



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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June 12, 2017

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1677-P
P.O. Box 8011
Baltimore, MD 21244-1850

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

**Subject: (CMS-1677-P)
Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care
Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed
Policy Changes and Fiscal Year 2018 Rates**

Dear Administrator Verma:

On behalf of over 18,000 board-certified orthopaedic surgeons represented by the American Association of Orthopaedic Surgeons (AAOS), we are pleased to provide comments on the Centers for Medicare and Medicaid Services (CMS) Inpatient Prospective Payments System Proposed Rule (CMS-1677-P) published in the Federal Register on April 28, 2017.

We commend CMS on its efforts to improve care quality and access. The Proposed Rule touches on several issues which directly affect our membership and we sincerely hope that you will take our comments into consideration when making any changes in policy.

Total Ankle Arthroplasty

We appreciate the proposed movement of Total Ankle Arthroplasty (TAA) from MS-DRG 470 to MS-DRG 469. As the Medicare claims data demonstrated, there is substantial cost difference between TAA and other lower extremity joint replacements. However, we believe that further examination of Total Ankle Arthroplasty with Major Complication (MS-DRG 469) and revision TAA is merited. CMS determined that the average cost of TAA in MS-DRG 470 was \$1689 higher than all cases in the group, yet, there was concern that the cost difference was insignificant. Due to the limited number (n=31) of TAA cases assigned to MS-DRG 469, CMS stated that a small number of expensive cases could artificially elevate the average cost. We would assert that the opposite is equally possible. A small number of lower cost procedures could underestimate average costs. The inherent difficulty and elevated complication rate associated with revision surgery supports the latter explanation. Consistent under-

reimbursement may render these procedures financially non-viable. Hospitals may be forced to restrict TAA to low risk patients, with fewer co-morbidities. This limitation of patient access to a proven treatment option for ankle arthritis, which decreases pain and increases functional activity, works against the Triple Aim.

Accounting for Social Risk Factors and Risk Stratification

We commend CMS for addressing the complicated issue of social risk factors within each of its quality programs. Social factors are well-studied determinants of health and are fundamental to understanding and measuring quality. In addition to the standard socio-economic covariates, such as education, marital status, and employment status, there are functional issues that affect outcomes, particularly with respect to orthopaedic conditions. Patients lacking family assistance or those having to navigate stairs at home tend to require more services, including longer length of stay, inpatient rehabilitation, or home care services. Additionally, distance and transportation to the site of care has a direct effect on outcomes and functional improvement. Consider the patient who does not have a means of transportation to a physical therapy facility after knee replacement surgery. Without extended home physical therapy services, this patient might develop significant post-operative scarring, a painful and restrictive condition, often requiring additional corrective surgery. It is clear that social needs are powerful drivers of care provision. Accounting for these factors can illuminate the cause and legitimacy of cost variation. Programs should be designed to enable teams of providers to redesign care in ways that reduce or eliminate avoidable spending, while ensuring that patients with greater needs have access to increased levels of care.

Risk stratification and adjustment are equally significant components of valid quality assessment. Outcome measures are only reliable in a relative sense, as a means to compare baseline and post-care status. Comorbidities, functional impediments, and cognitive limitations must be accounted for when assessing quality and costs. Importantly, the effects of multiple co-morbidities and social factors are often synergistic. Providers should not be financially penalized when caring for patients with greater needs. This could potentially discourage providers from performing certain procedures or lead to restriction of warranted care.

Physician-Owned Hospitals

Physician-Owned Hospitals (POH) have been shown to provide higher quality care at lower cost compared with those run by non-physicians or appointed boards. A higher percentage of POHs have received the top 5-Star Rating by CMS than non-POH hospitals, which have considerably higher risk of complications. Having physician-controlled operations, these hospitals are more agile. They are able to shift focus and address frontline issues without the administrative red-tape that cripples larger hospital systems. They contribute to local economies and meet a growing demand for health care services, especially in rural areas. Concerns that POHs could have an incentive to serve only the most profitable patients have been proven baseless. A comprehensive peer-reviewed study published by the British Medical Journal found that, overall,

“physician-owned hospitals have virtually identical proportions of Medicaid patients and racial minorities and perform very similar to other hospitals in terms of quality of care.”

The Stark Law, which has not been updated statutorily for more than two decades, limits the full potential of POHs as innovative health care delivery models. Its implementation has not realized the goal of decreasing medical costs. Rather, it has resulted in large hospital systems that disincentivize competition. These hospital systems are absorbing surrounding medical practices, becoming de facto monopolies. The presence of physician-owned hospitals serves to incentivize traditional hospitals to improve, innovate, and control costs. Additionally, as rural hospital failures accelerate, physicians (or physician-led groups) should be allowed to purchase them outright or partner in a joint venture with the current management structure. This is just another way to preserve access to rural medical care while driving down costs and increasing quality care.

We encourage the Secretary to explore all regulatory avenues to lift the arbitrary ban on new and expanding POHs. The Secretary has broad authority in creating a new demonstration project through the Center for Medicare and Medicaid Innovation for POHs which would include a waiver or exemption that would allow POHs to expand if they are accepted into the program. We also encourage the Secretary to explore a defined process for states to waive the Affordable Care Act’s provisions on POHs through state and regional waivers. Based on legal analysis of the relevant statutes, regulations, and guidance regarding state section 1115 waivers and the POH restrictions, the secretary has broad authority to modify section 1877 and lift the POH moratorium.

While the Stark Law is structured to control the volume of referred services, it is a liability statute that leads to heavy penalties for unintentional and technical errors by physicians and their staff. Liability statutes, such as the Stark Law, do not encourage physicians to participate in coordinated care models. The Bundled Payment for Care Improvement (BPCI) Initiative and the Comprehensive Joint Replacement (CJR) models reveal weaknesses in current law. The costs of compliance and disclosures required 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. As AAOS and several of our partners have noted earlier in our comments to CMS and the US Congress, we would like to reemphasize the importance of protecting the In-Office Ancillary Services Exception (IOASE) and the need to lift the ban on expansion and new construction of POHs.

“Communication About Pain” in HCAHPS

Orthopaedic surgeons are intimately aware of the difficulties of providing pain relief amidst the opioid crisis. Many orthopaedic conditions require narcotic pain management for weeks or

months, particularly those involving trauma or aggressive post-surgical physical therapy. We continue to utilize multimodal pathways for pain control, thus decreasing the need for oral pain medication.

We believe that payment incentives for higher scores on the Pain Management dimension of the HCAHPS survey may have created the unintended consequence of overprescribing opiates in the inpatient setting. This scoring system of “Pain as a Fifth Vital Sign” has also created a culture of opioid expectation among patients which has made discontinuation of narcotics challenging.

We appreciate the proposed change in the Pain Management category of HCAHPS, but maintain that it is unreasonable to expect physicians to solve the opioid crisis during an acute pain episode. It is important to distinguish between chronic and acute pain when regulating narcotic use. For example, states are restricting narcotics (i.e., the 7-day rule, required E-prescribing) and have mandated DEA logging for each narcotic prescription. These stop-gap regulations place extraordinary burden on patients and physicians treating acute pain in the post-operative period, when narcotics are necessary and warranted. Pain medication dosing is often increased as patients become more active in the days following hospital discharge. This leads patients to prematurely complete the 7-day supply. As can be expected, it is not uncommon for patients to suffer weekends without pain medication in the days following surgery when physicians lack access to the EMR.

Health Care System Flexibilities and Efficiencies

The AAOS commends the Administration’s efforts for initiating various payment, quality and delivery models under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). We appreciate your aim to reduce the administrative burden on clinicians and to introduce greater flexibility in reporting requirements and eligibility rules. However, there have been challenges for providers in meeting the requirements of the Physician Quality Reporting System (PQRS) and Meaningful Use (MU). We appreciate that the 2016 PQRS reporting requirements are reduced from eight to six measures. This is consistent with the Merit-based Incentive Payment System (MIPS) and will enable more physicians to succeed. In addition, we urge CMS to substantially expand the hardship exemption criteria for 2016 MU to include older physicians, low volume physicians (similar to MIPS), hospital based physicians, rural practices and small practices. Additionally, we request for 2018 to be treated as a transition year under MIPS, with no penalties for failing to report.

Further and more pertinent to the IPPS, the AAOS strongly supports voluntary bundled and episode-of-care payment models. The Comprehensive Care for Joint Replacement (CJR) and the soon-to-launch Surgical Hip Femur Fracture Treatment (SHFFT) models’ mandatory participation requirement for all surgical episodes triggered by MS-DRGs 469-470 and MS-DRGs 480-482 respectively in each of the 67 randomly selected Metropolitan Statistical Area (MSA) is flawed and should be replaced by a voluntary payment model for providers and

facilities. Many hospital systems use this program as a lever to coerce physicians to sell their practices, further limiting competition and patient choice. In effect, any provider practicing in these designated MSAs is mandated to participate in these programs. This will force many surgeons and facilities who lack familiarity, experience, or proper infrastructure to support care redesign efforts into these bundled payment models and will be at a disadvantage. A voluntary program 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. BPCI results clearly show physician-run bundles are more successful.

Thus, we strongly urge CMS to revise the mandatory nature of the proposals and instead create incentives for interested participants to participate voluntarily. Specifically, we recommend that CMS require that any participating entity have verifiable interoperability, infrastructure, and agreements between all necessary entities. We strongly urge the Administration to remove the requirement for providers to upgrade to 2015 Edition Certified EHR Technology (CEHRT), as most EHR developers have not yet met the 2015 CEHRT requirements. Only 54 of the more than 3,700 EHR products are currently certified and posted on the Certified Health IT Product List (CHPL). Any penalties envisioned should be directed to the EHR vendors, rather than the physician.

The AAOS is concerned about the requirement that all providers use G-codes for all post-operative patient encounters. In addition to being unnecessarily burdensome, this will most likely result in inaccurate data. While reviewing the requirements for reporting post-operative visits (99024), the American Academy of Orthopaedic Surgeons (AAOS) has uncovered many errors in the long descriptors on the code list published on the CMS website. We identified a 26% error rate in the long descriptors for just the musculoskeletal codes (20000 series). For example, the long descriptor listed for code 29822 is arthroscopy, shoulder, surgical; capsulorrhaphy. This descriptor is incorrect and should read arthroscopy, shoulder, surgical; debridement, limited. These errors are not insignificant and are causing tremendous confusion for providers in an already demanding reporting environment. AAOS believes these errors will cause the data collected to be incorrect and requests that the mandatory reporting period scheduled to begin on July 1, 2017, be postponed until the corrections can be made and provider education efforts reinstated with the corrected information.

The 21st Century Cures Act includes provisions meant to address the issues of data blocking and interoperability, which continue to interfere with efforts for quality improvement and participation in CMS quality programs. Again, data blocking is a system and vendor issue over which physicians have no control. We hope the Inspector General and Secretary Price will act on the authority provided by the 21st Century Cures Act to investigate claims of data blocking by EHR vendors and enforce compliance.

Furthermore, our recommendation to explicitly place a surgeon as head, or co-head, of episodes would significantly reduce barriers to achieving high quality patient outcomes. It is the orthopaedic surgeon who is involved in the patient's care throughout the episode-of-care, from the pre-operative workup, to the surgery itself, to inpatient post-operative care, to the post-operative care provided in rehabilitation facilities, at home, and in the physician's office. Therefore, it is logical that all episodes treated under the musculoskeletal condition/procedure-based bundles be overseen by orthopaedic surgeons and not an acute care hospital facility. Having the hospital in charge of the bundle provides 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.

The AAOS recommends that CMS eliminate all limits on gainsharing among providers to give providers flexibility to allocate the CMS payment among the members of program teams in ways that maximize incentives for each specific team to improve quality, as opposed to a one-size-fits-all model.

The AAOS urges the Administration to remove the burdensome requirements in the Affordable Care Act (ACA) for insurers and the healthcare industry to provide translation and interpreting services for limited English proficiency (LEP) individuals. In certain settings, such as rural areas, it is difficult to procure translation and interpreting services.

The AAOS opposes the Independent Payment Advisory Board (IPAB) and supports repeal of this entity. IPAB's mandate to contain Medicare costs will likely subject physicians to unfair cuts in reimbursement. IPAB is severely constrained in what it can recommend to slow the pace of Medicare spending growth. IPAB recommendations cannot increase beneficiary premiums or cost-sharing, cannot reduce benefits in any way, and cannot increase taxes. The only options available are adjustments to what Medicare pays for various medical services. Since hospitals are exempt from cuts until 2020, the burden of payment reductions will fall heavily on physicians.

Lastly, we support efforts that produce greater transparency and consumer education. However, we strongly oppose the publication of quality improvement surveys and plans of correction by accrediting organizations (AO) in current form. Quality Assurance (QA) committees and documentation have been held as non-discoverable in medico-legal actions by most states (Kentucky being an exception). To make the list of discrepancies public would essentially negate this protection. Without a proper determination of which elements should be made public, and sufficient time for AOs to standardize their reports for reasonable comparison, there is substantial risk of contextual misinterpretation. AOs must prepare the information in a way that limits unintended consequences when published. It is imperative to ensure that the accredited entities do not minimize safety concerns for fear of public reprisal or extricate

themselves from the accreditation process, altogether. This proposal of publication goes against quality assurance activities across health systems.

In conclusion, the AAOS appreciates CMS taking the opportunity provided by the Proposed Rule to ask for stakeholder comments on reducing burdens on providers, introducing flexibilities, improving competition via POHs, and improving the health care system for Medicare beneficiaries. Please do not hesitate to contact the AAOS Medical Director, William O. Shaffer, MD, at shaffer@aaos.org if you have any further questions or comments.

Sincerely,

A handwritten signature in black ink that reads "William J. Maloney". The signature is written in a cursive style with a large, sweeping loop at the end.

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

This letter has received sign-on from the following 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 Shoulder and Elbow Surgeons (ASES)
Arthroscopy Association of North America (AANA)
Cervical Spine Research Society (CSRS)
Musculoskeletal Tumor Society (MSTS)
Ruth Jackson Orthopaedic Society (RJOS)
Scoliosis Research Society (SRS)
Society of Military Orthopaedic Surgeons (SOMOS)
The Hip Society (HIP)
The Knee Society (KNEE)

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