

October 1, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
P.O. Box 8013
Baltimore, MD 21244-1850

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

**Subject: (CMS-1736-P)
Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals**

Dear Administrator Verma:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS) and the orthopaedic specialty societies that agreed to sign on, we are pleased to provide comments on the Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals Proposed Rule (CMS-1736-P) published in the Federal Register on August 4, 2020.

The AAOS appreciates the ongoing efforts of the Centers for Medicare and Medicaid Services (CMS) to reduce regulatory burden and facilitate maximum flexibility for physicians and patients during the COVID-19 public health emergency. We request the continued support of the Department of Health and Human Services (HHS) as physicians navigate the ongoing pandemic and the subsequent needs for personal protective equipment, financial support, and access to testing and therapeutics.

Proposed Elimination of the Inpatient Only List

The AAOS is gravely concerned that CMS proposes to eliminate the Medicare Inpatient Only (IPO) List starting with all 266 musculoskeletal procedures effective January 1, 2021. This is a complicated clinical and policy decision, and we urge the agency to consider the associated risks to Medicare beneficiaries before finalizing this drastic proposal.

As we have stated in previous comments, AAOS supports the removal of certain procedures from the IPO for which there is evidence that they can safely be performed in the outpatient setting, such as total shoulder arthroplasty and total ankle arthroplasty.¹ We agree with the agency that with developments in the practice of medicine, these procedures can safely be done in the outpatient setting. The AAOS believes that determining the appropriate setting of care should be done through the lens of patient safety and peer-reviewed evidence, and that physicians are best qualified for leading this individualized decision-making process with their patients.

Yet, we are mainly concerned by the removal of certain procedures that do not have data to support the appropriateness of their performance in the outpatient setting. Finalizing this policy as proposed will mean that complicated procedures from major trauma, such as pelvic, acetabulum, hip and fragility fractures and amputation that are mostly done with heavy inpatient monitoring, will be paid in the outpatient setting. AAOS experts believe that even with advances in medical practice, such procedures cannot be safely done in the outpatient setting currently. Hence, **AAOS asks that CMS set general criteria for procedure selection based upon peer-reviewed evidence, patient factors including age, co-morbidities, social support, and other factors relevant to positive patient outcomes. Also, we ask that CMS provide objective data on the safety of such complicated procedures that are never performed in the outpatient setting prior to allowing their removal from the IPO list.**

Specifically, we support the following social factors to consider when determining the best setting for musculoskeletal procedures: “lives alone,” “pain,” “prior hospitalization,” “depression,” “functional status,” “high risk medications,” and “health literacy.”² In some cases, a patient may be clinically stable but lack the resources to care for themselves once they go home. This can lead to an increased risk for adverse events or accidents that end in hospital readmission. We ask that CMS consider these criteria and social determinants when forming guardrails around the performance of procedures in the outpatient setting.

¹ Refer to:

1. “Neer Award 2016: Outpatient total shoulder arthroplasty in an ambulatory surgery center is a safe alternative to inpatient total shoulder arthroplasty in a hospital: a matched cohort study,” *Journal of Shoulder and Elbow Surgery*, T. J. Brolin, R. P. Mulligan, F. M. Azar, & T. W. Throckmorton, 26(2), 204-208 (2017).
2. “Ambulatory total shoulder arthroplasty: a comprehensive analysis of current trends, complications, readmissions, and costs,” *The Journal of Bone and Joint Surgery*, J. M. Cancienne, S.F. Brockmeier, L.V. Gulotta, D.M. Dines, & B.C. Werner, 99(8), 629-637 (2017).
3. “Outpatient total shoulder arthroplasty: a population-based study comparing adverse event and readmission rates to inpatient total shoulder arthroplasty,” *Journal of Shoulder and Elbow Surgery*, T.S. Leroux, B.A. Basques, R.M. Frank, J.W. Griffin, G.P. Nicholson, B.J. Cole, ... & Verma, N. N. 25(11), 1780-1786 (2016).

² Ohta, B, Mola, A, Rosenfeld, P and Ford, S 2016 Early Discharge Planning and Improved Care Transitions: Pre-Admission Assessment for Readmission Risk in an Elective Orthopedic and Cardiovascular Surgical Population. *International Journal of Integrated Care*, 16(2): 10, pp. 1–10, DOI: <http://dx.doi.org/10.5334/ijic.2260>

We are also concerned by the unintended consequences that the inevitable mass shift of procedures to the outpatient setting will have on patient access to care. One of these is the out-of-pocket costs to patients in traditional Medicare. As CMS states on their website, “the copayment for a single outpatient hospital service can’t be more than the inpatient hospital deductible.” However, a patient’s total copayment for the cumulative cost of all outpatient services may be equal to an amount greater than the inpatient hospital deductible.³

In addition to considering the impact of out-of-pocket costs, it is also critical to consider the negative impact on physical access to treatment that will result from removing musculoskeletal procedures from the IPO. In the experience of our members, the “option” for the outpatient setting becomes the justification for making it the default location. This issue is particularly salient for those patients living in rural areas where the proximity to hospital outpatient departments (HOPD) and ambulatory surgical centers (ASC) is limited. According to research presented in the March 2019 MedPAC Report to Congress, 92.9% of ASCs open in the year 2016 were for-profit institutions located in urban areas. Of the new ASCs opened in 2016, 94.4% were in urban areas.⁴ For those patients who are treated in ASCs, data from the same report reveals that they are by and large a less medically complex population. For example, using the CMS-hierarchical condition category (CMS-HCC) to risk adjust, the average risk score for ASC patients across all procedures in 2014 was 1.13. In contrast, the average risk score for patients in the HOPD setting was 1.57. These risk scores account for age, sex, patient diagnoses from the previous year, dual Medicaid/Medicare eligibility status, and whether they are 65 or older, but were initially Medicare-eligible as a result of a disability.⁵ AAOS advises CMS to account for these differences in population health at different sites of care by risk adjusting the reimbursement, due to risk stratification by physicians, to the most appropriate setting. This should be done with the understanding that free standing HOPD and ASC settings are equivalent.

Medicare’s Two Midnight Rule

AAOS is also concerned that the Two Midnight Rule will remain in effect as IPO changes are implemented. In light of the ongoing confusion surrounding the Two Midnight Rule and the subsequent decisions by hospitals and private payers to require that some procedures, including total knee arthroplasty and total hip arthroplasty, default to the outpatient setting, **AAOS urges CMS to reconsider the pace at which procedures are removed from the IPO.** Instead of eliminating all 266 musculoskeletal procedures from the IPO effective January 1, 2021 we suggest that the procedures be gradually removed over the next several years (beginning with the procedures that can be safely done in the outpatient setting) to allow time for hospitals, physicians, and private payers to understand the regulations and release appropriate guidance.

³ Inpatient or outpatient hospital status affects your costs. Medicare.gov. Available at: <https://www.medicare.gov/what-medicare-covers/what-part-a-covers/inpatient-or-outpatient-hospital-status>

⁴ MedPAC Report to the Congress. March 2019. Available at: http://www.medpac.gov/docs/defaultsource/reports/mar18_medpac_ch5_sec.pdf?sfvrsn=0

⁵ MedPAC Report to the Congress. March 2019. Available at: http://www.medpac.gov/docs/defaultsource/reports/mar18_medpac_ch5_sec.pdf?sfvrsn=0

Further, CMS should also consider waiving the Two Midnight Rule for procedures that are removed from the IPO list.

Related to this, AAOS appreciates the acknowledgement of physician decision making as the primary factor in determining site of service. However, given the ongoing nature of widespread payment denials for inpatient stays that span less than two midnights, we would like to present several illustrative case studies to inform further guidance issued from CMS to payers on the subject. Please see Appendix A for the complete case studies.

As discussed in prior meetings with CMS, AAOS suspects that some hospitals are switching to default outpatient status, regardless of the patient's clinical status, in the interest of administrative simplicity. This can lead to patients being forced into discharge when they may be clinically stable, but physically unable to care for themselves. This in turn significantly increases the risk of an adverse event or accident that will lead to a readmission.

The American Association of Hip and Knee Surgeons (AAHKS) released a position statement on Outpatient Joint Replacement⁶ stating that social support and environmental factors (family or professional outpatient support) must be considered to determine if the outpatient setting is indeed the safest and most appropriate setting for a patient. As AAHKS recommends to their members, a *“full discussion with the patient and family as to the risks and potential benefits of same-day discharge after hip and knee replacements be carried out.”* We believe that in the absence of socio-demographic considerations, patients, surgeons and hospitals in underserved communities will bear a disproportionate burden and unintended consequence of the elimination of the IPO.

AAOS requests that CMS consider the significant physician burden caused by the Two Midnight rule and reevaluate the meaningfulness of it considering this unprecedented shift toward site-neutrality.

In summary, AAOS recommends the following for your consideration

- In updating the IPO list, CMS should begin with musculoskeletal procedures that can already be done safely in the outpatient setting (such as total shoulder arthroplasty and total ankle arthroplasty)
- CMS should not eliminate the IPO list for complicated procedures such as amputations, major trauma and fragility fractures until the agency shares objective data on allowing these procedures in the outpatient settings
- CMS should develop general criteria to determine which procedures can be removed from the IPO list

⁶ Endorsed by The American Academy of Orthopaedic Surgeons, The Hip Society and The Knee Society: Position of the American Association of Hip and Knee Surgeons. Outpatient Joint Replacement. Available: <http://www.aahks.org/position-statements/outpatient-joint-replacement/>

- Medicare Part A's Two Midnight Rule is confusing to interpret and must be waived as CMS updates the IPO list

Proposed Changes to the Ambulatory Surgical Center Covered Procedures List

Considering the proposed changes to the IPO, AAOS supports the CMS proposal to add total hip arthroplasty (CPT code 27130) to the Ambulatory Surgical Center Covered Procedure List (ASC CPL). As we stated in our comments last year and have reiterated in this letter, it is imperative that only those patients who are strong candidates for the procedure have the option of undergoing the surgery in the outpatient settings including at ASCs. Toward that end, we encourage CMS to consider the previously discussed criteria for patient selection and the primacy of the physician-patient relationship in medical decision making.

Moreover, should there be an influx of procedures added to the ASC CPL as a result of the elimination of the IPO, we request that CMS update the OPSS Ambulatory Payment Classification (APC) Policies to reflect these additions. Currently, musculoskeletal procedures are categorized into six APCs (5111-5116). AAOS believes that the addition of more complex procedures, such as total hip arthroplasty, warrant assignment to a higher APC level. **A seventh musculoskeletal APC level would account for the greater level of preparation requisite to the successful performance of these procedures in the outpatient setting, such as discharge planning, care coordination, and durable medical equipment.**

Regarding the proposal to update the process for adding procedures to the ASC CPL, AAOS supports alternative proposal number one for a nomination process. As opposed to alternative proposal number two, in which CMS would revise the criteria for the procedure selection in the ASC, the first option would ensure that appropriate stakeholders and subject matter experts—namely, physicians—are the leaders in the process. **As physicians and the societies that represent them are the specialists on these procedures, AAOS requests that CMS follow through with the first proposal to add procedures to the ASC CPL based on stakeholder nomination.** In addition, we support the CMS proposal to keep some general criteria from the current process in place. We believe that the questions posed by CMS are generally acceptable principles for consideration during the review process. Similar to the suggestions for procedures removed from the IPO, we advise assessing the safety of both the procedure itself and the complexity of the patients generally undergoing the procedure.

Prior Authorization

AAOS has serious concerns with the increased use of prior authorization in the Outpatient Prospective Payment System. These concerns were previously raised in our comments on the 2020 OPSS proposed rule, and remain at present given that this year's proposed rule would expand prior authorization requirements to CPT codes 22551, and 22552 associated with Code (i) Cervical Fusion with Disc Removal, and CPT codes 63650, 63685, and 63688 associated with Code (ii) Implanted Spinal Neurostimulators. While AAOS understands that CMS seeks to reduce utilization of certain procedures, we are concerned that the continued use of these approaches will supersede physician autonomy, increase administrative burden, and negatively impact patient care.

1. Superseding Physician Autonomy

AAOS is concerned that requiring approval from a third-party removed from clinical decision-making erodes the doctor-patient relationship, and the ability to make decisions that are in the best interest of the patient. Clinicians go through years of training, and patients share personal information that dictates what type of care they seek, where, and how it is delivered. In fact, in this very rule, CMS notes that “the physician should use his or her clinical knowledge and judgment, together with consideration of the beneficiary’s specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required for the beneficiary”. We would agree with this sentiment but are concerned with the words that follow “subject to the general coverage rules requiring that any procedure be reasonable and necessary”. This last portion remains vague: are those who create the general coverage rules the arbiters of reasonable and necessary? This has the potential to supersede the process by which clinicians spend years training, get licensed, credentialed and certified to practice medicine.

2. Increasing Administrative Burden and Negative Impacts on Patient Care

The stated intent of these new requirements is to ensure that care is “medically necessary” and to reduce unwarranted variation. However, the approach of requiring documentation for all instances where these codes are used does not accomplish this goal – it assumes that all uses of these codes are suspect. It also creates additional burden for clinicians who are appropriately utilizing these codes. Unfortunately, patients may also suffer as a result of these across the board requirements. Necessary patient care could be significantly delayed, which could lead to adverse patient outcomes. Additional resources and energy may be diverted away from optimizing patient care and towards fulfilling these new administrative requirements.

In addition to broader prior authorization concerns, AAOS is troubled by the methodological approach CMS has taken to identify codes for new prior authorization requirements. CMS acknowledges “a rate of increase higher than the expected rate is not always improper”, but their analysis focuses primarily on utilization as a predictor of value, with little consideration for clinical quality metrics and patient-reported outcomes. CMS explains that they “considered the data” and “believe the increases in the utilization rate for this service are unnecessary”, but there is no clinical explanation for how this conclusion was reached, and whether or not application of these procedures produced better quality and outcomes for patients.

This new approach by CMS to increase the amount of prior authorization requirements for clinicians will set a very dangerous precedent. This is the second time that CMS is proposing new prior authorization requirements in the OPSS, and we urge reconsideration of these policies. Providers already face significant operational challenges to ensure patients receive appropriate, timely and effective care. Indeed, the unrelenting public health emergency has only exacerbated this. The addition

of external, third-party requirements in order to complete an internal process only adds to this challenge. AAOS requests that this proposal be formally removed from the final CY 2021 OPSS rule.

Physician-Owned Hospitals

AAOS applauds CMS for proposing to lift the prohibition on the expansion of Physician-Owned Hospitals (POHs). This change is one that AAOS has long advocated for, and while the proposal only applies to high Medicaid facilities, we view this as a positive step toward providing high quality care from value-driven physicians. We believe that the proposals for POHs to expand beyond 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and licensed beds as well as to expand beyond the hospital's main campus is essential to expanding access.

While we consider the proposal to match Medicaid inpatient admissions as the standard for expanding POHs in a specific county as an aspirational goal, it may be more realistic to set benchmarks that meet a target range in close proximity to the local Medicaid or Medicare rates. For example, meeting a target within 10-20 percent of the local Medicaid and Medicare rates as a minimum standard for expansion, and later within a 2-5-year period reduce that to within 5-10 percent of the local Medicaid and Medicare rates. We suggest this flexibility to allow for variations in Medicaid and Medicare utilization rates across conditions, including orthopedic care.

Thinking ahead to further expansion, we encourage CMS and HHS to explore all regulatory avenues for lifting the arbitrary ban on new and expanding POHs. Considering the ongoing issues brought to the forefront as a result of the COVID-19 pandemic, the value of POHs has never been as evident. They contribute to local economies, meet a growing demand for health care services, and can shift focus and address frontline issues without the administrative red tape that cripples larger hospital systems. Concerns that POHs could have an incentive to serve only the most profitable patients have been proven baseless, and this high Medicaid proposal would further diminish that argument. A comprehensive peer-reviewed study published in the *British Medical Journal* found that, overall, physician-owned hospitals have similar proportions of Medicaid patients and racial minorities as other hospitals and perform comparably to other hospitals on benchmarks for quality of care.⁷

The Secretary has broad authority in creating a new demonstration project for POHs through the Center for Medicare and Medicaid Innovation, which would include a waiver or exemption to allow POHs to expand if they are accepted into the program. Moreover, 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. AAOS asks that all the options are thoroughly explored as the healthcare ecosystem continues to diversify to meet the needs of our nation's most vulnerable beneficiaries.

⁷ Blumenthal Daniel M, Orav E John, Jena Anupam B, Dudzinski David M, Le Sidney T, Jha Ashish K et al. Access, quality, and costs of care at physician owned hospitals in the United States: observational study *BMJ* 2015; 351:h4466

Thank you for your time and attention to the concerns of the American Association of Orthopaedic Surgeons (AAOS) on the significant proposals made in the CY 2021 OPPI/ASC proposed rule. The AAOS looks forward to working closely with CMS on further improving the payment system, and to enhancing the care of musculoskeletal patients in the United States. Should you have questions on any of the above comments, please do not hesitate to contact Shreyasi Deb, PhD, MBA, AAOS Office of Government Relations at deb@aaos.org.

Sincerely,



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American Alliance of Orthopaedic Executives
American Association of Hip and Knee Surgeons
American Orthopaedic Foot and Ankle Society
American Orthopaedic Society for Sports Medicine
American Shoulder and Elbow Surgeons
American Society for Surgery of the Hand
Arkansas Orthopaedic Society
Arthroscopy Association of North America
Cervical Spine Research Society
Connecticut Orthopaedic Society
Delaware Society of Orthopaedic Surgeons
Florida Orthopaedic Society
Georgia Orthopaedic Society
Kansas Orthopaedic Society

Louisiana Orthopaedic Association
Massachusetts Orthopaedic Association
Michigan Orthopaedic Society
Missouri State Orthopaedic Association
Montana Orthopedic Society
Musculoskeletal Tumor Society
Nebraska Orthopaedic Society
New York State Society of Orthopaedic Surgeons
North Dakota Orthopaedic Society
Ohio Orthopaedic Society
Oregon Association of Orthopaedic Surgeons
OrthoForum
Orthopaedic Trauma Association
Pediatric Orthopaedic Society of North America
Pennsylvania Orthopaedic Society
Rhode Island Orthopaedic Society
Ruth Jackson Orthopaedic Society
Scoliosis Research Society
South Carolina Orthopaedic Association
South Dakota State Orthopaedic Society
Tennessee Orthopaedic Society
Washington State Orthopaedic Association
West Virginia Orthopaedic Society
Wisconsin Orthopedic Society
Virginia Orthopaedic Society

Appendix A

1. Clinical Examples of Case-by-Case Exception Policy

Case 1: Medical Record Documentation Supports Case-by-Case Exception for “Patient History and Comorbidities”:

Dates of Service: 06/28/2018-06/29/2018 (one midnight)

Case Summary: This 72-year-old male presented for elective primary total knee arthroplasty for osteoarthritis on June 28, 2018, and was admitted to inpatient status the same day based on past medical history and co-morbidities. His past medical history includes hypertension, mild chronic kidney disease, and paroxysmal atrial fibrillation (PAF) with a history of rapid ventricular response (RVR) and hypotension. He has one step to get into his front door and has planned for his wife and two children to help care for him after the operation. On June 29, 2018, he was discharged to home.

Rationale for Approval: This was an elective admission for a TKA. The procedure was performed without complications, the patient did not develop any new diagnoses postadmission, and the patient was quickly mobilized. The patient has adequate post-operative support and accessibility. This patient is not a safe candidate for outpatient status due to the risk of postoperative PAF with RVR provoked by the stress of surgery and possible electrolyte abnormalities likely to occur in the acute postoperative period. Therefore, it is reasonable to approve this case based upon patient history and comorbidities and current medical needs, severity of signs and symptoms, and presence of risk factors for an adverse event.

Case 2: Medical Record Documentation Supports Case-by-Case Exception for “Risk of Adverse Events”:

Dates of Service: 05/15/2018-05/16/2018 (one midnight)

Case Summary: This 81-year-old female presented for elective primary total knee arthroplasty for osteoarthritis on May 15, 2018. Her past medical history includes hypothyroidism, glaucoma, and hypertension. Medical management provided consisted of the surgical procedure, pre- and post-operative monitoring, imaging, and laboratory studies. On May 16, 2018, she was discharged to home.

Rationale for Approval: Despite hemodynamic stability, adequate pain control, and safety clearance for home from physical therapy, she is not a safe candidate for outpatient status because her age alone confers a significant risk of developing a significant adverse event in the acute postoperative period. Therefore, it is reasonable to approve this case based upon patient history and comorbidities and current medical needs, severity of signs and symptoms, and presence of risk factors for an adverse event.