy. Providing PGP physicians with a competitive standing with

² <http://www.milliman.com/uploadedFiles/insight/2018/comprehensive-care-joint-replacement-performance.pdf>

CJR hospitals for LEJRs will incentivize a greater number of PGPs to remain or enter BPCI Advanced in the next enrollment period and, as a result, a significantly greater number of Medicare joint replacements will fall under a value-based care umbrella. As the financial and quality results above indicate, with more widespread engagement among PGPs, the Medicare trust fund will receive the greatest return and a higher proportion of Medicare beneficiaries will experience improved care outcomes. Also, with extensive engagement among all providers, there is a much higher likelihood that healthcare delivery transformation will be sustained over the long-run.

- Wastage of valuable learning on care coordination and improvement. As you can understand, these phenomenal monetary savings were generated by in-depth investment in care improvement. For example, a Texas orthopaedic physician group hired patient coordinators to compile every aspect of a patient's LEJR episode of care, including pre-surgical preparation and post-surgical rehabilitation. The orthopaedic surgeons at this group even built their own skilled nursing facility to ensure that the LEJR patients who needed a higher level of post-acute care beyond home health care were provided care in a setting that could be managed by the surgeon who performed the surgery. Another physician group and their convener in Austin, Texas, implemented nurse navigation systems, preoperative education classes at the practice, preoperative rehabilitation and safety assessment, hospitalist preoperative optimization, and coordinated home health and skilled nursing facility networks with assisted living facility options. They have seen extraordinary results from baseline numbers with over a 50% reduction in emergency department visits, 32% reduction in readmissions for elective surgeries, and over a \$21.2M reduction in costs over the first eight quarters of the BPCI program.
- Feedback from stakeholders. Notice-and-comment rulemaking should be used to establish the precedence policy to allow public input, including from physicians and hospitals that have participated in BPCI Classic. CMS established the BPCI/CJR precedence policy through notice-and-comment rulemaking, but now has used guidance to reverse that policy by giving LEJR episode precedence to CJR hospitals over BPCI Advanced participants. There is an argument that this is inconsistent with the Administrative Procedural Act (APA), as interpreted by the Supreme Court. The starting point for this discussion is a CMS final rule that was promulgated last December (82 Fed. Reg. 57066; December 1, 2017). This final rule made various changes to the CJR regulations.
 - At 82 Fed. Reg. 57104, CMS restated/rewrote the CJR/BPCI precedence rule in 42 CFR 510.210:

- Section 510.210 is amended by revising paragraph (b) to read as follows:
- **§510.210 Determination of the episode.**
- (b) *Cancellation of an episode.* The episode is canceled and is not included in the determination of NPRA as specified in §510.305 if any of the following occur:
 - The beneficiary does any of the following during the episode:
 - Ceases to meet any criterion listed in §510.205.
 - Is readmitted to any participant hospital for another anchor hospitalization.
 - Initiates an LEJR episode under BPCI.
 - Dies.
- For performance year 3, the participant hospital did not submit a participation election letter that was accepted by CMS to continue participation in the model.

CMS first established its CJR/BPCI precedence policy through notice-and-comment rulemaking and has also modified that policy through rulemaking. Therefore, the agency should also establish the precedence rules for BPCI Advanced using notice-and-comment rulemaking. It should not use guidance, particularly when the relationship between that guidance and the current precedence regulation is unclear. The regulation quoted above does not distinguish between BPCI Classic and BPCI Advanced.

Recommendations:

- *Allow operating physicians to lead these episodes (thereby recreating the success of BPCI Classic Model 2) and not make precedence dependent on the model. As you know, BPCI Classic followed time-based precedence for attribution of clinical episodes.*
- *Allow notice-and-comment rule-making with comments so that surgeons and the PGP practices that have been adversely impacted by the CJR precedence policy have an opportunity to weigh in.*

Model evaluation

The Innovation Center has yet to publish a peer-reviewed evaluation of the PGP-led BPCI bundles. Mentioned earlier in this letter, we have quoted findings from PGP-led BPCI episodes and stacked them against the potential performance of CJR hospitals for the same episodes. Until the October 2018 Evaluation of BPCI Classic, The Lewin Group only reported on hospital-led bundles. The October 2018 report has severe limitations on the evaluation of PGP performance, however, including a methodology that does not capture cost savings in comparison to historic baseline. They also excluded nearly 40% of the PGPs participating in

Model 2. As you are aware, one of the requirements for the Innovation Center under Section 1115A of the Social Security Act is evaluating each model to analyze its effects on spending and quality of care and making these evaluations public. The March 2018 Government Accountability Office (GAO) report³ found that the Innovation Center has only partially met the goals of reducing the growth of health care costs and accelerating the spread of successful models.

Recommendations:

- *Publish peer-reviewed evaluation reports of PGP-led BPCI Classic episodes.*
- *Create a level-playing field for PGPs to lead health care improvements in the CMMI programs. Truly expand the BPCI Classic Model 2 through BPCI Advanced, since the former has been found to be highly successful in meeting the triple aim of reducing per-capita health care costs, improving quality of care, and improving population health.*

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 fulfills 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 either must 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.

Recommendations:

- *Work with Congress to reduce these thresholds and make them achievable for specialists. Write regulations with alternative pathways for specialists to become QPs or rather be deemed QPs and achieve the performance bonus.*
- *Provide additional exceptions from Merit-based Incentive Payment System (MIPS) reporting for eligible clinicians who already participate in an Advanced APM-like model. We applaud the All-Payer Advanced APM model and the newly announced exceptions in the Medicare Advantage program.*

³ Available: <https://www.gao.gov/assets/700/690875.pdf>

Advanced APM Physician Patient Advisory Committee

Recommendation:

As more care models are designed around a value-based concept, financial reimbursement becomes contingent upon financial and quality outcomes. The two stakeholders most central in this transition to value-based care are the physician and the patient, yet these CMMI models appear to be lacking significant input from these two constituencies, especially in the development stages. The current philosophy appears to be to develop models internally within CMMI, run the experiment, assess success or lack thereof, and fine-tune or abandon the model. This operating process can produce useful insights into which models have the greatest efficacy yet can also lead to an inefficient allocation of resources within medical practices due to poorly conceived model design at the outset. We believe the chances of model success can be much greater with input from patient and physician organizations and directly from physicians working within such models currently, such as in ACOs, BPCI Advanced and CJR.

We hope that you will take note of our feedback and work on the revisions that will make BPCI Advanced a more effective model. We also strongly urge you to launch additional Advanced APMs that allow participation by specialists. 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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American Society for Surgery of the Hand (ASSH)
American Spinal Injury Association (ASIA)
Arthroscopy Association of North America (AANA)
Cervical Spine Research Society (CSRS)
Limb Lengthening and Reconstruction Society (LLRS)
Orthopaedic Rehabilitation Association (ORA)
Orthopaedic Trauma Association (OTA)
Ruth Jackson Orthopaedic Society (RJOS)
Scoliosis Research Society (SRS)
The Hip Society (HIP)
The Knee Society (KNEE)

Alabama Orthopaedic Society
Arkansas Orthopaedic Society
California Orthopaedic Association
Connecticut Orthopaedic Society
Delaware Society of Orthopaedic Surgeons
Eastern Orthopaedic Association
Florida Orthopaedic Society
Iowa Orthopaedic Society
Indiana Orthopaedic Society
Maine Society of Orthopaedic Surgeons
Massachusetts Orthopaedic Association
Michigan Orthopaedic Society
New Jersey Orthopaedic Society
New York State Society of Orthopaedic Surgeons
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