



September 27, 2019

The Honorable Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1717-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Via online submission at www.regulations.gov

Re: CMS-1717-P – Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; etc.

Dear Administrator Verma:

The Ambulatory Surgery Center Association (ASCA) supports the Centers for Medicare & Medicaid Services (CMS) in its pursuit of policies that save Medicare and its beneficiaries money without compromising quality. This value proposition is the essence of the ambulatory surgery center (ASC) model. The 5,831¹ Medicare-certified ASCs nationwide are instrumental in efforts by CMS to contain costs, as our facilities reduce Medicare spending by billions of dollars annually while providing a high-quality, efficient environment for outpatient surgery.² On the top 100 surgical codes by volume in the ASC setting, CMS would have spent \$3.3 billion more in 2017 if those procedures had been performed in a hospital, and policies that encourage further migration of procedures to the ASC setting will result in even greater savings to the Medicare program.

The calendar year (CY) 2020 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 it is clear through these proposals 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 that will encourage the clinically appropriate migration of services into the

¹ As of September 13, 2019, according to CMS’ Survey & Certification (S&C)’s Quality, Certification and Oversight Reports (QCOR), available here: <https://qcor.cms.gov/main.jsp>.

² *Medicare Cost Savings Tied to Ambulatory Surgery Centers*, University of California-Berkeley Nicholas C. Petris Center on Health Care Markets and Consumer Welfare, September 2013; and the U.S. Department of Health and Human Services. Office of Inspector General. Washington: Government Printing Office, April 2014. (A-05-12-00020).

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:

- **Conversion Factor.** ASCA strongly 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 the additional codes being proposed for addition to the ASC-payable list. CMS should also reimburse ASCs for all surgical codes for which it reimburses hospital outpatient departments (HOPDs).
- **ASC Quality Reporting.** ASCA supports CMS’ testing of web-based reporting for those outcomes measures suspended in 2019, which would allow ASCs to report on all patients cared for in their facilities. ASCA also supports efforts to better align the ASC and HOPD quality reporting program requirements.

Continued Divergence of Payment Rates

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 55 percent of CMS-certified ASCs³ 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.

³ ASCA analysis of Provider of Services Current Files, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/>.

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.

Whereas ASCs accounted for 6.63 percent of the total spend between ASCs and HOPDs in 2016, the ASC percentage of that spend between the two settings has been declining ever since. According to CMS' projections in the proposed payment rule, ASCs will account for only 5.83 percent of that spend in 2020. 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, will eventually threaten patient access to outpatient surgical care in the ASC setting.

Annual Payment Update Policies

ASCA strongly 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 goal was to encourage high-quality, efficient care in the most appropriate outpatient setting and to align payment policies to eliminate payment incentives favoring one care setting over another.⁴ Since the payment systems were aligned, ASCA has urged CMS to adopt the same update factor for both the ASC and OPSS payments, and thanks CMS for having implemented this first, necessary step last year.

ASCs have been increasing their share of outpatient surgical volume for many years. As we have consistently reported to CMS, that growth has been tempered 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. Over time, the cost structures of the HOPD and inpatient hospital setting have diverged significantly with the

⁴ CY 2007 OPSS/ASC Proposed Rule (<https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2006-Fact-sheets-items/2006-08-08.html?DLPage=1&DLEntries=10&DLFilter=ambulato&DLSort=0&DLSortDir=descending>).

tremendous growth in off-campus locations of HOPDs that likely have a cost structure more similar to ASCs than inpatient hospitals.

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 least burdensome 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 of the facility.

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.

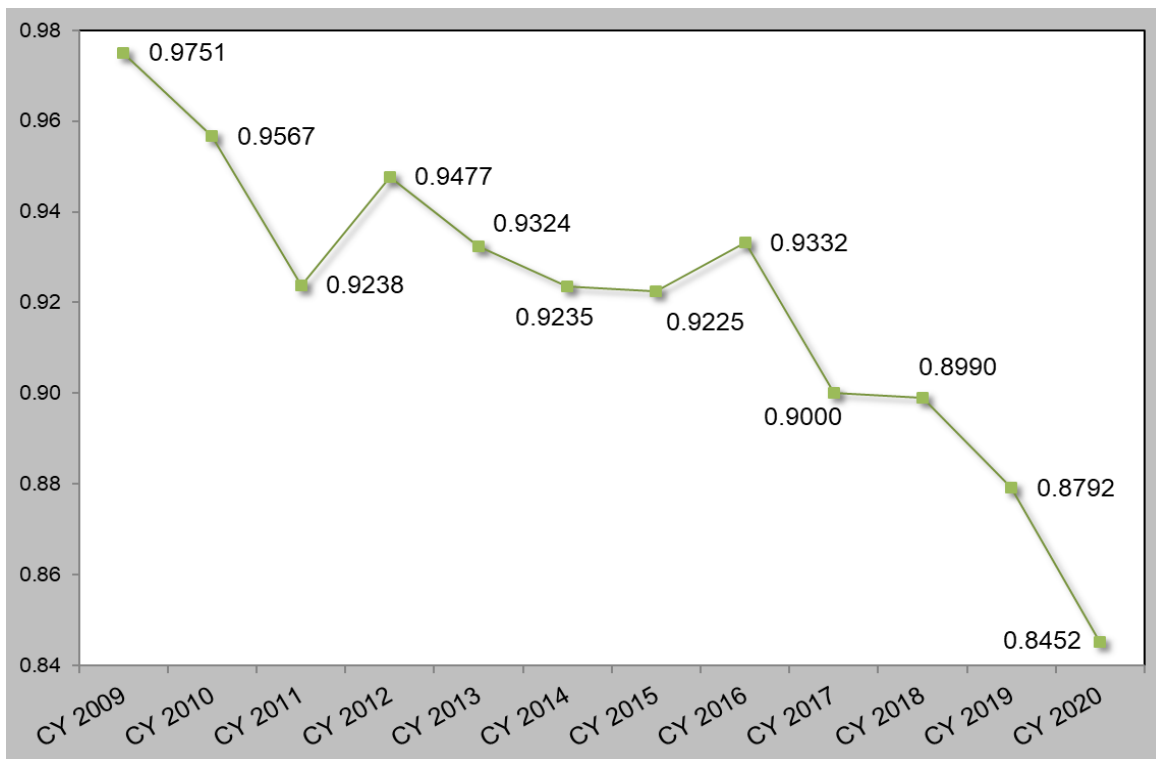
ASCA strongly encourages CMS to discontinue the ASC weight scalar.

The additional scaling factor, referred to as the ASC weight scalar, that CMS applies is intended to maintain budget neutrality within the ASC payment system. A major consequence of this siloed approach to budget neutrality, however, is the ever-increasing payment differentials between ASC and HOPD payments. If costs are supposed to be contained 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 2.7 percent across the payment system, once the ASC weight scalar is factored in, the effective update drops to 2.47 percent for the top 100 codes and 1.29 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.

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 scaling factor for ASCs 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. For the first time ever, 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 2020, CMS is proposing a staggeringly low adjustment of 0.8452, which if finalized, would result in a 15.5 percent reduction.

ASC Weight Scalar: 2009 – 2020 (Proposed)



Application of the ASC weight scalar operates to widen the gap between hospital and ASC payments and discourage beneficial migration. The historical trend seen above, 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. In so doing, 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 therefore 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 49.94 percent of the HOPD rate in 2019. If the 2020 policies are finalized, that percentage will drop to 48.15 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.⁵ 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.

Procedures Permitted in ASCs

ASCA supports the proposed addition of eight new codes to the ASC-payable list.

CMS has proposed to add the following eight codes to the ASC list for 2020:

- 27447 (Total knee arthroplasty)
- 29867 (Allgrft implnt knee w/scope)
- 92920 (Prq cardiac angioplast 1 art)
- 92921 (Prq cardiac angio addl art)
- 92928 (Prq card stent w/angio 1 vsl)
- 92929 (Prq card stent w/angio addl)
- C9600 (Perc drug-el cor stent sing)
- C9601 (Perc drug-el cor stent bran)

ASCA supports CMS adding these codes to the ASC-payable list in 2020, including total knee arthroplasty (TKA), which we have been advocating for the past several years. In addition to the specific policies found in the Proposed Rule, we provide general guidance on how CMS might better align ASC and HOPD lists since the sites of service are subject to much of the same regulatory oversight.

ASCA supports alignment between the ASC-payable list and surgical codes payable in the HOPD setting.

ASCA strongly supports the addition of all the codes proposed for inclusion on the 2020 ASC-payable list. However, there are 358 codes that CMS is proposing to reimburse in HOPDs but not in ASCs. Surgeons in ASCs are performing these procedures safely on non-Medicare patient populations. These procedures are designated as Surgical Procedures Excluded from Payment in

⁵ 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.

ASCs but are not included on the inpatient-only list. With technological advances increasingly driving procedures from the inpatient to the outpatient setting, and research indicating the clinical similarities between HOPDs and ASCs⁶, we urge the Agency to leverage the high-quality and cost-effective care that ASCs provide by reforming its current policy of unnecessarily limiting the types of outpatient surgical procedures that ASCs are allowed to perform.

As the Agency well knows, 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 since 2008, further safeguards have been implemented to enhance patient safety and quality of care in the ASC.

Since the survey and certification requirements are essentially the same in both ASCs and HOPDs, the primary difference between them is simply the payment rate assigned to each facility type. There is no credible safety argument to justify the expansive list of codes that are reimbursable in HOPDs but not ASCs. Like ASCs, many HOPDs performing these services are separated from an acute care hospital by many miles, and therefore, are similarly situated regarding their ability to furnish emergency or inpatient services should a patient need additional resources. Accordingly, ASCA requests that CMS simply maintain an inpatient-only list and allow all other surgical codes to be performed in either an HOPD or an ASC.

ASCA supports the proposed addition of several cardiology codes as part of its revised definition of surgery established in 2019.

ASCA supports the recognition by CMS that there are “services that do not directly crosswalk and are not clinically similar to procedures in the CPT surgical range, but that nonetheless may be appropriate to include as covered surgical procedures payable when furnished in the ASC setting.”⁷ Strict adherence to the CPT surgical code groupings has not properly accounted for advances in treatment and “the dynamic nature of ambulatory surgery and the continued shift of services from the inpatient setting to the outpatient setting over the past decade.”⁸

While we support the addition of the six coronary intervention codes that are proposed for the ASC-payable list due to the revised definition of surgery, we would request that CMS also include the following CPT codes on the list of ASC codes that are eligible for separate payment.

⁶ Need better citation for comparison studies ASCA has recently highlighted: <http://ortoday.com/independent-research-proves-quality-benefits-of-the-asc-model/>

⁷ 82 Fed. Reg. 33655

⁸ 82 Fed. Reg. at 33655

Cardiac Diagnostic Catheterization - Catheter Placement with Angiography
93463
93530
93531
93563
93564
93565
93566
93567
93568
Cardiac Interventions - Catheter Placement with Angiography
92937
92938
92973
92978
92979
C9604
C9605
Other Cardiology Procedures
93312
93313
93315
93316
92960

The services we propose would create a seamless site of service for diagnosis and treatment of cardiac conditions consistent with the care many commercially insured patients receive. These codes are for interventional and diagnostic procedures currently covered when delivered in the HOPD but not in the ASC. Absent their inclusion, CMS may not see the desired migration of diagnostic cardiology services because most cardiologists and patients prefer to progress to an intervention during the initial encounter if a problem can be efficiently addressed in a single session.

ASCA strongly supports adding Total Knee Arthroplasty (TKA) to the ASC-payable list.

While TKA 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 TKA safety.

Orthopedic surgeons in ASCs are increasingly performing these procedures safely and effectively on non-Medicare patients, and appropriate Medicare beneficiaries would be able to benefit from TKA in the ASC setting. Physicians who are credentialed to perform TKA in the ASC 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 TKA in an outpatient setting to prevent comingling with patients with infections requiring IV AB 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 TKA to the ASC-payable list does not mean that all patients will 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, TKA 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 TKA 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 TKA 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 a lower wage index, it will not be economically feasible for ASCs to perform these procedures at the proposed reimbursement. One issue is the fact that CMS adjusts the device portion of the payment by the wage index. ASCA would recommend that CMS, for all device-

intensive codes including TKA, 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 less in rural communities, and the current policy hinders patient access to ASCs.

ASCA supports the removal of total hip arthroplasty (THA) from the inpatient-only (IPO) list.

As noted in the CY 2012 OPPI/ASC final rule with comment period (76 FR 74353), CMS uses five criteria when reviewing procedures to determine whether they should be removed from the inpatient-only list and assigned to an APC group for payment under the OPPI when provided in the hospital outpatient setting. While CMS notes that a procedure is not required to meet all the established criteria to be removed from the IPO list, ASCA believes that THA meets all the criteria below and should be removed from the inpatient-only list. The decision to remove TKA from the inpatient-only list in 2018 was based on CMS staff's belief that the procedure can meet these criteria, and ASCA believes that since the same criteria are met for hip arthroplasty, THA should also be removed from the inpatient-only list.

1. Most outpatient departments are equipped to provide the services to the Medicare population.

While we cannot speak directly to how HOPDs are equipped, ASCs that are performing these procedures are certainly equipped to do so. The surgeons often perform many cases in an HOPD or treat patients in the inpatient hospital as outpatient patients (i.e., discharge within 24 hours) prior to moving the cases to the ASC setting. Physicians and staff have worked hard to develop protocols specific to the performance of these procedures, including clear patient selection criteria determined in conjunction with the anesthesiologist. While not all Medicare patients are appropriate for the outpatient setting, those outpatient facilities that are already performing these procedures are clearly equipped to handle Medicare patients.

2. The simplest procedure described by the code may be performed in most outpatient departments.

If the facility is equipped to handle these cases for some segment of the Medicare population, the answer will also be "yes" to this question. If the patient meets appropriate selection criteria for outpatient total joint replacement, the procedure can take place in an outpatient setting. This should not be determined by age or payer but, rather, by the patient's physical status and readiness for total joint replacement surgery. Currently, there are ASCs across the country safely and effectively performing THA on commercially insured patients and some have been doing so for several years. Facilities that have decided to perform joint replacements have invested significant time and money ensuring that the facility is equipped to handle total joint replacements for all patients who meet the patient selection criteria (regardless of payer status) established by the operating surgeon and anesthesiologist.

3. The procedure is related to codes that we have already removed from the IPO list.

Our surgeons tell us that THA is clinically similar to the following procedures that are permitted in the ASC: CPT code 27446, arthroplasty knee condyle and plateau media or lateral replacement, CPT code 27438, arthroplasty patella with prosthesis, CPT code 24361, arthroplasty of the elbow with distal humeral prosthetic replacement and CPT codes 22551 and 22554, anterior cervical disk fusion. Many of our surgeons tell us that THA is an easier procedure to perform than TKA, which was removed two years ago from the inpatient-only list. These procedures are already being done in HOPDs and ASCs and have been for many years. It is not safety concerns, but CMS payment policies that exclude THA from being performed in the outpatient setting on the Medicare population.

4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.

While we do not have firm numbers, we do know that numerous hospitals are performing this procedure on an outpatient basis. In addition, an increasing number of ASCs are performing these procedures at our facilities. We now conservatively estimate at least 300 ASCs nationwide are performing joint replacements. This number will continue to grow as more patients require these procedures. A research study published in 2007 indicated that by 2030, TKAs are estimated to grow by 673 percent to 3.48 million procedures annually, and THAs are expected to increase by 174 percent to 572,000 procedures annually.⁹

5. A determination is made that the procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.

Some Medicare patients would clearly be good candidates for the outpatient setting and would rely on the physician's judgment in conjunction with the patient's interest in having the procedure performed on an outpatient basis. Medicare patients who are active, have a relatively low anesthesia risk, are without significant comorbidities and have family members at home who can assist them would likely be excellent candidates for an outpatient THA procedure. Having options allows the physician and patient to determine the most appropriate setting of care.

Surgeons who perform outpatient THA procedures know the importance of careful patient selection and strict protocols to optimize outcomes. These protocols typically manage all aspects of the patient's care, including the at-home preoperative and postoperative environment, anesthesia, pain management, and rehabilitation to maximize rapid recovery and ambulation.

Where and when a THA takes place is a decision that should be between the patient and their surgeon. There are three options – hospital inpatient, hospital outpatient and the ASC. If Medicare allowed THA to be performed at an ASC, that would offer patients and surgeons the flexibility to choose the most appropriate site of service for the procedure. Ultimately, the most appropriate setting for the patient to receive care should be determined based on their health

⁹ J Bone Joint Surg Am. 2007 Apr; 89(4):780-5. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/17403800>

status, not by a rule that dictates where a patient must be treated based on insurance plan design. Medicare, its beneficiaries and taxpayers are spending more money than necessary because these procedures are not reimbursed in lower-cost, highly regulated settings.

ASCA strongly urges CMS to remove THA from the inpatient-only list, as this is as an important first step to ultimately seeing ASCs reimbursed by Medicare for these codes and eventually other joint replacement procedures. We also urge CMS to set the reimbursement for these procedures at an appropriate level to allow for them to be performed in outpatient settings. Without adequate payment, these procedures will continue to be performed on an inpatient basis, thereby undermining the intent of this policy change. We believe it would be appropriate to follow long-standing CMS policy and assign these procedures to APCs based on correctly coded HOPD claims with C-codes for devices.

ASCA supports the consideration of removal of additional spine codes from the IPO list.

ASC physicians who perform spine procedures also perform these procedures in the hospital. The physicians will be performing the cases regardless – they will just evaluate each patient carefully to determine the best fit clinically for that patient. Patient safety is the top priority for our physicians, and they will not be moving cases to the ASC unless they know that facility is equipped to handle them, and it is the best site of service for the patient. We are happy to meet with CMS staff during the coming year to present on the viability of these procedures being done on an outpatient basis. We encourage CMS to pursue their removal from the inpatient-only list.

Proposed Changes for CY 2020 to Covered Surgical Procedures Designated as Office-Based

ASCA supports CMS' proposal for reimbursement of vascular access codes 36902 and 36905.

ASCA appreciates that CMS heard concerns from the industry last year and decided not to assign an office-based designation to CPT codes 36902 and 36905 for 2019. There must be adequate volume data over a sufficient period to ensure that the designation is appropriate. CMS added vascular access codes to the ASC fee schedule in 2017 and ASCs are now increasingly offering access creation services that were previously only provided in high volume in HOPDs at a much higher cost. As indicated in this proposed rule, CMS is already seeing these procedures shift to the ASC setting, and we applaud CMS for proposing to continue to assign both codes a payment indicator of “G2” – nonoffice-based surgical procedure based on OPPS relative weights in 2020.

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 strongly 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 post-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.

During many procedures, an anesthesiologist uses an ultrasound, often CPT 76942, to locate the nerve that needs to be blocked and injects the nerve with a numbing medication (one of the pain codes listed above) before surgery and before the general anesthesia process in the operating room in order to minimize a patient's post-operative pain. The effects of the pain block can last up to 72 hours, by which time the most severe pain has naturally subsided. Pain blocks are routinely used on non-Medicare patients in ASCs, but lack of reimbursement by Medicare makes these products cost-prohibitive for use on the Medicare population.

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

Key Comments on Quality Reporting Program Changes

ASCA and the ASC community have a proven track record of proactively promoting quality reporting in our facilities. 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. The ASC QC will submit detailed comments on the aspects of the rule relating to the ASC Quality Reporting Program (ASCQR Program), and ASCA strongly supports the ASC QC's comments. In addition, we wish to highlight below our position on select policies.

ASCA Recommends Reconsideration of the Proposed Removal of ASC-1 through ASC-4

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*. However, 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 being reported using quality data codes on ASC Medicare claims. As we noted in our comments to last year's payment rule, 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 further evaluating this option.

ASCA also encourages CMS to continue aligning measures across all sites of outpatient surgery, as has been the approach from the Agency for the past few rulemaking cycles. If there is quality data currently being reported by hospitals that makes sense for the ASC setting, we are happy to collect and report that data. Likewise, we would recommend that data being collected and reported by ASCs be collected and reported by HOPDs and physicians performing surgery in their offices in order to provide patients with more meaningful data to compare sites of service. We appreciate CMS' discussion in the Proposed Rule asking if HOPDs should be required to report on the same outcomes measures ASCs previously reported. ASCA strongly supports this potential alignment of measures.

New Measure Proposed for Addition in the ASCQR Program

CMS has proposed to adopt *ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers* for 2024 payment determinations and beyond. While ASCA supports quality reporting, we continue to be concerned with these types of all-cause measures that rely on a retrospective analysis of claims over an extended period. We have concerns that, as with current measure *ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy*, measure scores and results will not be received until months after the patient's visit, significantly limiting the usefulness of the information.

Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

ASCA supports CMS' commitment to helping patients understand their healthcare charges and increasing price transparency and access to healthcare data to assist providers, payers, and especially patients, as they consider choices in healthcare. The ASC community supports efforts by employers, insurers and government officials to allow comparison of quality, outcomes, and price for comparable services that are provided in multiple settings, such as HOPDs and ASCs.

ASCA strongly believes that patients would benefit from being able to compare procedure costs across sites of service. Many procedures can be performed safely and effectively at more than

one site of service (i.e., HOPD and ASC). Congress demonstrated the importance of comparing costs across these two sites of service by passing legislation in 2016 instructing the Department of Health and Human Services (HHS) to develop a cost-comparison website for Medicare patients. This tool is now publicly available, and a great resource for those considering having elective outpatient surgery.

Unfortunately, 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. So when Medicare beneficiaries utilize the CMS cost comparison tool, they will actually see a higher cost to them in the ASC than the HOPD for higher-cost procedures since ASCs do not have the same patient responsibility cap. Beneficiaries who would otherwise save money by coming to the convenient, high-quality ASC setting are disadvantaged by this lack of alignment in policy. While 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, this is changing as more and more procedures are added to the ASC-payable list. As this requires a statutory fix, ASCA will be working with Congress to address this issue.

While ASCA believes this site is beneficial to consumers, as we discussed in the quality reporting section of these comments, it would also be beneficial to have quality data available across sites of service to provide a more complete picture to beneficiaries of not only the cost but the quality of care being provided at different healthcare settings.

Summary

While we are encouraged by the Agency's stated desire for ASCs to remain a viable outpatient surgical option for Medicare beneficiaries, not all the current policies align with this goal. The recommendations in this comment letter highlight several areas where CMS can facilitate movement of outpatient procedures to the ASC setting in a fiscally responsible manner without compromising patient outcomes or quality of care. We appreciate the opportunity to provide feedback on the Agency's work and are prepared to discuss these issues further at your convenience.

As always, ASCA welcomes the opportunity to meet with policymakers to collaborate on payment policy changes that will encourage migration and reduce the total cost of care to Medicare. 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 Knee Arthroplasty Research

Low complication rates in outpatient total knee arthroplasty

May 2019

Knee Surgery, Sports Traumatology, Arthroscopy

Finding: Study examined roughly 1,000 patients undergoing outpatient TKA between 2013 and 2016. Reoperation within 90-day rate was 0.7%, 0.8% of patients required revision, deep infection rate of 0.17%. Authors conclude that outpatient TKA is safe for a large proportion of patients, though certain co-morbidities may increase the risk of overnight stay.

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.

Inpatient versus Outpatient Total Knee Arthroplasty

February 2019

The Journal of Knee Surgery

Finding: Authors evaluate outcomes for outpatient TKA in light of removal from Medicare IPO list. They note that there have been no differences in patient-reported outcomes or satisfaction levels between outpatient and inpatient TKA (possibly slight patient satisfaction in favor of OP). The literature is largely in agreement supporting that OP TKA can be safely performed. However, a considerable amount of Medicare patients may not be candidates for OP TKA (authors recommend BMI < 35, ASA < 3, Age < 70).

[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.

[Quality of Recovery, Postdischarge Hospital Utilization, and 2-Year Functional Outcomes After an Outpatient Total Knee Arthroplasty Program](#)

July 2018

The Journal of Arthroplasty

Finding: Study compared 43 inpatients and 43 outpatient TKAs between 2010 and 2015 by a single surgeon. Patients were given a diary to complete at post-discharge intervals, and study tracked 90-day complications, readmissions, and ED visits. Outpatient TKA in selected patients produced similar short-term and 2-year patient-reported outcome measures and a comparable 90-day post-discharge hospital resource utilization when compared to an inpatient cohort, supporting further investigation into outpatient TKA.