September 7th, 2017

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Via online submission at www.regulations.gov

Re: CMS-1678-P – Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Verma:

The Ambulatory Surgery Center Association (ASCA) submits these comments on behalf of the 5,500 Medicare-certified ASCs nationwide in response to the calendar year (CY) 2018 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule ("Proposed Rule") (82 Fed. Reg. 138, July 20, 2017).

We appreciate the willingness of the Centers for Medicare and Medicaid Services (CMS) to engage industry stakeholders in a dialogue regarding ways to improve the payment systems. It is encouraging to see the agency engaging in new thinking about ways in which the health system can be improved through greater efficiencies. Below are our comments that outline ASC payment policy proposals that will encourage the appropriate migration of services into the lower-priced ASC setting – offering the Medicare program and its beneficiaries a substantial savings opportunity while ensuring access to the high-quality care that ASCs provide.

Specifically, our comments focus on the following key topics:

- **Conversion Factor.** CMS should replace the Consumer Price Index for Urban Consumers (CPI-U) with the hospital market basket as the update mechanism for ASC payments. Hospital outpatient departments (HOPDs) are updated based on the hospital market basket, and the annual increases in the cost of doing business in an HOPD – equipment, devices, implants, facility upkeep and staffing costs – are comparable in ASCs.

- **Rescaling adjustment**. CMS should apply the OPPS relative weights to ASC services and discontinue its practice of rescaling the ASC relative weights. This secondary scaling adjustment is exacerbating the gap between the ASC and OPPS rates that discourages the use of lower-cost ASC settings.

- **Procedures Permitted in ASCs.** CMS should expand the definition of surgical codes and should reimburse ASCs for all surgical codes for which it reimburses HOPDs.

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- **Joint Replacements.** CMS should remove total knee arthroplasty (TKA), partial hip arthroplasty (PHA) and total hip arthroplasty (THA) from the Medicare inpatient-only list and add these codes to the ASC-payable list. These procedures are currently being done safely and effectively on appropriate patient populations in ASCs.

- **Device-Intensive Procedures.** CMS should lower the device-intensive threshold to 30 percent to enable migration of services into the less-expensive ASC setting.

- **ASC Quality Reporting.** CMS should approve an electronic survey option and shorten the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) before mandating use of the survey.

Continued Divergence of Payment Rates

As we have mentioned in previous comment letters, analysis by university researchers[1] and the federal government[2] demonstrate that ASCs reduce Medicare system costs by billions of dollars annually. ASCs have achieved cost savings and produced high-quality outcomes for the Medicare program and its beneficiaries, but an increasing disparity in payment rates threatens patient access to the ASC setting. Whereas ASCs were paid approximately 85 percent of HOPD rates in 2003, under the proposed CY 2018 payment rates ASCs would be paid approximately 53.5 percent of what hospitals receive for performing the same procedures.[3]

Most ASCs are small businesses, and as such, must run efficiently to remain viable. As of June 2017, there are 5,561 CMS-certified ASCs[4], and over 55 percent – 3,077 – 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, since they do not have the same purchasing power of a hospital or large health system. ASCs must compete with hospitals and other health care providers for the same nurses and other staff, all while complying with similar state and federal regulations and an ever-growing Medicare quality reporting program. And yet, CMS updates ASCs using ant annual update factor that drives this growing disparity in reimbursement rates. While ASCs pride themselves on running efficiently, being reimbursed less than 54 percent on average for the same procedures being provided in a similar site of service jeopardizes the ability of our facilities to perform Medicare cases.

Surgical care in too many markets continues to be provided predominantly in hospitals, which we attribute to Medicare's failure to pay competitive 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.

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[1] *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.

[2] U.S. Department of Health and Human Services. Office of Inspector General. Washington: Government Printing Office, April 2014. (A-05-12-00020)

[3] Based on a volume-weighted ratio of the ASC rate to the OPPS rate since 2012 for the top 200 codes by volume in the ASC setting. This analysis examined the ratio only for surgical codes for which the rate is based off the OPPS rate, excluding office-based rates and codes where the ASC and OPPS rate were the same (i.e. drugs).

[4] 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/.

CMS should act to halt the divergence between ASC and OPPS payment rates by better aligning payment policies

CMS should replace the Consumer Price Index for Urban Consumers (CPI-U) with the hospital market basket as the 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.[5] Unfortunately, there are several areas in which the payment systems are not aligned, thwarting CMS's objectives. While the ASC update is based on the Consumer Price Index for All Urban Consumers (CPI-U), the OPPS update is based on the inpatient Hospital Market Basket (HMB), which has historically been a better reflection of the impact of inflation on the type of outpatient care provided in ASCS. Consistent with our past comments, ASCA strongly urges CMS to adopt the same update factor for both the ASC and OPPS payments.

Members of Congress are supportive of ASCA's position as evidenced by the *Ambulatory Surgical Center Quality and Access Act of 2017* (H.R. 1838/S. 1001), which has broad and bipartisan support. This legislation requires CMS to use the HMB to update ASC payments, which would equalize the playing field between ASCs and HOPDs and allow patients continued access to the ASC setting.

Consumer Price Index for All Urban Consumers (CPI-U)

CPI-U is not a suitable inflation index to update ASC payments because it does not accurately represent the costs borne by facilities, ASCs or otherwise, to furnish surgical procedures. The CPI provides an estimate of the price change of consumer goods between any two periods (typically monthly). The CPI follows the prices of a sample of items in various categories of consumer spending that residents of urban or metropolitan areas buy for day-to-day living. A detailed listing of the major categories in the CPI index and their "relative importance" are listed below in **Table A.**

Table A. CPI-U: Relative Importance by Expenditure Category, December 2016

Expenditure Category	Relative Importance
Food and Beverages	**14.649**
Food	13.698
Alcoholic Beverages	0.952
Housing	**42.634**
Shelter	33.652
Fuels and Utilities	4.954
Household Furnishings and Operations	4.029
Apparel	**3.034**
Men's and Boys' Apparel	0.750

[5] CY 2007 OPPS/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).

Women's and Girls' Apparel	1.228
Infants' and Toddlers' Apparel	0.150
Footwear	0.691
Transportation	**15.318**
Private Transportation	14,232
Public Transportation	1.086
Medical Care	**8.539**
Medical Care Commodities	1.852
Medical Care Services	6.687
Recreation	**5.663**
Education and Communication	**6.984**
Education	3.209
Communication	3.775
Other Goods and Services	**3.178**
Tobacco and Smoking Products	0.665
Personal Care	2.513
All Items	**100.000**

Source: https://www.bls.gov/cpi/cpi_dr.htm

Only approximately 8.5 percent of the index's inputs track anything having to do with healthcare, and even those inputs track a consumer's experience purchasing healthcare items, rather than a provider's experience purchasing the items necessary to furnish a healthcare service. As such, if the amount a provider charges a consumer remains flat – *e.g.*, because Congress allows for inadequate inflation updates for physician services or insurers compress payment growth – the "medical care" components of the CPI-U also will remain flat. However, that says nothing of whether a facility's costs increase, such as the cost of purchasing supplies and equipment or personnel labor costs.

The ASC payment system is one of the last CMS payment systems to be tied to the CPI-U. The other payment systems still using CPI-U are the ambulance fee schedule, the clinical lab fee schedule (which will begin using market-based rates in 2018 pursuant to the *Protecting Access to Medicare Act of 2014*), and durable medical equipment, prosthetics/orthotics, and supplies fee schedule (much of which is now subject to competitive bidding and therefore not inflated using CPI or any other measure). As seen in **Table B**, other payment systems use indices derived from the basket of goods that those providers purchase.

Table B. Inflation Updates by Medicare Fee-for-Service Payment System

Payment System	Inflation Update
Ambulance Fee Schedule	CPI-U
Ambulatory Surgical Center Payment	
Clinical Lab Fee Schedule*	
DMEPOS Fee Schedule	
End Stage Renal Disease PPS	ESRD Bundled Market Basket
Federally Qualified Health Center PPS	Medicare Economic Index
Home Health PPS	Home Health Market Basket
Hospice	Hospital Market Basket Index
Hospital Outpatient PPS	

Payment System	Inflation Update
Inpatient PPS (includes inpatient PPS, children's hospitals and cancer hospitals)	
Inpatient Psychiatric Facility PPS	Rehabilitation, Psychiatric and Long-term Care (RPL) Market Basket
Inpatient Rehabilitation Facility PPS	
Long-Term Care PPS	Long-Term Care (LTC) Hospital Market Basket
Skilled Nursing Facility PPS	Skilled Nursing Facility Market Basket Index

Source: FFS payment systems under Medicare (http://www.cms.gov/Medicare/Medicare.html)
* Starting CY 2018, the rates will be updated by private payer reported rates on a one-year or three-year basis.

Hospital Market Basket (HMB)

Alternatively, the HMB index, the annual inflation update used for HOPDs, is comprised of data that reflects the cost of items and services necessary to furnish an outpatient surgical procedure, such as compensation, utilities, labor-related services and non-labor related services. A detailed listing of all categories, their weights, and price proxies are summarized in **Table C**.

Table C. HMB Categories, Proposed Weights and Proposed Price Proxies

HMB Category	Proposed 2014-Based Cost Weights	Proposed 2014-Based IPPS Market Based Price Proxies
Compensation	**55.8**	
*Wages and Salaries**	*43.4*	ECI – Wages and Salaries for All Civilian Workers in Hospitals
*Benefits**	*12.4*	ECI – Total Benefits for All Civilian Workers in Hospitals
Utilities	**2.5**	
*Electricity****	*1.0*	PPI – Commercial Electric Power
*Fuel: Oil and Gas****	*1.3*	Blend of PPIs for Petroleum Refineries and Natural Gas
*Water Sewage****	*0.1*	CPI – Water & Sewage Maintenance
Professional Liability Insurance	**1.2**	
*Malpractice***	*1.2*	CMS Hospital Professional Liability Insurance Premium Index
All Other	**40.5**	
All Other Products	*17.4*	
Pharmaceuticals	5.9	PPI – Pharmaceutical for Home Use
Food: Direct purchases***	2.3	PPI – Processed Foods and Feeds
Food: Contract services***	1.3	CPI – Food Away From Home
Chemicals***	0.9	Blend of Chemical PPIs
Blood**	0.8	PPI – Blood and Organ Banks
Medical Instruments ***	2.9	Blend of PPIs for Surgical and Medical Instruments and Medical and Surgical Appliances and Supplies
Rubber and Plastics***	0.8	PPI – Rubber and Plastics Production
Paper and Printing Products***	1.5	PPI – Convert Paper and Paperboard
Miscellaneous Products***	1.1	PPI – Finished Goods Less Food and Energy
Labor-Related Services	*12.5*	

HMB Category	Proposed 2014-Based Cost Weights	Proposed 2014-Based IPPS Market Based Price Proxies
Professional Fees: Labor Related***	6.8	ECI – Compensation – Professional and Related (Private)
Administrative***	1.0	ECI – Compensation – Office and Administrative Support (Private)
Installation, Maintenance and Repair***	2.4	ECI – Compensation – Installation, Maintenance and Repair
All Other: Labor Intensive***	2.3	ECI – Compensation – Service Occupations (Private)
Non-Labor Related Services	*10.7*	
Professional Fees: Non-Labor Related***	5.1	ECI – Compensation – Professional and Related (Private)
Financial Services***	3.0	ECI – Wages and Salaries – Financial Activities (Private)
Telephone***	0.8	CPI – Telephone Services
All Other: Non-Labor Intensive***	1.7	CPI – All Items Less Food and Energy
Total HMB	**100.00**	

Note: Weights may not add due to rounding.
Source: FY 2018 Inpatient Prospective Payment System Proposed Rule
https://s3.amazonaws.com/publicinspection.federalregister.gov/2017-07800.pdf
* Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.
*** Represents cost category where cost weight is derived using 2002 Benchmark I-O data.

Proposed Alternatives to the CPI-U

While ASCA continues to believe the HMB is the most appropriate update factor for ASCs and HOPDs, there are a variety of other indices found in the CPI and Medicare Economic Index (MEI) that also would be suitable for both settings. In the Proposed Rule, CMS requests feedback on alternative update factors, which we have provided below. **Table D** shows how the alternative update factors compare to the CPI-U from 2010 – 2017 (e.g., if the CPI-Medical Care index was used during this timeframe instead of the CPI-U, the ASC conversion factor would be 10.6% higher.)

Table D. Comparison of Update Factor Indexes

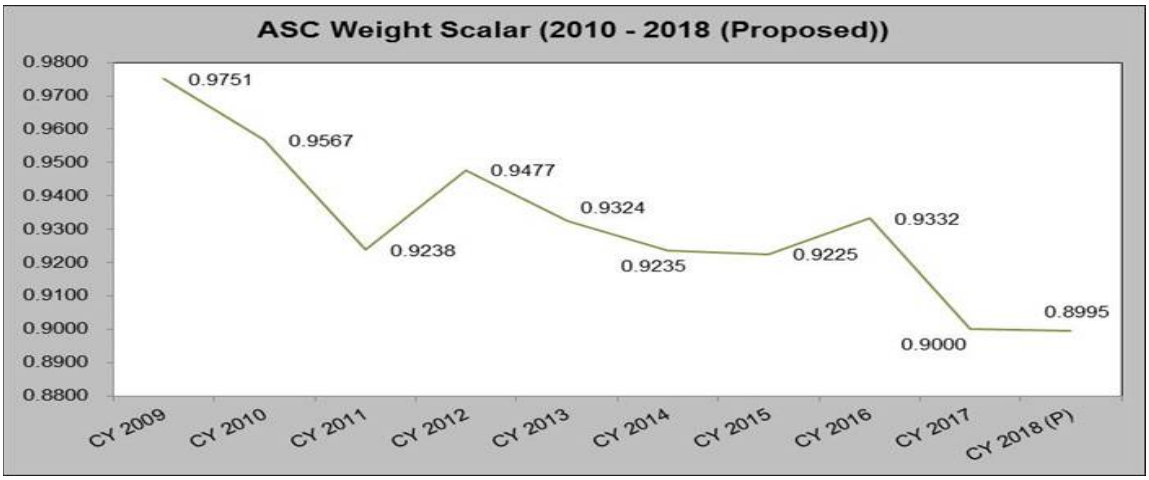
Index	% Diff. from Existing Conversion Factor, 2010 – 2017
Hospital market basket	7.6%
CPI-Medical care	10.6%
CPI-Medical care services	11.4%
CPI-Outpatient hospital services	26.4%
CPI-Medical care commodities	8.3%
PPI-Health care services	1.1%
PPI-Hospital Outpatient Care	6.6%
PPI-Outpatient care (partial)	-1.6%

Taking into consideration the percent difference of the alternative indexes from the CPI-U over a seven-year period and the inputs to the alternative indexes, we believe the HMB basket index is still the most appropriate factor to be used for updating the ASC Payment System. While we appreciate that the HMB does not perfectly align with the ASC cost structures, the HMB is more representative of the cost structure than the CPI-U or other factors considered. Therefore, we once again urge CMS to update the ASC Payment System using the HMB starting with CY2018.

CMS should eliminate the secondary rescaling adjustment that is applied to the ASC relative weights.

The additional scaling factor that CMS applies to the ASC weights is intended to maintain budget neutrality within the payment system; however, a consequence of this scaling is the ever-increasing payment differentials between ASC and HOPD payments. There is no evidence of growing differences in capital and operating costs in the two settings to support this growing payment differential.

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 result in an increase in ASC relative weights. As the graph below indicates, the rescaling adjustment has decreased the relative weights for ASC surgical procedures significantly since the ASC payment system was implemented. For the first time ever, for 2018, the secondary rescalar is proposed to be less than 0.9000.



The historical trend seen above, and the absence of any indication that it is likely to reverse in the future, suggests that the application of the rescalar in the ASC setting will continue to erode the relationship between ASC and HOPD rates.

By applying ASC-specific adjustments like the scalar, CMS is exacerbating the gap between OPPS and ASC rates. In so doing, the Agency is needlessly increasing 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 in which to perform needed care for Medicare beneficiaries, CMS should discontinue use of the ASC relative weight scalar.

If CMS declines to suspend the rescalar as we suggest, the Agency should at least create a minimum relationship ratio of ASC payment to OPPS payment for any service where the payment rate is based on OPPS payments (*i.e.*, excluding those that are based on physician fee schedule payment amounts). With respect to both suggestions – discontinuing the scalar or creating a minimum relationship ratio – CMS should implement these changes without also applying a budget neutrality adjustment within ASC payments. To do otherwise would undermine and dilute the very objective CMS should be striving for: to encourage more procedures to migrate to a lower-cost, high-quality setting.

There are a variety of ways CMS could empirically set an appropriate minimum relationship ratio. As an initial test to evaluate the impact of a policy change of this type on migration of surgical procedures, and in recognition of the budget constraints of the Medicare program, ASCA recommends that CMS *begin* with a very conservative minimum relationship ratio of 55 percent, meaning that no ASC payment amount could be less than 55 percent of the corresponding OPPS payment rate. Payment amounts for procedures where the relationship ratio is greater, such as those designated as device intensive, would continue to be set by CMS policy for those types of codes. If after a period of time CMS sees that procedures are not migrating with sufficient speed to the ASC setting, CMS could gradually increase that minimum relationship ratio.

ASCA is proposing that CMS set the initial minimum relationship ratio at 55 percent of the comparable OPPS payment rate because 55 percent was the typical payment ratio between these sites of care in CY 2014, when CMS policies, including expanded packaging and the creation of the Comprehensive APCs, contributed to further divergence between the payment systems. We recommend that, for OPPS codes that fall into Comprehensive APCs, this floor should be implemented relative to the alternative payment rate (i.e., without C-APC status) for those codes that CMS already calculates in the process of setting ASC rates. We believe addressing this issue will help shift more procedures into the ASC setting, reducing overall Medicare expenditures.

Importantly, CMS already has the authority to implement either change. CMS implemented the scalar pursuant to its own perceived authority, and not pursuant to any identified statutory requirement. As such, CMS can likewise discontinue the scalar at its discretion under the same rationale.

The same goes for a percentage relationship-based minimum, or floor. The statute that required CMS to implement a revised payment system for Ambulatory Surgical Centers (Section 626(b) of the Medicare Modernization Act of 2003) granted CMS broad authority to design the payment methodology and placed no limit that would inhibit the agency's ability to implement a floor, and nothing elsewhere within Section 1833(i) of the Social Security Act limits the agency's ability to implement the kind of adjustment proposed here.

In addition, 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.[6] CMS has full authority to increase payments to ASCs (for example, by preventing the further relative deterioration of rates compared to hospitals performing the identical services), particularly if it believes such policies will help constrain overall Medicare spending. CMS should pursue policies that encourage greater competition and savings across the health care system.

CMS Should Revise its Definition of ASC Surgical Procedures

CMS is requesting public comments regarding "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]

Since 2008, CMS has defined surgical procedures permitted in an ASC as those described by Category I CPT codes in the surgical range from 10000 through 69999, as well as those Category III CPT codes and Level II HCPCS codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that CMS has determined do not pose a significant safety risk, would not expect to require an overnight stay when performed in an ASC, and are separately paid under the OPPS.

Strict adherence to the CPT surgical code groupings, as CMS notes in the Proposed Rule, does not properly account 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] The current definition is also inconsistent with how CMS defines surgery for other purposes. For example, in a 2009 National Coverage Determination in which CMS explained payment policies for certain surgical errors, the definition was much broader:[9]

> "Surgical and other invasive procedures are defined as operative procedures in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. Invasive procedures include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. ***They include all procedures described by the codes in the surgery section of the Current Procedural Terminology (CPT) and other invasive procedures such as percutaneous transluminal angioplasty and cardiac catheterization.*** They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include use of instruments such as otoscopes for examinations or very minor procedures such as drawing blood." (Emphasis added)

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[6] 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.

[7] 82 Fed. Reg. 33655

[8] 82 Fed. Reg. at 33655

[9] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R101NCD.pdf

Medicare's State Operations Manual: Appendix L[10] adopts a similarly broad definition of "surgical procedures," which CMS adopted from the American College of Surgeons. ASCA, therefore, recommends that CMS revise the definition of surgical procedure such that it can better accommodate not only existing procedures, but procedures made available through technical advances that we have not yet considered.

As CMS undertakes its annual update to the ASC list of covered surgical procedures and covered ancillary services, and considering the interest in expanding the scope of covered services to certain "surgery-like" procedures, we would request that CMS include the following 38 CPT codes on the list of ASC codes that are eligible for separate payment.

Cardiac Diagnostic Catheterization - Catheter Placement with Angiography
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93531
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93564
93565
93566
93567
93568
Cardiac Interventions - Catheter Placement with Angiography
92920
92921
92928
92929
92937
92938
92973

[10] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_l_ambulatory.pdf

92978
92979
C9600
C9601
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.

In the proposed rule, CMS suggests that the CPT surgical range of codes may be better used "as a guide rather than a requirement. . ."[11] ASCA strongly supports this approach, as a reliance on current designations has resulted in some procedures being included on the covered procedures list while other, very similar procedures, remain excluded. For example, many cardiac catheterization procedures that allow for endovascular diagnosis and treatment of cardiac vessel conditions are excluded, while similar endovascular procedures, including the stenting of arteries performed on peripheral blood vessels is permitted. This rigid dichotomy in coverage is driven by the CPT groupings and is not a logical result when the clinical underpinnings of the disease and treatment are considered. The disease processes leading to peripheral artery and heart disease are the same. Modern diagnosis and treatment of the conditions are the same.

ASCA strongly encourages CMS to move forward as quickly as possible with an expanded definition for surgical procedures to make these services available to Medicare beneficiaries in a lower cost, more convenient, and highly preferred site of service. We also encourage CMS to immediately consider the codes we recommend that are within the CPT surgical range and are clinically similar to existing services already covered by the ASC payment system. Given that these codes meet the standards established by CMS for inclusion on the ASC code list, we believe they should be included on the ASC-Payable List for CY 2018.

CMS Should Expand the ASC-Payable List

Proposed addition of three new codes to ASC-Payable List

We appreciate that CMS has proposed to add the following three codes to the ASC list in 2018:

- 22856 (Cerv artific diskectomy)

[11] 82 Fed. Reg. at 33655

- 22858 (Second level cer diskectomy)
- 58572 (Tlh uterus over 250 g)

That said, as we've discussed in previous comments, second level spine codes such as CPT 22858 come with significant additional costs, including increased operating room and staff time. CMS will not see volume migrate out of the inpatient setting and into the ASC without providing adequate reimbursement for this code. We would appreciate the opportunity to further discuss how the decision to package this and other codes together have negatively impacted the migration of procedures to the outpatient setting.

Codes Payable in HOPD Setting Excluded from ASC-Payable List

Currently, there are still hundreds of codes that CMS reimburses in HOPDs but not ASCs. Surgeons in ASCs are performing these procedures safely on non-Medicare patient populations. Specifically, there are 345 surgical CPT codes that are separately payable in the HOPD but not the ASC. These procedures are designated as Surgical Procedures Excluded from Payment in ASCs, but are not included on the inpatient-only list. With technological advances increasingly driving procedures from the inpatient to the outpatient setting, 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. 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.

CMS should remove total knee arthroplasty (TKA), partial hip arthroplasty (PHA) and total hip arthroplasty (THA) from the Medicare inpatient-only list.

Total knee arthroplasty (TKA), CPT code 27447, partial hip arthroplasty (PHA), CPT code 27125, and total hip arthroplasty (THA), CPT code 27130, were historically inpatient surgical procedures that required lengthy hospital stays. As CMS acknowledges in the Proposed Rule, 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.

Orthopedic surgeons in ASCs are increasingly performing these procedures safely and effectively on non-Medicare patients, and appropriate Medicare beneficiaries who meet patient selection criteria would be able to benefit from TKA, PHA and THA in the outpatient setting. They would be able to leave the hospital within 24 hours, and should expect high levels of satisfaction, good pain control, and minimal risk of readmission or ER visits post-operatively.

As CMS mentions in this rule, 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, PHA or THA 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. Removing a procedure from the inpatient-only 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, PHA and THA need 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, PHA or 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 TKA, PHA and THA procedures with us have emphasized the importance of careful patient selection and strict protocols to optimize outpatient joint replacement outcomes.

As noted in the CY 2012 OPPS/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 OPPS 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 TKA, PHA and THA meet all the criteria below and should be removed from the inpatient-only list. The decision to propose removal of TKA from the inpatient-only list in 2018 was based on CMS staff's belief that the code can meet these, and ASCA believes that since the same criteria are met for the hip arthroplasty codes, those 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 TKA, PHA and 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.

TKA (27447) is related to partial knee replacement, CPT 27446, which is currently on the ASC-payable list. The only difference between a partial knee replacement and a total knee replacement is approximately 15 minutes of additional operative time for the TKA procedure. Patient selection criteria are the same, and the patient will still need the same pre- and post-procedure instructions and therapies no matter which is performed (CPT 27447 or 27446). The procedures are similar in technique, recovery time and pain management, and the same equipment is needed to perform the surgery. The same anesthesia services are provided, and the same post-surgical observation period prior to discharge from the PACU is required. 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 TKA from being performed in the outpatient setting on the Medicare population.

Procedures described by CPT codes 27125 and 27130 are 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.

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 know that an increasing number of ASCs are performing these procedures. A few years ago, there were relatively few facilities performing these procedures. We now conservatively estimate between 200-250 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.[12]

Mississippi Valley Surgery Center in Davenport, Iowa, for example, has performed more than 1,400 total joint replacement procedures since 2007, including 984 TKAs and 431 THA. Already in 2017, they have performed 117 TKAs and 47 THAs. Extensive review by insurance providers was required with eventual approval only after review of outcomes data.

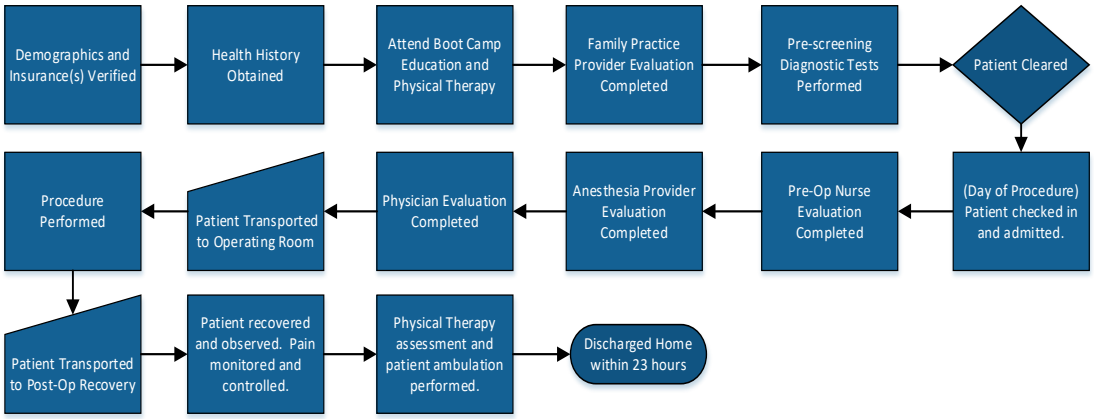
At the Advisory Panel on Hospital Outpatient Payments (HOP) August 2017 meeting, Dr. Sohrab Gollogly presented data from a retrospective study of 100 ASC total joint replacement patients from two facilities near Monterey, California. At this meeting, the HOP unanimously voted to recommend removal of TKA from the inpatient-only list. Dr. Gollogly and his facility expanded the study to 200 patients and presented as a Poster Paper at the American Academy of Orthopaedic Surgeons (AAOS) 2017 Annual Conference. The patients ranged in age from 38 to 84, with an average age of 59 years old. Of those patients, there were zero infections reported, only two emergency room visits for pain management only, and two hospital admissions within five days, one for an allergic reaction and one for deep vein thrombosis (DVT). The results also showed very high patient satisfaction scores, as 98 percent would recommend the ASC for this type of procedure to their friends and family.

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 judgement 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 TKA, PHA or THA procedure. Having options allows the physician and patient to determine the most appropriate setting of care.

Surgeons who perform outpatient TKA, PHA and THA procedures know the importance of careful patient selection and strict protocols to optimize outpatient TKA, PHA and THA 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. Please see below the process in place at Mississippi Valley Surgery Center once joint replacement is selected as the appropriate course of action.

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



Where and when a TKA, PHA or THA should take 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 27447, 27125 and 27130 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 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 TKA, PHA and 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 would 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. We would support the analysis that has been submitted by another commenter, Smith & Nephew, showing the appropriate APC classification.

CMS Should Lower the Device-Intensive Threshold to Encourage Migration of Services to the ASC Setting

CMS classifies codes with high, fixed device costs as "device-intensive codes," which are currently defined as those procedures that have a device offset greater than 40 percent of the mean cost of the procedure when provided in the HOPD setting. ASCA appreciates that CMS released HCPCS level device-intensive offset calculations with the proposed rule, as it allows us to better articulate how our proposed policy change could help encourage migration of procedures to the lower-cost ASC setting.

CMS should lower the device intensive threshold to 30 percent of the HCPCS code level.

When ASC services have device costs that are less than 40 percent of the overall cost in the HOPD setting, the conversion factor is applied to the entire relative weight for the service, effectively discounting the payment for the device by more than 40 percent over what is paid to the HOPD. Since an ASC's non-device reimbursement is approximately 53.5 percent of that in the HOPD setting, CMS should lower the 40 percent threshold to allow for ASCs to perform more procedures with substantial device costs.

As an example, if the overall procedure cost is $1,000 and the calculated device offset percentage is 39.9%, i.e., the device costs the hospital $399, the ASC would receive no added reimbursement for the device and only $535 to perform the procedure. The ASC would receive just $136 to cover all the facility's other costs for that patient encounter. As mentioned above, the actual device cost to the ASC might even be higher than what is reflected by HOPD device offset amounts since the ASC does not have the purchasing power of a hospital or large health system.

Although there are many codes that could be highlighted, one real-life example of the challenge with the current device-intensive policy is easily identified in CPT 19357 (Breast reconstruction). The ASC proposed payment rate for this code is $3,042.59, ***$266.88 less than*** the 2018 proposed device-offset for this code of $3,309.47.

As a comparison, the proposed payment rate in the HOPD setting for CPT 19357 is $10,407.15. CMS has deemed this procedure safe and effective for the ASC setting, but the agency will not see any significant volume in the ASC because at this payment rate, ASCs will not even be able to cover the device cost.

Given that our non-device payment is already less than 54 percent of that paid to HOPDs, ASCA strongly recommends that CMS drop the device-intensive threshold to 30 percent for ASCs to encourage migration of these codes to the ASC setting. Based on the HCPCS-level device offset document that was released with the proposed rule, there are currently 164 codes that have a device-offset between 30 and 40 percent. These are codes for which CMS will not see significant volume in the ASC setting until payment reflects the significant device costs involved.

Once again using one of those 164 codes – CPT 19357 – as an example, if the device threshold were lowered, the ASC would be reimbursed $3,309.47 for the device plus $3,042.59 for the non-device portion. At $6,352.06 total, this rate would allow an ASC to pay for the device and the routine overhead expenses associated with the procedure, and this rate would also save CMS and its beneficiaries $4,055.09 every time the procedure is performed in the ASC setting instead of the HOPD. By dropping the device-intensive threshold to 30 percent, CMS will reduce costs for both the system and its beneficiaries by allowing f volume to shift to the ASC setting.

In addition to lowering the device intensive threshold, we request that CMS use the Final rule to outline its methodology for calculating the device intensive threshold percentages to allow stakeholders to replicate the methodology. This will allow us to more adeptly advocate for policies that save Medicare and its beneficiaries money.

Key Comments on Quality Reporting Program Changes

A decade ago, the ASC community coalesced behind a group of stakeholders, the ASC Quality Collaboration (ASC QC), to develop, test and seek endorsement of measures specific to the ASC setting. As CMS acknowledges in this rule, the ASC QC is "an entity recognized within the community as an expert in measure development for 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 highlight below some of the proposed policies that are of utmost interest to ASCA members.

ASCA Supports Proposed Delay of the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) Survey

CMS cited its desire to "appropriately account for the burden associated with administering the survey in the outpatient setting of care" as one reason for delaying mandatory implementation of the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) survey and the five measures based on this survey. ASCA appreciates this reconsideration, and supports delaying mandatory implementation of the survey until it is shortened and there is an electronic option available. Both developments would significantly reduce the cost and administrative burden to our facilities and make the survey easier for our patients to complete.

Cost to Facilities

Besides the cost of finding and securing a third-party vendor, of which there are currently 23 that are CMS-approved, the direct costs associated with the current modes of conducting this survey are higher than necessary. Presently, there are three approved modes of administration: mail only, telephone only and mail with a telephone follow-up. Based on the data we have collected from vendors, we project that in 2018 an average cost per center will be approximately $500 per month, but this amount could be higher depending on the mode selected by the ASC. This cost estimate includes:

- Survey vendor fees for one of the approved modes;
- Report maintenance fees (could be up to $125/month depending on the billing company);
- Time to upload the files

Internet access and email accounts are common today and should be an approved mode for data collection. Survey vendors already offer electronic survey options to their customers, and the return rates are as good as, and often better than, other survey modes for patient populations of all ages. Particularly if facilities would like to include their own questions, making the survey even longer, it is critically important that the survey be as user-friendly and as inexpensive as possible.

Survey length

The survey should be significantly shorter, focusing on actionable aspects of patient experience in the outpatient setting and essential demographic data. We continue to believe that the inclusion of 13 demographic questions in the "About You" section of the survey is excessive.

In addition, there are currently 24 questions regarding the patient's experience. If a facility chooses to add its own questions to collect information to enhance the patient experience in their facility (facilities can add up to 15 questions), this could become a 52-question survey. Our facilities have found that they achieve the highest success rate with short, concise surveys of no more than 5-10 questions. Our fear is that the return rate for a survey five to ten times that length will be extremely low, and that patients and facilities will not be able to glean any meaningful information due to low response rates.

ASCA strongly supports quality reporting measures that speak to the quality of care being provided by the facility and that will help improve both care and the patient experience. We have serious concerns, however, that the survey will not be as helpful as it could be, for facilities and potential patients alike, if the issues outlined above are not addressed. We ask that CMS maintain the voluntary nature of the OAS CAHPS survey until it is shortened and an electronic option is added as an approved survey mode.

New Measures Proposed for Addition in the ASCQR Program

CMS has proposed to adopt *ASC-16: Toxic Anterior Segment Syndrome (TASS)* for CY 2021 payment determination and subsequent years. As referenced in the rule, this measure is maintained by the ASC QC, and ASCA supports its inclusion in the ASCQR Program.

CMS also proposed two new measures for CY 2022 payment determination and subsequent years: *ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures* and *ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures.* 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.

CMS is also inviting public comment on the Ambulatory Breast Procedure Surgical Site Infection Outcome measure (NQF #3025) for potential inclusion in the ASCQR Program in future rulemaking. ASCA supports the inclusion of this measure in the ASCQR Program.

Suggestions for Reforming the ASC Payment System

ASCA appreciates CMS' solicitation of comments on how to reform the ASC payment system.

Alternatives to the CPI-U

As discussed on pages 3-7 of these comments, ASCA has evaluated update factors that could be used as an alternative to the CPI-U, and has not found any more appropriate than the hospital market basket, considering the inputs considered and the cost to the program. Since ASC payments are tied to the OPPS, ASCA recommends that CMS utilize the same update factor used for HOPDs to update ASC payments moving forward.

Cost data

CMS is also soliciting comments on "payment reform for ASCs, including the collection of cost data which may support a rate update other than CPI-U." We appreciate this request and welcome the opportunity to work with you in the future to collaborate on ideas.

We know that the same types of costs that apply to the hospital outpatient department are also present in the ASC, 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, perhaps voluntary in nature, that calculates expense categories as a percentage of total expenses to help

determine the appropriate weights and price proxies for the ASC setting. A complicating factor, however, remains the heterogeneity of the ASC model—the range of size and specialty care varies greatly from one ASC to the next.

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.

Institutional claim form

CMS requests input as to whether transitioning from use of the professional claim (CMS-1500) to an institutional claim (UB-04) would "address some of the issues affecting ASC payment reform." ASCs incur a downward payment adjustment based on a secondary rescalar that is not mirrored in the OPPS. ASC payments are updated annually based on the CPI-U even though the payment system to which we are tied, the OPPS, is updated based on the hospital market basket. It is economically infeasible for ASCs to perform many procedures that have significant device costs but do not meet the device intensive offset threshold. These are the major issues impacting ASC-HOPD payment differentials, and none of them would be fixed by shifting to the institutional claim form.

If all other payers were fully using the UB-04 there might be a more compelling case for requiring ASCs to do so. However, several payers, such as the Department of Labor and automobile carriers, still require the CMS-1500 claim form, and Medicaid, workers compensation insurers and some private payers allow for submission of either the CMS-1500 or the UB-04 depending on state requirements and private payer contracts. For facilities that solely use the CMS-1500, requiring a new form would add needless administrative burden. We request that if CMS chooses to pursue this change in the future, the Agency provide an extensive transition period to allow for successful implementation across facilities.

Comment Solicitation on Intraocular Procedure APCs

CMS is requesting feedback as to whether the Agency should create a new Intraocular Procedures comprehensive APC (C-APC) that includes complex cataract surgeries identified by CPT code 66982 (along with other intraocular procedures that are similar in resources). Making this change would separate complex cataract procedures from those identified by CPT code 66984. CMS acknowledges in the rule that although "it is impracticable and contrary to the principles of a prospective payment system to assign each procedure to its own APC, thus resulting in a cost-based, fee schedule payment system," the Agency seeks "to ensure our clinical groupings appropriately group like items and services while maintaining the integrity of a prospective payment system under which bundled, encounter-based payments are essential."

ASCA supports the comments of the Outpatient Ophthalmic Surgery Society that it is both impractical and unnecessary to create a new C-APC value to encompass complex cataract surgeries. Accurately identifying facility costs for a diversity of complex cataract diagnoses and surgical plans is unrealistic, and already appropriately reflected in surgeon's professional fees. ASCA recommends that these codes remain in one APC, consistent with CMS' desires to create clinically homogeneous APC groups.

Physician-Owned Hospitals

In this rule, CMS seeks comments on the appropriate role of physician-owned hospitals in the healthcare delivery system. ASCA supports opportunities for physicians to engage directly with patients to decrease costs and increase quality of care.

Summary

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.

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