October 5, 2020

The Honorable Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1736-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Via online submission at www.regulations.gov

Re: 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:

Before offering our comments to the above-referenced rule, we wish to offer our appreciation for the time and energy that you and your staff devoted to meeting the challenges of the COVID-19 pandemic this year. The pandemic has wreaked enormous financial harm on the economy and our healthcare system, and we look forward to working with CMS to assure that Medicare beneficiaries continue to have access to the care they require.

To that end, we are pleased to report that recent research\(^1\) shows that ambulatory surgery centers (ASCs) saved the Medicare program $28.7 billion in the period between 2011–2018. This study, which provides an update to ASC cost savings research released several years ago,\(^2\) indicates an increase in annual savings from $3.1 billion in 2011 to $4.1 billion in 2018. This increase is, no doubt, due in part to an emphasis by the Centers for Medicare & Medicaid Services (CMS) under the current Administration on encouraging competition in healthcare.

The Ambulatory Surgery Center Association (ASCA) supports CMS in its pursuit of policies that save Medicare and its beneficiaries money without compromising quality, and this value

---


proposition is the essence of the ASC model and can be seen in the care provided by the 5,909^3 Medicare-certified ASCs nationwide. Importantly, if volume migration continues at the same rate as 2011–2018, ASCs are projected to save Medicare $74.2 billion from 2019–2028.^4 Policies that encourage further migration will promote even greater savings than those projected.

The calendar year (CY) 2021 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (“Proposed Rule”) (84 Fed. Reg. 154, August 9, 2019) once again includes encouraging signs that the Administration is committed to improving the healthcare delivery system through greater efficiencies and by providing broader clinical discretion to physicians. These proposals indicate that CMS views ASCs as having a significant role in generating those efficiencies while maintaining quality.

Below are our comments that outline ASC payment policy proposals to encourage the clinically appropriate migration of services into the lower-priced ASC setting—providing the Medicare program and its beneficiaries with a substantial savings opportunity while ensuring continued access to the high-quality care that ASCs provide and beneficiaries deserve.

Specifically, our comments focus on the following key topics:

- **Procedures Permitted in ASCs.** ASCA supports the sweeping changes proposed for the ASC covered procedures list (ASC-CPL) and encourages further policy changes to ensure that the appropriate site of care is determined by healthcare providers.

- **Conversion Factor.** ASCA supports CMS’ continued use of the hospital market basket as the annual update mechanism for ASC payments. However, the migration of services to ASCs will be limited due to the siloed budget neutrality adjustments.

- **ASC Weight Scalar Adjustment.** ASCA supports the discontinuation of the ASC weight scalar. With the 2019 change in the conversion factor, it is even clearer that removing this secondary scaling adjustment is necessary to truly align the payment systems and enable ASCs to capture the value of the conversion factor, which will afford greater opportunity to motivate increased migration of surgery and lower the cost of care.

**Procedures Permitted in ASCs**

*ASCA supports broad expansion of the ASC Covered Procedures (ASC-CPL) List.*

---


^4 Reducing Medicare Costs by Migrating Volume from Hospital Outpatient Departments to Ambulatory Surgery Centers.
ASCs are subject to a rigid set of survey and certification standards designed to ensure patient safety. The requirements for achieving and maintaining CMS certification were increased in 2008 with the overhaul of the ASC Conditions for Coverage and further safeguards have since been implemented to enhance patient safety and quality of care in ASCs. Technological advances increasingly drive procedures to the outpatient setting and research supports ASC community assertions that outcomes are similar between hospital outpatient departments (HOPD) and ASCs.\textsuperscript{5} Survey and certification requirements are essentially the same in both ASCs and HOPDs; the primary difference between them is the payment rate assigned to each facility type.

Of recent note, CMS highlights in this rule how the COVID-19 pandemic has “highlighted the need for more healthcare access points throughout the country,” and that “looking ahead to after the pandemic, it will be more important than ever to ensure that the health care system has as many access points and patient choices for all Medicare beneficiaries as possible.” ASCs throughout the country have been willing to help during this public health emergency. Facilities have taken on additional outpatient volume in recent months to alleviate the backlog of cases caused by postponements and cancellations this spring and to help hospitals in their communities that are still focused on caring for COVID-19 patients. In addition, dozens of ASCs provided expanded capacity by serving as hospitals under the “hospital without walls” program CMS established during the COVID-19 public health emergency.

ASCA appreciates CMS’ faith in the ability of our facilities to serve in these capacities and urge the Agency to continue to leverage the high-quality and cost-effective care that ASCs provide after the public health emergency ends by reforming its current policy of unnecessarily limiting the types of outpatient surgical procedures that ASCs are allowed to perform.

This proposed rule also places much more emphasis on the clinician’s discretion to select the appropriate site of service by use his or medical training, and ASCA commends CMS for taking this approach. There are three different proposals that directly address the ASC-CPL. The first proposal would add the following codes to the ASC-CPL for 2021 using the Agency’s current evaluation process:

- 0266T (Implt/rpl crtd sns dev total)
- 0268T (Implt/rpl crtd sns dev gen)
- 0404T (Trnscrv uterin fibroid ablty)
- 21365 (Opn tx complx malar fx)
- 27130 (Total hip arthroplasty)
- 27412 (Autochondrocyte implant knee)
- 57282 (Colpopexy extraperitoneal)
- 57283 (Colpopexy intraperitoneal)

• 57425 (Laparoscopy surg colpopexy)
• C9764 (Revasc intravasc lithotripsy)
• C9766 (Revasc intra lithotrip-ather)

ASCA supports the addition of these codes to the ASC-CPL list in 2021, including total hip arthroplasty (THA)—a procedure we have been encouraging the Agency to add for the past several years.

**ASCA supports adding Total Hip Arthroplasty (THA) to the ASC-CPL.**

While THA was historically an inpatient surgical procedure that required lengthy hospital stays, as CMS acknowledges in the Proposed Rule and prior rulemaking, recent innovations have enabled surgeons to perform joint replacement procedures “on an outpatient basis on non-Medicare patients (both in the HOPD and in the ASC).” Innovations such as minimally invasive techniques, improved perioperative anesthesia, alternative postoperative pain management and expedited rehabilitation protocols” have made it possible for these procedures, along with other total joint replacement surgeries, to be performed in the outpatient setting. There have been more than 100 peer-reviewed articles published on the topics of outpatient joint replacement, appropriate patient selection, multi-modal pain management, rapid rehabilitation and clinical outcomes. Attached as Appendix A to this comment letter are several studies that specifically speak to outpatient THA safety.

Orthopedic surgeons in ASCs are increasingly performing these procedures safely and effectively on non-Medicare patients and appropriate Medicare beneficiaries can benefit from THA in the ASC setting. Physicians credentialed to perform THA in ASCs are accountable and responsible for meeting patient selection criteria, as they are with any other surgery performed in the ASC setting. In addition, ASCs have protocols that must be adhered to by all credentialed physicians to ensure there are safeguards in place for patient safety.

As CMS mentioned in previous rulemaking, the benefits of outpatient total joint replacement “include a likelihood of fewer complications, more rapid recovery, increased patient satisfaction, recovery at home with the assistance of family members, and a likelihood of overall improved outcomes.” In many cases, it may be safer to have a THA in an outpatient setting to prevent comingling with patients with infections requiring intravenous (IV) antibiotic therapy or other inpatient conditions/treatments.

As with any procedure that a surgeon is contemplating performing in an ASC, qualified patient selection is paramount. Our facilities develop and follow strict protocols for total joint replacements to ensure that only appropriate patients are considered, which results in consistent and predictable successful outcomes. Adding THA to the ASC-payable list will not mean that all patients must have surgery in the outpatient setting; it simply provides skilled orthopedic surgeons the discretion to choose the most appropriate setting for each patient based upon medical conditions.
Like most surgical procedures, THA needs to be tailored to the individual patient’s needs. Patients with a relatively low anesthesia risk and without significant comorbidities, and with family members at home who can assist them post-operatively, would be good candidates for an outpatient THA procedure. On the other hand, patients with numerous comorbidities aside from their osteoarthritis would more likely require inpatient hospitalization and possible post-acute care in something akin to a skilled nursing facility. Surgeons who have discussed outpatient THA procedures with us have emphasized the importance of careful patient selection and strict protocols to optimize outpatient joint replacement outcomes.

Even though these procedures can be safely performed on the Medicare population, CMS will not see volume migrate into the ASC without providing adequate reimbursement for this code. Particularly in areas with lower wage indices, it will not be economically feasible for ASCs to perform these procedures at the proposed reimbursement. One issue that we explore later in these comments is that CMS adjusts the device portion of the payment by the wage index. ASCA recommends that, for all device-intensive codes including THA, CMS adjust only the non-device portion by the wage index. This is consistent with the Agency’s policy for separately payable drugs and biologics. Device costs are certainly not significantly lower in rural communities, and the current policy hinders patient access to ASCs.

Since the inclusion of THA and the other ten codes referenced above is also proposed with each of the two alternative proposals, ASCA prefers those alternatives, with some suggested changes to the criteria that would be used to determine whether codes should be added to the ASC-CPL.

ASCA supports the nomination process for adding codes to the ASC-CPL under alternative one.

Although stakeholders are currently able to schedule meetings with CMS and present data on codes that should be added to the ASC-CPL, a more formal nomination process would provide greater transparency to the process. The proposed rule states that CMS would establish a nomination process for CY 2021 through which external stakeholders, such as professional specialty societies, would nominate procedures for addition to the ASC-CPL. Nominations would be due to CMS by March 1 and CMS would review and finalize procedures through annual rulemaking, beginning with the CY 2022 rule. CMS also requests comments on the use of the following parameters when making the determination of inclusion.

- Does the procedure involve a risk of life-threatening complications?
  - If the procedure involves lower risk for life-threatening complications, it may be a reasonable candidate for consideration.
  - If the procedure involves a higher risk, consider the next question.
- Is there a need for specialized resources, not generally available in an ASC, to mitigate the risk of one or more life-threatening complications?
  - If specialized resources are not needed for this procedure, it may be a reasonable candidate for consideration.
  - If specialized resources are needed to reduce the patient’s risk of life-threatening complications, consider the next question.
• What is the average length of time for patients to be stabilized for transport to another facility?
  • If a patient undergoing the procedure cannot be stabilized for 90 minutes, this would be a serious consideration regarding the appropriateness of performing the procedure for Medicare beneficiaries in the ASC setting.
  • If a patient undergoing this procedure can be stabilized for 90 minutes, please consider the next question.
• Are resources and providers required for intervention generally available at nearby facilities for intervention?
  • If a team cannot be mobilized and prepared to intervene within this period, then this procedure should not be considered for the ASC-CPL.
  • If a team can be mobilized and prepared to intervene within this period, then this procedure could be a reasonable candidate for consideration.

ASCA supports the first three parameters but believes that the last parameter would be specific to individual ASCs and the hospitals with which they coordinate care. ASCA believes that the first three parameters are sufficient to ensure that only appropriate procedures are being added to the ASC-CPL.

Currently, CMS is not required to disclose a rationale for excluding a given procedure. This makes it difficult for ASCs to marshal the data needed to challenge these decisions. In the 2021 proposed rule, CMS indicates that if the Agency were to disagree with the addition of a nominated code, the Agency would provide a rationale for exclusion in the final rule. This proposal is similar to a provision in legislation supported by ASCA, the Ambulatory Surgical Center Quality and Access Act of 2019 (H.R. 4350/S. 3085), which would require CMS to disclose what criteria trigger the exclusion of the procedure from the ASC-CPL. ASCA supports this more formal and transparent process.

ASCA supports the broader expansion of the ASC-CPL in 2021 under alternative two.

ASCA has long requested that CMS align the list of procedures that may be performed in the ASC and HOPD settings, and as such, supports the second alternative that would add 267 codes to the ASC-CPL in 2021. However, even under this proposal, there would be 46 codes that are currently reimbursed in the HOPD setting that would not be added to the ASC-CPL in 2021.

There is one spine code that stood out – CPT 22633. While there have been good strides in adding spine codes to the ASC-CPL over the past several years, there are still some that are commonly done in ASCs on other patient populations but are not reimbursed under Medicare. A recent publication on lumbar fusion\(^6\) focused on 30-day safety outcomes for ASC and hospital patients and found that readmissions and reoperations are on par with (or below) what has been

reported by other author groups (whether direct evidence from a specific provider or population-based studies). ASCA requests that 22633 and the other 45 codes not included in this proposal but currently reimbursed in the HOPD setting be added to the ASC-CPL for 2021.

In this proposed rule, CMS indicates the Agency plans to finalize only one alternative – either the nomination process for future years (2022 ASC-CPL and beyond) or the evaluation of the ASC-CPL if certain general exclusion criteria are removed, resulting in the addition of at least 267 codes for 2021. It is unclear why CMS could not implement both, as they are sound, complementary policies. ASCA recommends the adoption of both, but if truly only one will be implemented, it should be alternative two which will allow the broadest expansion of the ASC-CPL in the near term.

**ASCA does not believe any ASC Conditions for Coverage (CfCs) need to be changed if alternative two is adopted.**

As previously mentioned, the ASC Conditions for Coverage (CfCs) were greatly expanded in 2008, closely align with conditions of participation (CoPs) that apply to HOPDs and are adequate to ensure the safety of Medicare beneficiaries under the proposed expansion of the ASC-CPL. ASCA has provided feedback below on the four specific areas for which CMS requested input.

1) **Current §416.42 (a)(1)(i) and (ii):** (i) A physician must examine the patient to evaluate the risk of the procedure to be performed; and (ii) A physician or anesthetist as defined at §410.69(b) of this chapter must examine the patient to evaluate the risk of anesthesia.

   **Public comment requested:** Whether these risk evaluations should be more prescriptive and require additional elements such as requiring the referring physician to submit pertinent health information and attest that the patient can safely undergo the procedure in an ASC.

   **ASCA’s comments:** ASCA supports the current CfC §416.42 (a)(1)(i) and §416.42(a)(1)(ii). On a case-by-case basis, the admitting physician, in consultation with the anesthesia provider, makes the decision if more pertinent health information regarding the patient is needed due to the patient’s age, medical history, current medications and type of procedure being performed. In addition, within the past two years, CMS eliminated the requirement that all patients must have a medical history and physical assessment (H&P) performed prior to surgery. A requirement to be more prescriptive here runs counter to CMS’ desire to reduce burden and rely more on the discretion of the clinician.

2) **Current §416.46 (a):** A registered nurse must be available for emergency treatment whenever there is a patient in the ASC.

   **Public comment requested:** Whether to require that an adequate number of nurses be on duty in the ASC at all times that the ASC has patient(s), consistent with the standard required of hospitals under § 482.23(b) and the associated guidance in the Medicare State Operations Manual A-0392, which is more prescriptive as to the types of nurses required.
ASCA’s comments: ASCA believes the current CfC §416.46(a) provides appropriate safeguards. The ASC follows its policy regarding the nurse-to-patient ratio as well as the time the nursing staff is present in the ASC. This would be based on criteria such as the type of procedure performed and the post-operative acuity level of the patient.

3) Current §416.44(e): CMS requires personnel trained in the use of emergency equipment and cardiopulmonary resuscitation are available if there is a patient in the ASC.

Public comment requested: Whether CMS should require staff to be certified in Advanced Cardiac Life Support (ACLS) and capable of providing a full and complete medical resuscitation response in the ASC.

ASCA’s comments: The current CfC is much preferred, as it provides the flexibility for the facility to determine the level of emergency certification and training (basic life support, advanced cardiac life support, pediatric advanced life support) required for ASC staff to care for patients as determined by the scope of procedures performed and the population the ASC serves.

4) Current §416.52(a): The ASC must develop and maintain a policy that identifies those patients who require a medical history and physical examination prior to surgery. The policy must -- (i) Include the timeframe for medical history and physical examination to be completed prior to surgery. (ii) Address, but is not limited to, the following factors: patient age, diagnosis, the type, and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level. (iii) Be based on any applicable nationally recognized standards of practice and guidelines, and any applicable State and local health and safety laws.

Public comment requested: Whether to make specific requirements in the CfC regulations at 42 CFR 416.52(a) for specific patient conditions or more complex and invasive surgical procedures ASCs would need to meet and for any evidence that would support such recommendations.

ASCA’s comments: CMS just relaxed the H&P requirement to provide more flexibility to facilities to determine what is appropriate for its patient population. ASCA agrees with the current language in CfC §416.52(a), as the ASC will follow its policy regarding an H&P based on the types of procedures performed and the population the ASC serves.

**CMS should eliminate the exclusionary criteria.**

Under both alternatives, CMS proposes to revise the exclusionary criteria under 42 CFR 416.166 (c) by eliminating 42 CFR 416.166 (c)(1) – (5); (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life threatening in nature; (5) commonly require systemic thrombolytic therapy. In addition, due to the changes being proposed to the IPO list, CMS is also
proposing to modify this criterion to exclude procedures designated as requiring inpatient care under 419.22(n) as of December 31, 2020.

ASCA recommends that CMS remove all of the exclusionary criteria. The criteria in the Code of Federal Regulations (CFR) are imprecise and subjective. Many States, which look to the CMS regulations when determining what to allow in their jurisdictions, misinterpret the exclusionary criteria for the Conditions for Coverage (CFCs) and impose onerous limitations on ASCs based on this misinterpretation. The CFCS that are in place already ensure that all ASC patients receive care in a highly regulated, quality environment regardless of payer.

That said, CMS should evaluate codes for safety before adding them to the ASC-CPL. If CMS deems a particular procedure to be unsafe for the outpatient setting, CMS can use the parameters proposed in the nomination process to decline to add said procedure instead of the exclusionary criteria currently found in 42 CFR 416.166 (b) and (c).

Two criteria proposed to remain in the CFR that are particularly problematic are those that require “active medical monitoring and care at midnight following the procedure” and the automatic denial of all unlisted codes.

**Active Medical Monitoring and Care Past Midnight**

CMS-certified ASCs are facilities for patients “not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.” However, for Medicare beneficiaries, CMS seems to be interpreting “hospitalization” as equivalent to “active medical monitoring and care at midnight following the procedure.” If non-Medicare beneficiaries are permitted to stay in an ASC up to 24 hours, it should be clear that the same standard apply to Medicare beneficiaries. A procedure can be extremely safe, but a beneficiary might be best served by staying overnight or would feel more comfortable spending the night. It is also unclear what is meant by “medical monitoring and care.” If the patient is stable and could be discharged but is simply being monitored at an ASC instead of at home by a family member or caregiver, it is puzzling, from a safety perspective, why that should not be permitted.

**Unlisted Codes**

The Code of Federal Regulations §416.166 - *Covered surgical procedures* states that “covered surgical procedures do not include those surgical procedures that…can only be reported using a CPT unlisted surgical procedure code.” There is no clear safety rationale for this provision, and commercial payers commonly provide ASCs the flexibility to use unlisted CPT codes to report procedures. Facilities must document why they need to use the unlisted code and receive approval from the payer to be reimbursed. This is also a practice CMS permits for HOPDs and physician offices but not for ASCs and is yet another example of an area where CMS could derive savings for both the Medicare program and its beneficiaries.

One code that is requested for addition to the ASC-payable list every year by our members is 41899 (dental surgery procedure). This is the only CPT code available for dental surgery. While
it is not significant for the Medicare population, this procedure is frequently performed on pediatric dental patients, many of whom are covered by Medicaid. Some state Medicaid plans only reimburse ASCs for codes found on the ASC-CPL, which causes access issues. If physicians have the ability to choose to perform these procedures in HOPDs, outpatient facilities that are often identical to ASCs, and physician offices that are not regulated by the federal government, physicians should be able to use unlisted codes in the ASC setting. ASCA requests that CMS revise the Code of Regulations to eliminate this restriction.

**Proposal to Eliminate the Inpatient-Only (IPO) List**

*ASCA supports this proposal in theory but has concerns about implementation.*

As with the ASC-CPL proposals, it is refreshing to see CMS providing additional discretion to clinical decision-making. However, there are elements to the proposal that are confusing. First, CMS indicates the transition will occur over three calendar years but will not be fully eliminated until January 1, 2024. That would indicate that the transition is four calendar years: 2021, 2022, 2023 and 2024. ASCA supports a transition period that is four years or longer, as CMS must account for the large influx of new codes to Ambulatory Payment Classification (APC) groups.

For 2021, CMS is proposing to remove 266 musculoskeletal-related services from the IPO-list. It is true that many of these procedures are already being done on other patient populations and should be available to Medicare beneficiaries in the outpatient setting, as well. However, CMS is not proposing to add any new APC groups to account for this influx of codes. CMS is proposing to add an APC group for urology codes (8 in total if finalized) but proposes to maintain only six musculoskeletal APCs (5111–5116). ASCA has advocated for an additional APC group for total joint replacements prior to this influx of 266 new codes. ASCA believes that CMS should add a seventh musculoskeletal APC group to account for the greater level of preparation required to ensure the successful performance of these procedures in the outpatient setting, such as discharge planning, care coordination and durable medical equipment.

*ASCA opposes the language proposed for 42 CFR §416.166 (c)(7).*

Current language in 42 CFR §416.166 (c)(6) prohibits codes from being added to the ASC-CPL if they “are designated as requiring inpatient care under §419.22(n) of this subchapter.” CMS proposes to “modify this criterion to exclude procedures designated as requiring inpatient care under §419.22(n) as of December 31, 2020.” However, the way this proposal is worded, it would prohibit CMS from ever adding codes to the ASC-CPL that are currently on the IPO list for as long as this language is in the CFR. We fervently hope that this is unintended, and that CMS meant simply to exclude those codes from consideration for the year that they are removed from the IPO list. Even that policy may be overreaching, as there are many codes, such as spine and joint replacement codes, that are currently performed on non-Medicare patients but are currently on the IPO list. ASCA asks CMS to revise this language to ensure these codes would not be permanently prohibited from consideration for the ASC-CPL.
Device-Intensive Codes

CMS should lower the device-intensive threshold to 25 percent.

ASCA has been working with the Agency for many years to address the device offset threshold and its impact on ASC volume. We appreciate the Agency recognizing the important role that device costs can play in a facility’s ability to perform these procedures, dropping the device threshold twice over the past few years, from 50 percent to 40 percent and then down to the current 30 percent threshold.

ASCA examined the impact on procedure migration when CMS lowered the device-intensive threshold from 50 percent to 40 percent. In the first year following the effective date of that policy (2015), there was a marked reduction in surgical services affected by the policy being performed in the HOPD, and an increase in affected procedures being performed in the ASC setting, resulting in a net savings when comparing the total combined ASC and HOPD dollars spent for the impacted codes. There was migration of services from the HOPD to the ASC among the procedures affected by the changed device-intensive threshold, so ASCA anticipates a further reduction in the device-intensive threshold will lead to additional migration of services from the HOPD to the ASC. While we do not have 2019 volume data yet, we anticipate that increasing the number of device-intensive codes from 154 in 2018 to 264 in 2019 resulted in another shift in volume from the higher-cost HOPD setting to the ASC setting.

ASCA requests that CMS encourage Congress to implement an ASC co-pay cap.

Recent changes to the device-intensive threshold have greatly increased the number of device-intensive codes on the ASC-CPL, but they have also shone a spotlight on how the lack of complete alignment in the HOPD and ASC payment systems serves as a barrier to access for Medicare beneficiaries. While there is a statutory cap on the patient responsibility when a procedure is done in a hospital, including an HOPD, that policy is not in place for the ASC setting. Even though the Medicare beneficiary’s patient responsibility is capped, the hospital is made whole by the Medicare program.

In years past, this had not been a huge issue due to the lack of codes for which the reimbursement rate was high enough to trigger a potential cap in the ASC, but this is changing as more procedures in general have been added to the ASC-CPL, and as more procedures have been identified as device-intensive. There are 139 codes on the 2021 proposed ASC-CPL for which the patient responsibility based on the national reimbursement rate would be higher in the ASC than the HOPD; 138 of those codes are device-intensive. Codes such as TKA and THA are included in that group. Beneficiaries who would otherwise have access to the high-quality, convenient ASC setting are disadvantaged by this lack of alignment in policy. As this requires a statutory fix, ASCA will be working with Congress to address this issue and we ask CMS to work with Congress to do so.

ASCA requests that CMS pay separately for additional levels of spine procedures.
Another issue that impedes Medicare beneficiary access to ASCs for codes with significant device costs is the packaging of additional levels for spine codes. The majority of anterior cervical discectomy and fusion (ACDF) and lumbar spine fusion procedures involve multiple levels, and the number of implants, hardware and grafts increases based upon the number of levels that are performed. However, while the add-on CPT codes for these procedures indicate an implantable, graft and hardware are used in the case, coupled with the additional level surgical procedure codes for the case, these add-on codes have a payment indicator of N1, meaning they are packaged with no additional payment. The codes impacted include the following:

- Allograft CPT codes: 20390, 20931
- Autograft CPT codes: 20936 – 20938
- Each additional interspace (cervical fusion): 22552, 22585
- Each additional vertebral space (lumbar fusion): 22614
- Instrumentation: 22840, 22842, 22845
- Application of Cage: 22853, 22845, 22859

ASCA requests that CMS assign a payment weight to these codes so that the ASC will gain access to additional reimbursement to offset the increased cost with the add-on codes that are performed in these cases.

**ASCA asks CMS to refrain from adjusting the device portion of payments by local wage index.**

The impact of the concerns raised above are exacerbated in rural communities, where the wage index is so low that it makes it financially untenable for facilities to perform device-intensive procedures on Medicare beneficiaries. To address this, CMS should refrain from adjusting the device portion of the payment by the local wage index. This is consistent with the Agency’s policy for separately payable drugs and biologics, and it is highly unlikely that a facility in a rural community is getting a better deal on devices than ASCs in large cities.

One example of how much the wage index can impact device-intensive codes is for a knee reconstruction code, CPT code 27429. The current national rate for 27429 is currently $10,113.69 and CMS estimates the device costs at $8,866.89. In rural Tennessee, where the local wage index is currently 0.7076, the current reimbursement rate for 27429 is $8,635.07, which is less than the device costs. There are currently 27 device-intensive codes for which the device cost exceeds the total reimbursement rate in rural Tennessee, and this issue impacts all communities with a lower wage index and causes access issues for Medicare beneficiaries.

**Continued Divergence of Payment Rates**

No matter how many codes are added to the ASC-CPL, the top 100 rarely change. Due to problematic payment policies that contribute to a lack of alignment between the ASC payment system and the OPPS, CMS will not realize its desired Medicare cost reductions as there will be no incentive for providers to migrate services to our facilities.
Medicare currently reimburses HOPDs, on average, **100 percent more** than ASCs performing the same procedures. Most ASCs are small businesses that operate in extremely competitive markets, and as such, must run efficiently to remain viable. Approximately 54 percent of CMS-certified ASCs\(^7\) have only one or two operating rooms. These facilities must purchase the same equipment, devices and implants as hospitals to perform surgery. In fact, smaller ASCs often pay more for these supplies and high-cost implants since they do not have the same purchasing power of a hospital or large health system. ASCs must compete with hospitals and other healthcare providers for the same nurses and other staff, all while complying with similar state and federal regulations. While ASCs pride themselves on their efficiency, being reimbursed less than half the HOPD reimbursement rate for providing the same procedures in a similar site of service jeopardizes continued access for Medicare beneficiaries to ASCs.

Whereas ASCs accounted for 6.63 percent of the total spend between ASCs and HOPDs in 2016, the ASC percentage between the two settings is declining. According to CMS’ projections in the proposed payment rule, ASCs will account for only 5.9 percent of that spend in 2021. While the alignment of update factors is a positive first step, the lack of alignment between payment systems, most evident in the ASC (secondary) weight scalar, as discussed later in these comments, will eventually threaten patient access to outpatient surgical care in the ASC setting.

**Annual Payment Update Policies**

**ASC supports CMS’ continued use of the hospital market basket as the annual update mechanism for ASC payments.**

When CMS implemented the revised ASC payment system in 2008, the Agency’s stated goal was to encourage high-quality, efficient care in the most appropriate outpatient setting and align payment policies to eliminate payment incentives favoring one care setting over another.\(^8\) Since 2008, the ASC community has urged CMS to adopt the same update factor for both the ASC and OPPS payments and appreciates that CMS took this first, necessary step toward better alignment of the payment systems.

ASCs have been increasing their share of commercial outpatient surgical volume for many years. As we have consistently reported to CMS, that growth has been tempered under Medicare by a lack of parity in reimbursement between hospital outpatient and ASC payment increases. The alignment of conversion factors is a promising sign, and migration will occur across all ASCs as the industry gains confidence that CMS is moving to put it on a more level playing ground with hospital outpatient reimbursement.

---


Request for Cost Data

In this proposed rule, the Agency once again expresses a desire to “assess the feasibility of collaborating with stakeholders to collect ASC cost data in a minimally burdensome manner” and “propose a plan to collect such information.” If CMS chooses to collect cost data to develop a market basket, the agency should consider expanding its research approach to focus on establishing a market basket that can be applied to both the ASC and hospital outpatient setting to ensure that payments using the same relative weights remain aligned over time.

We know that many of the same types of costs incurred by hospital outpatient departments are also incurred by ASCs, but we do not know if they are weighted the same. We welcome the opportunity to discuss how we might potentially use a simple, cost-effective survey or other low burden but effective data collection activity, perhaps voluntary in nature, and suggest as a starting point an effort to identify and calculate expense categories as a percentage of total expenses to help determine the appropriate weights and price proxies for the ASC setting.

Under any such undertaking, we urge CMS to recognize the variability among facilities and that cost experience can differ greatly depending on factors such as specialties served, size of the facility and geographic location. There are already excessive administrative burdens placed on ASC staff to meet current regulations and requiring any formal cost reports from ASCs would run counter to the Agency’s desire to promulgate rules and establish policies that allow facilities to maintain efficiency in the Medicare program. We welcome the opportunity to collaborate on this endeavor.

ASCA encourages CMS to discontinue the ASC weight scalar.

Since the payment systems were aligned, CMS has taken the relative weights in the OPPS, which have already been scaled, and then applies a secondary weight scalar, known as the ASC weight scalar, before arriving at the ASC payment weights. In the Final Rule establishing the ASC payment system (72 Fed. Reg. 42532, August 2, 2007), CMS suggested that the scaling of the relative weights is a design element that will protect ASCs from changes in the OPPS relative weights that could significantly decrease payments for certain procedures. However, the trend in the OPPS relative weights suggests that the ASC weight scalar will rarely, if ever, result in an increase in ASC relative weights. As the graph below indicates, the reduction due to application of the ASC weight scalar has increased significantly since the ASC payment system was aligned with the HOPD payment system. In 2018, the ASC weight scalar fell under 0.9000 to 0.8995, for a 10.1 percent reduction to the ASC weights, and in 2021, CMS is proposing a staggeringly low adjustment of 0.8494 which, if finalized, would result in a 15.06 percent reduction.
The historical trend seen in the above chart and the absence of any indication that it is likely to reverse in the future suggests that the continued application of the ASC weight scalar will exacerbate the growing divergence in ASC and HOPD rates and discourage beneficial migration.

Too much surgical care that could be safely performed in ASCs continues to be provided predominantly in hospitals, which we largely attribute to Medicare’s failure to pay reasonable rates to ASCs. This lack of migration comes at a high price to the Medicare program, the taxpayers who fund it, and the beneficiaries who needlessly incur higher out-of-pocket expenses.

Gastrointestinal endoscopies are among the highest-volume procedures performed in the ASC setting, accounting for six of the top 12 codes by volume in 2018. (Top six CPT codes: 43239, 45378, 45380, 45385, G0105, and G0121.) According to Tom Deas, MD, former ASCA Board Member and American Society for Gastrointestinal Endoscopy (ASGE) President, over 95 percent of these high-volume GI cases can be safely and efficiently performed in the ASC setting at greater patient convenience. Taking out current savings (cases already being done in ASCs instead of HOPDs), if 90 percent of these six GI endoscopies were performed in ASCs instead of HOPDs, the volume migration would represent $611 million in additional (“new”) savings annually. The total annual reduction in cost to the Medicare program would be approximately $1.4 billion.

However, there is no incentive for ASCs to shift volume. If CMS seeks to contain costs looking at the ASC payment system alone, that means that any increase in volume would lead to stagnation or a decrease in reimbursement rates. Our highest volume procedures are hit the hardest by this policy. While the conversion factor provides an average update of 2.6 percent
across the payment system, once the ASC weight scalar is factored in, the effective update drops to 2.3 percent for the top 100 codes and 2.08 percent for the top 10 codes by volume in the ASC setting.

There is no evidence of growing differences in capital and operating costs in the two settings to support this growing payment differential. By maintaining budget neutrality in silos, instead of looking at HOPDs and ASCs collectively, the positive impact of the conversion factor alignment is negated and CMS will not achieve the long-term savings desired.

Accordingly, the Agency is needlessly increasing Medicare program costs by making it financially untenable for ASCs to perform many procedures that are otherwise clinically appropriate and instead encouraging physicians and hospitals to furnish those procedures in the more expensive HOPD setting. To ensure that ASCs remain a viable alternative for Medicare beneficiaries in need of outpatient surgical care, CMS must discontinue use of the ASC weight scalar.

CMS’ proposal to align update factors eliminates an important variable when we are evaluating the growing disparity in payments between ASCs and HOPDs and makes it easier to see the true impact of the ASC weight scalar, primarily on those codes done in high volume in the ASC setting. For the top 100 codes by volume, ASCs are currently reimbursed on average 46.76 percent of the HOPD rate in 2020. If the 2021 policies are finalized that percentage will drop to 45.94 percent. CMS is unlikely to realize the procedure migration it seeks without addressing the largest contributor to the growing disparity: the ASC weight scalar.

Under the statute implementing the new ASC payment system in 2008, CMS was only required to apply budget neutrality in the first year of implementation of the new payment system. CMS has full authority to increase payments to ASCs (for example, by preventing the further relative deterioration of rates compared to hospitals performing identical services), particularly if it believes such policies will help constrain overall Medicare spending. CMS continued the scalar after the initial year of the new ASC payment system pursuant to its own perceived authority and not pursuant to any identified statutory requirement. As such, CMS has the authority to likewise discontinue the scalar at its discretion under the same rationale. ASCA implores CMS to encourage savings and greater access to ASCs for Medicare beneficiaries by eliminating the ASC weight scalar.

ASCA recognizes that the elimination of the ASC weight scalar would represent an initial increase in cost to the Medicare program until cost savings are achieved by shifting volume to the ASC setting. Alternatively, ASCA proposes that CMS refrain from applying the “secondary scalar” to the ASC payment system. Instead, CMS could combine the OPPS and ASC utilization

---

9 See Social Security Act 1833(i)(D)(ii): In the year the system described in clause (i) is implemented, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary and taking into account reduced expenditures that would apply if subparagraph (E) were to continue to apply, as estimated by the Secretary.
and mixes of services to establish a single weight scalar. In other words, CMS could apply a single budget neutrality calculation to the OPPS and ASC payment systems. By incorporating the ASC volume into the OPPS weight scalar calculations, CMS would further the alignment of the payment systems and more accurately scale for outpatient volume across both sites of service.

**Payment for Non-Opioid Pain Management Treatments**

*ASCA supports payment for non-opioid pain management treatments that lead to a reduction in opioid prescriptions.*

ASCA supports the Administration’s efforts to combat the opioid epidemic. We support CMS’ policy established in 2019 to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting. As part of our continued desire to align the HOPD and ASC payment systems, we also encourage CMS to establish this same policy for the HOPD setting.

We encourage CMS to consider reimbursing for other peri-operative non-opioid pain management tools, such as Ofirmev (IV Tylenol), CPT J0131, which is a highly effective medication that also decreases use of post-op opioids. In addition, CMS should consider reimbursement for pain blocks represented by CPT codes 64415, 64416, 64417, 64445, 64446, 64447, 64448, 64450. Currently these codes are listed on ASC Addenda AA, meaning they are only reimbursed as surgical codes, primarily for chronic pain management. Many physicians, rightly anticipating that a surgical procedure will result in significant post-operative pain, use the pain blocks described by the surgical codes above to mitigate the post-operative pain that is otherwise typically addressed with short-term opioid use.

For many interventions an anesthesiologist employs ultrasound guidance, often CPT 76942, to locate the nerve that needs to be blocked and injects medication (one of the pain codes listed above) in order to supplement the other anesthetic agents and therefore minimize a patient’s post-operative pain. The therapeutic effects of the pain block can last up to 72 hours, by which time much of the immediate post-operative severe pain has diminished and is usually responsive to non-narcotic pharmaceuticals. Pain blocks are routinely administered to non-Medicare patients in conjunction with a wide range of procedures but, unfortunately, the present lack of reimbursement by Medicare makes these valuable therapies cost-prohibitive for use on Medicare beneficiaries.

ASCA supports separate payment for non-opioid pain management products that will help reduce the prescription and use of opioids after surgery.

**Key Comments on ASC Quality and Proposed Reporting Program Changes**

More than a decade ago the ASC community coalesced behind a group of stakeholders that established the ASC Quality Collaboration (ASC QC) to develop, test and publicly report quality measures specific to the ASC setting. As part of its mission to support the collection and reporting of quality data, the ASC QC conducted a survey of more than 700 ASCs during the
early days of the COVID-19 pandemic when surgeries were limited to urgent and emergent cases. The study found that ASCs continued to perform essential outpatient surgeries safely during March and April this year with patients facing virtually no heightened risk of contracting the coronavirus either during or following their procedure.

Specifically, 709 outpatient surgery centers in 8 states\textsuperscript{10} were surveyed, including 3 states—New York, New Jersey and Louisiana—that were experiencing high rates of COVID-19 infection in the general population. A total of 84,446 patients were included in the survey. Only 16 of those patients tested positive for COVID-19 within 14 days after their procedure, an infection rate of just .02 percent, and no evidence of any of those cases were connected to the patients’ procedures.

This survey data confirms that ASCs, using the safety protocols that have been developed and implemented over the years to prevent the spread of infections and nimbly applying the enhanced protocols developed to respond to the pandemic, are well-equipped when a crisis arises to meet the healthcare needs of our communities.

The ASC QC will submit detailed comments on the aspects of the rule relating to the ASC Quality Reporting Program (ASCQR Program), and ASCA supports the ASC QC’s comments. In addition, we wish to highlight below our position on select policies.

As ASCs and other healthcare providers continue to deal with the COVID-19 global pandemic, we appreciate CMS’ decision not to make changes to the ASCQR Program measure set at this time. That said, we ask that CMS evaluate the following changes for future consideration.

\textit{ASCA recommends that CMS reestablish ASC-1 through ASC-4 data collection and submission in future rulemaking.}

When the ASC community began advocating for its own Medicare quality reporting program, we sought to report on measures that provide information on patient outcomes. We understand CMS’ rationale for suspending ASC-1: Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; ASC-4: All-Cause Hospital Transfer/Admission. Although these events are rare and there is little deviation in reporting amongst ASCs, we continue to believe it is important information for patients and facilities.

These measures were reported using quality data codes on ASC Medicare claims. As noted in our comments to the 2019 and 2020 payment rules, it would be more beneficial to all stakeholders if this data were submitted via QualityNet and reporting expanded to all patients served by the ASC, not just Medicare patients. This would considerably expand the scope and transparency of public reporting as well as the accountability related to these measures. The ASC QC is the measure developer and steward for the measures and the ASC QC attests that, as originally developed, these measures are suitable for the type of aggregate data collection and submission in use at the QualityNet site. We appreciate that CMS is evaluating this option.

\textsuperscript{10} Connecticut, Illinois, Louisiana, Massachusetts, Michigan, New Jersey, New York, Pennsylvania
In this rule, CMS requests information on other measures that “would facilitate meaningful comparisons between ASCs and hospitals.” ASCA is encouraged by this desire to align measures between various sites of outpatient surgery, as has been the approach from the Agency for the past few rulemaking cycles. ASCA recommends that CMS reestablish data reporting for ASC-1 through ASC-4 in future rulemaking, and also add similar measures for HOPDs and physicians performing surgery in their offices in order to provide patients with more meaningful data to compare sites of service.

**Other Measures for Future Consideration**

In this proposed rule, CMS expresses a desire to “develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality improvement in the ASC setting,” and requests comments on new measures for consideration. ASCA respectfully requests that CMS first reevaluate measures that were previously considered but not yet added to the ASCQR Program.

In the 2018 OPPS/ASC proposed rule, CMS proposed to adopt ASC-16: *Toxic Anterior Segment Syndrome (TASS)* for CY 2021 payment determination and subsequent years. This measure is maintained by the ASC QC, and as indicated in the 2018 proposed rule, it is an appropriate measure for the ASCQR Program because ophthalmic procedures are commonly performed in ASCs and “the inflammatory response associated with TASS can cause serious damage to patients’ vision, but TASS is also preventable through careful attention to solutions, medications, ophthalmic devices, and to cleaning and sterilization of surgical equipment.” ASCA requests that CMS reconsider adding this measure.

CMS also solicited public comment on the Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome measure (NQF #3025) in the 2018 proposed rule, and ASCA supported this measure’s inclusion in the ASCQR Program. Of the healthcare acquired infections, SSIs are those that are most applicable to the ASC setting and important for ASCs to try to track. However, as CMS indicates in the 2018 proposed rule, “although standardized metrics have been developed to measure SSI rates for inpatient surgeries in the hospital setting, these have not yet been developed for outpatient surgeries in ASCs. We believe this measure, if adopted in the future, could serve as a quantitative guide for ASCs, enabling them to benchmark SSI rates in their facilities against nationally aggregated data and set targets for improvement.” ASCA agrees, and requests CMS reconsider this measure for future inclusion in the ASCQR Program.

**ASCQR Program Data Submission Deadlines**

As CMS states in this rule, “while the ASCQR Program has established submission deadlines (42 CFR 416.310), there is no specified policy for deadlines falling on nonwork days.” In 2021, the May 15 submission deadline falls on a Saturday, making it important that this be addressed in current rulemaking. ASCA supports CMS’ proposal that all program deadlines falling on a nonwork day be moved forward consistent with section 216(j) of the Social Security Act (the Act), 42 U.S.C. 416(j), "Periods of Limitation Ending on Nonwork Days."
Summary

On September 24, 2020, President Trump announced a healthcare executive order in line with continued efforts to bring “great healthcare to the American people…and improve the efficiency and quality of healthcare in the United States.” ASCs are well-positioned to do both – improve efficiencies and provide high-quality care. While CMS has taken strides in both this proposal and those over the past several years to ensure that ambulatory surgery centers remain viable Medicare providers, there is still much work to be done. ASCA appreciates the Trump Administration’s efforts to encourage competition between high-quality healthcare providers and we welcome the opportunity to collaborate with CMS on the additional payment policy changes outlined in this letter that will assure safe and high quality care to beneficiaries and reduce the cost of care to them and the Medicare program. Please contact Kara Newbury at knewbury@ascassociation.org or (703) 836-8808 if you have any questions or need additional information.

Sincerely,

William Prentice
Chief Executive Officer
Appendix A: Total Hip Arthroplasty Research

**Outpatient vs Inpatient Hip Arthroplasty: A Matched Case-Control Study on 90-Day Complication Rate and 2-Year Patient Reported Outcomes**

August 2020

Journal of Orthopaedic Surgery and Research

**Conclusion:** Authors matched 91 outpatient and inpatient total hip arthroplasty cases, selecting patients with similar demographics and comorbidities. Authors examined a group of patient reported outcomes (PRO) as well as perioperative and postoperative complications. The outpatient cohort experienced less pain and higher satisfaction compared to the inpatient cohort, with no significant difference in perioperative or postoperative complication rates. The average length of stay for outpatients was very significant (6.8 hours vs. 43.2 hours) and, the authors estimate, represents a savings of $3,676 per patient.

**Outcomes of the First 1,000 Total Hip and Total Knee Arthroplasties at a Same-day Surgery Center Using a Rapid-recovery Protocol**

March 2019

Journal of the AAOS

Conclusion: Our immediate and short-term complications and readmissions for all patients compared favorably, if not superiorly, with benchmark data. These included infection rate, readmission rate, early/unplanned access to care, adverse events, opioid analgesia, functional outcomes, pain outcomes, ambulation, satisfaction levels, and recovery time. This was true for both TKA patients and THA patients.

These results serve as an internal and external benchmark for both inpatient and ASC-based THA/TKA programs. Quantitative outcome measures and baseline PROMs have been established to advance toward best practices in ASC-based total joint arthroplasty.

**Transition to outpatient total hip and knee arthroplasty: experience at an academic tertiary care center**

November 2018

Arthroplasty Today

Finding: Retrospective review of 105 patients who underwent outpatient THA/TKA protocol compared to inpatient arthroplasty patients from the same period. Outpatient readmission and complication rates (0.95%, 1.9%) were better than inpatient rates (3.7%, 2.9%). Authors conclude that Outpatient THA and TKA in a well-selected patient is feasible in an academic
multidisciplinary tertiary care hospital, with complication rates approximating inpatient surgery. The findings reported can be used to further optimize outpatient arthroplasty protocols.

**Inpatient Versus Outpatient Hip and Knee Arthroplasty: Which Has Higher Patient Satisfaction?**

July 2018

The Journal of Arthroplasty

Finding: Although satisfaction was high in both outpatient and inpatient groups, when differences were present, patients favored outpatient surgery in the ambulatory surgery center. Study uses components from the HCAHPS survey.

**Low Rates of Adverse Events Following Ambulatory Outpatient Total Hip Arthroplasty at a Free-Standing Surgery Center**

August 2017

The Journal of Arthroplasty

**Conclusion:** Study reviews 145 total hip arthroplasties (THA) performed by a single surgeon from 2013 to 2016 at two separate ambulatory surgery centers. Only 1 patient (0.7%) required transfer to a hospital for a blood transfusion; there were no other direct admissions to a hospital or emergency department. 3 patients (2%) required a surgical intervention in the 90-day postoperative period. The authors found that the complication rates compared favorably to those reported after standard inpatient THA and conclude that same-day discharge to home following THA can be done safely with proper patient selection and facility protocols.

**Same Day Total Hip Arthroplasty Performed at an Ambulatory Surgical Center: 90-Day Complication Rate on 549 Patients**

October 2016

The Journal of Arthroplasty

**Conclusion:** Authors reviewed 549 consecutive posterior total hip arthroplasties (THA) performed at an ambulatory surgery center between 2008 and 2014. Every patient was successfully discharged to their home, with only 3 patients (0.5%) requiring a hospital admission. Overall infection rate in the study cohort was 0.9%. Authors conclude that outpatient THA at an ASC can be safe and effective when performed on appropriately selected patients and with careful facility planning.