September 6, 2016

Andy Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1656-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

*Via online submission at [www.regulations.gov](http://www.regulations.gov)*

**Re: CMS-1656-P – Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; etc.**

Dear Mr. Slavitt:

The Ambulatory Surgery Center Association (ASCA) submits these comments on behalf of the over 5,400 Medicare-certified ASCs nationwide in response to the calendar year (CY) 2017 proposed ASC payment rule (81 Fed. Reg. 135, July 14, 2016).

Our comments focus on our continued and growing concern about how policies implemented by the Centers for Medicare and Medicaid Services (CMS) are furthering the divergence in the payment rates within the OPPS and ASC payment systems. This growing divergence is facilitating a migration of services from the lower-priced ASC setting to the higher priced hospital setting, thereby costing the Medicare program and its beneficiaries scarce money that could have been spent elsewhere. With CMS increasingly promoting a value-based approach to care delivery, we encourage the agency to take a more holistic view of how outpatient surgical services are provided and incentivize beneficiaries to obtain high quality care in the most efficient setting. As an example, a short-sighted focus on budget neutrality within the ASC space— which is not statutorily required— is preventing the agency from using payment policy to leverage efficient provision of care.

Specifically, our comments focus on the following key topics:

- **Rescaling adjustment**. CMS should apply the OPPS relative weights to ASC services and discontinue its practice of rescaling the ASC relative weights. This scaling adjustment is accelerating the gap between the ASC and HOPD payment rates that allow market forces to discourage use of lower-cost ASC settings. At the very least, CMS should consider policy changes to mitigate the effect that OPPS payment policy adjustments are having on ASC payment rates and that are extending the divergence between OPPS and ASC payments.

- **Conversion Factor.** CMS must replace the Consumer Price Index for Urban Consumers (CPI-U) with the hospital market basket as the update mechanism for ASC payments.

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Hospital outpatient departments (HOPDs) are updated based on the hospital market basket, and the same increases in the cost of doing business in a HOPD – equipment, devices, implants, facility upkeep and staffing costs – apply to ASCs.

- **Alignment of Policies.** CMS should mirror any changes to the APCs adopted in the OPPS in a manner that preserves the alignment between the payment systems and ensures accurate payment for services in ASCs. The agency should engage stakeholders in discussions about how to implement those changes given the proposed differences in how services are reported and paid.

- **Device-Intensive Procedures.** CMS should implement additional policy changes for setting payments for device-intensive procedures to encourage migration of services into the less-expensive ASC setting.

- **Procedures Permitted in ASCs.** CMS should reimburse ASCs for all surgical codes for which it reimburses HOPDs.

- **Total Knee Arthroplasty.** CMS should remove total knee arthroplasty (TKA) from the Medicare inpatient-only list. This procedure, along with other total joint replacement surgeries, is currently being done safely and effectively on other patient populations in the outpatient setting in general, and increasingly in ASCs.

- **Implementation of Section 603.** CMS should reconsider its proposed implementation of section 603 of the Bipartisan Budget Act of 2015 to ensure it aligns with Congressional intent and does not inhibit Medicare patient access to outpatient surgery.

- **ASC Quality Reporting.** CMS should refine the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) and the measures it has proposed that are based on the survey to ensure that the data collected by facilities is meaningful and actionable. In addition, CMS should evaluate the modes of conducting the survey as well as the number of completed surveys required to ensure that HOPDs and ASCs are not overly burdened by this new requirement, especially in its initial year of implementation.

## Savings Potential of ASCs

CMS is actively promoting the need for innovation in healthcare, and pushing for "alternative payment models." In a recent press release[1], CMS touted the successes of the Medicare Shared Savings Program and the Pioneer Accountable Care Organization (ACO) Model. In 2015,

[1] *Medicare Makes Enhancements to the Shared Savings Program to Strengthen Incentives for Quality Care*, Centers for Medicare & Medicaid Services, June 2016. https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-06-06.html.

Medicare ACOs had a combined total net program savings of $466 million, or about 0.1% of total Medicare spending. Comparatively, the high-quality and efficient ambulatory surgical center (ASC) setting have already achieved billions of dollars a year in savings for Medicare and its beneficiaries, and has the potential to generate even larger reductions in the future.

A report released by the US Department of Health and Human Services (HHS) Office of the Inspector General (OIG) outlined potential savings for Medicare and its beneficiaries by aligning payments between hospital outpatient departments (HOPD) and ASCs. According to the report, reducing HOPD payment rates to ASC payment rates could create $15 billion in savings for the government and an additional $3 billion in savings for Medicare beneficiaries over the next six years.[2] Moreover, as we have mentioned in previous comment letters, an analysis by researchers at the University of California-Berkeley found that ***ASCs saved the Medicare program and its beneficiaries $7.5 billion during the four-year period from 2008 to 2011***.[3] The Berkeley researchers projected that ASCs have the potential to reduce Medicare costs by ***an additional $57.6 billion*** over the next decade *if* policymakers take steps to encourage the use of these innovative healthcare facilities within the Medicare system.

A recent analysis of private health insurance claims from across the country found that ***ASCs reduce the cost of outpatient surgery by more than $38 billion dollars per year*** by providing a lower cost site of care[4]. The research concluded that ASC prices are significantly lower than HOPD prices for the same procedures throughout the country, regardless of payer.

ASCs have achieved cost savings and produced high-quality outcomes for the Medicare program and its beneficiaries in spite of CMS policies that systematically disadvantage ASCs. While we understand the intent in applying the design fundamentals of Medicare's prospective payment system to ASCs, we believe that an overly-rigid interpretation of the law has resulted in great and continuing divergence between ASC and hospital outpatient prospective payment system (OPPS)[5] rates, and threatens to drive up costs for the Medicare program if ASCs no longer remain a viable alternative for Medicare beneficiaries.

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[2] *Medicare Beneficiaries Could Save Billions if CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates*, Department of Health and Human Services, Office of Inspector General, April 2014.

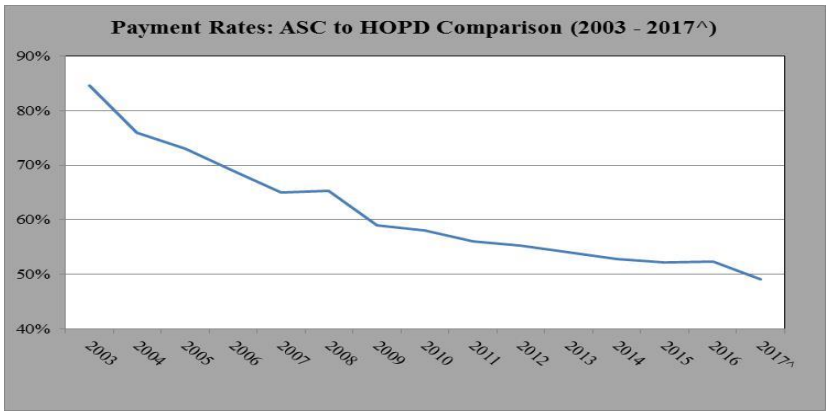
[3] *Medicare Cost Savings Tied to Ambulatory Surgery Centers*, University of California-Berkeley Nicholas C. Petris Center on Health Care Markets and Consumer Welfare, September 2013.

[4] *Commercial Insurance Cost Savings in Ambulatory Surgery Centers*, Healthcare BlueBook and Health Smart, June 2016.

[5] Throughout this letter we use OPPS to refer to the payment system and HOPD to refer to the site of service/type of facility.

## Continued Divergence of Payment Rates

There continues to be a substantial growing disparity in reimbursement rates in the OPPS versus the ASC payment system. While ASCs were reimbursed approximately 85 percent of HOPDs rates in 2003, under the proposed CY 2017 payment rates ASCs would be reimbursed on average only 49 percent of what hospitals are paid for performing the same procedures.[6] This includes a substantial drop of four percent from 53 percent in 2016, if the rule is finalized as proposed for 2017.




Even worse, when excluding CPT codes that are in comprehensive APCs in the OPPS (a policy not in place with ASCs), our facilities would be reimbursed at 47 percent of HOPD rates in CY 2017.[7]

Most ASCs are small businesses, and as such, must run efficiently to remain viable. ASCA purchased from CMS the list of certified ASCs as of June 2016. In that file, there are 5,486 facilities listed, and over half – 3,060 – have only one or two operating rooms. These facilities must purchase the same equipment including emergency medical equipment (e.g., defibrillators), devices and implants as hospitals to perform surgery. In fact, ASCs may pay more, since they do not have the same purchasing power of a hospital or large health system. Moreover, the cost of the equipment and supplies is defrayed across a much smaller revenue base in an ASC than in a hospital. ASCs must also 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 a different annual update factor that drives a growing disparity in reimbursement rates. While ASCs pride themselves on running efficiently, being reimbursed less than 50 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.

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[6] This was calculated by creating a ratio of the ASC rate to the OPPS rate at the individual code level and then taking the average. This analysis examined the ratio for surgical codes and excludes the codes where the ASC and OPPS rate were the same (i.e. drugs).

[7] The same process as above was used except we excluded codes that were in APCs defined as comprehensive APCs in 2016 and 2017.

Advances in medical technology and patient safety are increasing the number of procedures that are clinically appropriate for ambulatory settings and have expanded the types of patients who can be safely treated outside the hospital.

Despite these advances, however, we have observed slow or negative growth in Medicare volume for some common ASC procedures. We are now witnessing a disturbing migration of many high volume services, including some common gastroenterology procedures such as colonoscopy (a critical preventive service rated A by the U.S. Preventative Task Force), that should be performed in ASCs.

**Table A. Examples of Procedure Migration Away from ASCs**

| CPT | Short Descriptor | 2014 ASC Volume | ASC Setting | | Physician Office | | HOPD Setting | |
|---|---|---|---|---|---|---|---|---|
| | | | 2010 | 2014 | 2010 | 2014 | 2010 | 2014 |
| 29822 | Arthroscopy, shoulder, surgery | 5,225 | 28.5% | 25.4% | 0.4% | 0.4% | 66.6% | 71.3% |
| 43235 | Upper GI endoscopy, diag. | 69,200 | 19.8% | 18.9% | 2.0% | 1.4% | 35.0% | 36.9% |
| 45378 | Diagnostic colonoscopy | 161,308 | 34.4% | 31.5% | 5.0% | 4.6% | 45.1% | 45.3% |
| 45381 | Diagnostic colonoscopy with submucosal inj. | 28,398 | 37.2% | 36.7% | 3.5% | 3.0% | 46.0% | 49.0% |

Source: Physician/Supplier Procedure Summary (PSPS) Master Files from 2010-2014

In some cases, migration is occurring when volume in both settings is growing but increasing at a higher rate in the HOPD than in the ASC. In other cases, the volume for the codes is declining in both settings but the rate of decline is greater in the ASCs. The migrating of market share – regardless of the reason – has substantial cost implications; halting this migration will generate savings for the Medicare program and its beneficiaries. For instance, a very common procedure, CPT 43235, is performed almost twice as often in the higher-priced HOPD setting than in ASCs. At the 2017 proposed rates, a modest five percent migration of volume of this one code from the HOPD to the ASC would save $2 million annually for Medicare and its beneficiaries. Another common procedure, CPT 45378, is performed nearly 50 percent more often in the higher-priced HOPD setting than in ASCs. Unfortunately, for CPT 45378, the ASC reimbursement rates proposed for 2017 drop by nearly 15 percent (compared to 11% in the HOPD setting). We expect this reduction and growing divergence in reimbursement between the two settings to lead to further reverse migration to the HOPD. Cuts in proposed ASC payment rates for other high volume codes (e.g., 45329, G0105, G0121, 29880, and 29881) are likely to lead to more codes experiencing reverse migration to higher-cost settings.

Surgical care in too many markets continues to be predominantly provided in hospitals, which we attribute to Medicare's failure to pay competitive rates to ASCs. This lack of migration

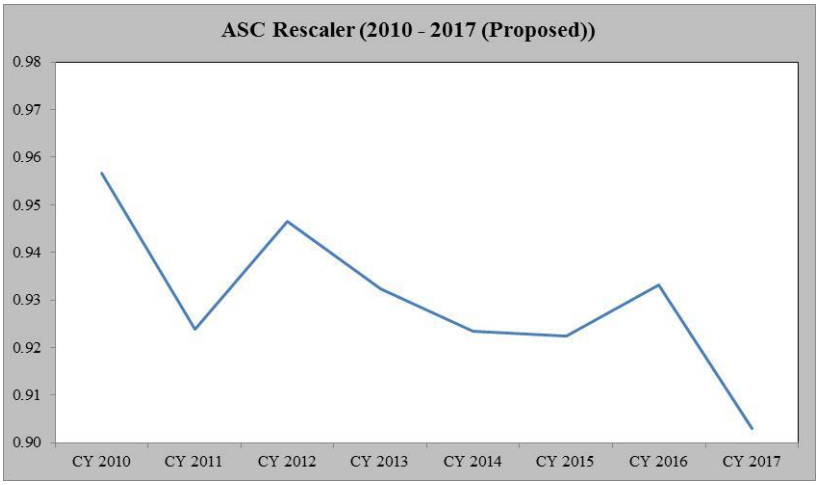
comes at a high price to the Medicare program, the taxpayers who fund it, and the beneficiaries who needlessly incur higher out-of-pocket expenses.

## CMS should take steps to halt the divergence between ASC and OPPS payment rates arising from increasingly disconnected payment policies

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

The additional scaling factor that CMS applies to the ASC APC weights is intended to maintain budget neutrality within the payment system; however, this scaling is instead contributing to increasingly large payment differentials between ASC and HOPD payments without evidence of growing differences in capital and operating costs in the two settings.

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. In fact, since the ASC system was implemented, the rescaling adjustment has decreased the relative weights on ASC surgical procedures each year. More specifically, as the graph below illustrates, since 2010, the ***rescaler has decreased the relative weights in the ASC system by, on average, 7.0% each year***.




In the last 7 years, the size of the rescaling has increased nearly each year. As an example, the rescaler was 0.9332 in CY 2016 and proposed to be 0.9030 in CY 2017 – a three percentage point change in the scaler in one year. This historical trend, and the absence of any indication that it is likely to reverse in the future, suggests that the application of the rescaler in the ASC setting will continue to erode the relationship between ASC and HOPD rates.

By creating even more distinctions between OPPS and ASC payment policy (*e.g.*, Comprehensive APCs) and applying ASC-specific adjustments like the scaler, CMS is accelerating and exacerbating the gap between OPPS and ASC rates. In so doing, the agency is reducing the incentives for shifting volume to the ASC setting and encouraging it to be furnished in the more expensive (and in many cases, now doubly expensive) HOPD setting and depriving

the program and its beneficiaries of substantial cost savings. For this reason, we urge CMS to make changes to ASC payment policy to arrest this growing gulf in payment. Specifically, we urge CMS to discontinue use of the ASC relative weight scaler that contributes substantially to the rate divergence.

While we believe that the facts—ASC payment rates are now falling below 50 percent of OPPS rates—should be justification enough to discontinue use of the scaler, we recognize that CMS has repeatedly declined to take this step in the past. In order to ensure that ASCs remain a viable alternative in which to perform needed care for Medicare beneficiaries, CMS must act now to ensure that budget neutrality calculations used to set ASC rates do not create disincentives to provide care in ASCs. Specifically, if CMS declines to suspend the rescaler as we have suggested, CMS should 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 scaler 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 setting.

There are a variety of ways that CMS could determine empirically 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 minimum relationship ratio of 55 percent such 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 naturally by CMS policy. If after a period of time CMS continues to see that procedures are migrating to the HOPD, or are not migrating with sufficient speed to the ASC setting, CMS could gradually increase that minimum relationship ratio.

ASCA is proposing that CMS peg the 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.

CMS has the authority to implement either change. CMS implemented the scaler pursuant to its own perceived authority, and not pursuant to any identified statutory command. As such, CMS can likewise discontinue the scaler 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 frustrate 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 constrained in determining budget neutrality in the first year of implementation of the new payment system.[8] 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 be pursuing policies that encourage more services to be provided in the ASC setting where Medicare saves billions of dollars a year. Such a policy is entirely consistent with the CMS approach to value-based health care and in encouraging greater competition and savings across the health care system.

***CMS must replace the Consumer Price Index for Urban Consumers (CPI-U) with the hospital market basket as the update mechanism for ASC payments.***

The clearest example of the lack of alignment between ASC and OPPS payment policies is the continued use of different inflation update factors. The OPPS update is based on the Inpatient Hospital Market Basket (HMB), which is comprised of data that reflects the cost of items and services necessary to furnish an outpatient surgical procedure and has historically been higher than the CPI-U. As we and the CMS Actuaries have previously noted, CPI-U is not a suitable inflation index to update ASC payments because it does not accurately represent the costs borne by facilities to furnish surgical procedures. The CPI is an index that measures the average change over time in the price of consumer goods – "goods and services that people buy for day-to-day living." The CPI-U represents the buying habits of the residents of the urban or metropolitan areas in the United States, not the ever-increasing costs of operating a health care facility.

Although CMS acknowledges year after year in the OPPS/ASC payment rule that they are not statutorily required to adopt any particular update mechanism, it continues to be used by default, since the CPI–U must be used in the absence of any update implemented by the Secretary of the US Department of Health and Human Services (HHS). As previously mentioned, while ASCs were being reimbursed at approximately 85 percent of the HOPD payment rate in 2003, in 2017, ASC rates for the highest volume codes are proposed to be reimbursed on average at less than 50 percent of HOPD rates for the first time. The consequence of CMS's inaction are market forces that have are causing increased migration of services to the hospital setting, resulting in higher

[8] 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.

costs for the Medicare program and its beneficiaries. 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. The *Ambulatory Surgical Center Quality and Access Act of 2015* (H.R. 1453/S. 2071), which would require CMS to use the hospital market basket to update ASC payments, has bipartisan support in both chambers, with 81 cosponsors in the US House and seven in the US Senate. We already have more co-sponsors as similar legislation introduced in 2013, showing that there is increasing support by Congress to equalize the playing field for ASCs and HOPDs by using the hospital market basket to update ASC payment rates.

The ASC payment system is one of the last CMS payment systems to be tied to the CPI-U (the others being the Ambulance Fee Schedule, Clinical Lab Fee Schedule (which will begin using market-based rates in 2018 pursuant to Section 216 of the *Protecting Access to Medicare Act of 2014*), and Durable Medical Equipment (much of which is now subject to competitive bidding and therefore not inflated using CPI or any other measure), Prosthetics, Orthotics and Supplies). All other payment systems besides those referenced above, use indices derived from the basket of goods actually purchased by those providers, as shown in Table BC.

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

| Payment System | Inflation Update |
|---|---|
| Ambulance Fee Schedule | CPI-U |
| Ambulatory Surgical Centers Payment | |
| Clinical Lab Fee Schedule | |
| DMEPOS Fee Schedule | |
| End Stage Renal Disease PPS | ESRD Bundled Market Basket |
| Federally Qualified Health Center PPS | Statutory Updates |
| Home Health PPS | Home Health Market Basket |
| Hospice | Hospital Market Basket Index |
| Hospital Outpatient PPS | |
| 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 |
| Physician Fee Schedule | Medicare Economic Index |
| Skilled Nursing Facility PPS | Skilled Nursing Facility Market Basket Index |

Source: FFS payment systems under Medicare (http://www.cms.gov/Medicare/Medicare.html)

Until CMS develops an outpatient-specific market basket, and as long as CMS continues to base ASC payment rates off of HOPD rates, the update factors should be the same. Using different

update factors is short-sighted as it results in a growing disparity in payments that may drive procedures toward higher cost settings. Therefore, we once again request that CMS begin updating the ASC Payment System with the HMB starting with calendar year (CY) 2017.

## ASCs Impacted by 2016 OPPS Ambulatory Payment Classification (APC) Restructuring

***CMS should mirror any changes to APCs adopted in the OPPS in a manner that preserves the alignment between the payment systems and ensures accurate payment for services within the ASC.***

ASCA acknowledges the motivations for last year's APC restructuring of nine clinical families in the OPPS, including greater simplicity and improved clarity of the OPPS APC structure. However, we have concerns about the approach taken by CMS in reviewing the APCs and how it further demonstrates and exacerbates the growing disconnect in the payment policies for HOPDs and ASCs.

In reviewing and revising the APC assignments, CMS addressed the impact on the OPPS by conducting a detailed analysis of OPPS claims data. The sole focus of the analysis was on the OPPS site of service and we believe that no consideration was given to the implications of the proposed changes to the ASC Payment System. Over 50 percent of ASC approved surgical procedures were in the APCs restructured in 2016 and had their reimbursement rates based on the revised OPPS payment weights. While CMS has proposed limited APC restructuring for CY 2017, and thus the incremental impact of this policy for this year will be minimal, we request that CMS in future rulemaking take into consideration the implications of the APC restructuring not only on hospitals and the OPPS rates but also on ASCs and ASC payments.

***CMS should make adjustments in the ASC setting to account for the impact of the comprehensive APC policy.***

In CY 2015, CMS also implemented a policy that combines multiple procedures into comprehensive APCs (C-APCs) in the OPPS, another policy that is not mirrored in the ASC setting. These new combinations create bundles of services, primarily focused around the former "device-intensive" codes, that present a challenge and an opportunity for HOPDs. If HOPDs successfully manage services and supplies within the bundle, their margins on those procedures will improve. However, those HOPDs with higher-than-average costs for delivering services will lose under this policy. New incentives will likely cause shifts in relative cost and frequency of the comprehensive codes and the codes within the bundle in the OPPS. The effects of these shifts will be transferred to ASCs through the application of OPPS-derived relative weights to ASC codes, and through the application of the scaler that adjusts the total ASC weighting system to remove the effect of higher weights on total ASC payments.

In 2016 there were only 9 codes in the ASC top 100 by volume that were in C-APCs under the OPPS. However, for 2017, that number would increase to 55 codes. As ASCA argued two years ago in response to the 2015 proposed payment rule, "through weighting and scaling, the new comprehensive APCs for the OPPS will cause more volatility in the ASC payment rates from which they are derived." We urged CMS to monitor the impact of C-APCs on ASC payments

and to alleviate unintended consequences, especially if they lead to further divergence in payment rates across the two settings.

While CMS has addressed the reimbursement concern for this code in the 2017 proposed rule, other codes may be similarly impacted in 2017 and future years. It is unclear what recourse providers would have if this were to happen again, or how stakeholders are expected to prepare for changes when they arise in the final rule without being contemplated in the proposed rule. Abrupt reductions of this magnitude could be financially devastating to an ASC. Many ASCs are single specialty and a substantial majority of their services may consist of a relatively small set of procedures. We again urge CMS to monitor more closely the impact of APC changes themselves or the unintended consequences of those changes on ASC payments to ensure continued access to ASCs for program beneficiaries.

## Device-Intensive Policy Encourages 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 are assigned to an APC with a device offset greater than 40 percent of the mean cost of the procedure in the HOPD. Currently, in assigning device-intensive status to an APC, the device costs of all of the procedures within the APC are calculated and the geometric mean device offset of all of the procedures within the APC must exceed 40 percent. For 2017, CMS is proposing to assign device-intensive status to procedures that require the implantation of a device and have an individual HCPCS code-level device offset of greater than 40 percent, regardless of the APC assignment. ASCA supports this proposal, as it should more accurately relate payment to costs.

In the proposal, CMS says a "HCPCS code-level device offset would, in most cases, be a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC." We agree. Although there are 19 codes that will lose device-intensive status due to this policy change, there are 43 codes that will be newly-considered device-intensive because the actual code – regardless of APC assignment – has a device cost that exceeds the 40 percent threshold. This policy change should encourage the migration of those 43 codes to ASCs, while saving Medicare and beneficiaries significant money.

While we support this policy change, we recommend further adjustments to allow even more procedures to migrate to the lower cost ASC setting.

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

For all other ASC services that have device costs 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 around 49 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 $490 to perform the procedure. The ASC would receive just $91 to cover all of the facility's other costs for that patient encounter.

A real-life example of the challenge with the device-intensive policy is with CPT 57310 (Closure of urethrovaginal fistula). This code was newly-added to the ASC payable list last year, and although not meeting the CMS definition of device-intensive, it still requires a significant device cost. The proposed payment rate in 2017 for ASCs is $2,551.81, which is less than 43 percent of the payment rate of $5,938.4807 proposed in the HOPD. CMS has deemed this procedure safe and effective for the ASC setting, but the agency will not see any significant volume migration to the ASC because at this payment rate, ASCs will not be able to cover the device cost and other expenses.

Another example of an entire APC that is negatively impacted by the lack of device-intensive status is APC 5155, endoscopic sinus surgery codes. In the HOPD, these predominantly device-intensive codes (31254, 31255, 31267, 31276, 31287 and 31288) are proposed to receive $4,324.85 in reimbursement for 2017. In the ASC, however, the same codes have a proposed reimbursement rate of $1,672.23, less than 39 percent of the HOPD proposed rate. Considering that most of these codes require the use of disposables that are not payable in the primary code, this reimbursement rate makes it unlikely that these procedures will be done in ASCs on the Medicare population.

**ASCA recommends that CMS drop the device-intensive threshold to 30 percent for ASCs, given that our non-device payment is already under 50 percent of that paid to HOPDs. In the example given above, if the device threshold were lowered, the ASC would be reimbursed $399 for the device plus $295 for the non-device portion (49 percent of $601). This $694 total, which would allow an ASC to pay for the device and the routine overhead expenses associated with the procedure, would also provide CMS with a significant cost reduction from the HOPD rate.**

## Changes to the ASC Covered Procedures List

### *Proposed addition of eight new codes*

We appreciate that CMS has proposed to add the following eight codes to the ASC list in 2017:

- 20936 (Sp bone agrft local add-on)
- 20937 (Sp bone agrft morsel add-on)
- 20938 (Sp bone agrft struct add-on)
- 22552 (Addl neck spine fusion)
- 22840 (Insert spine fixation device)
- 22842 (Insert spine fixation device)

• 22845 (Insert spine fixation device)

• 22851 (Apply spine prosth device)

ASCA strongly supports the addition of all of these spine codes and appreciate that CMS is recognizing instrumentation codes that are integral to spinal fusions as appropriate for the ASC setting. However, we urge CMS to ensure that the replacement codes for 22851 are added to the ASC list. As CMS is aware, code 22851 will be deleted from the 2017 code set and replaced by 22X81, 22X82 and 22X83. CMS included these three codes in Addendum EE, "Surgical Procedures Proposed to be Excluded from Payment in ASCs for CY 2017." We request that CMS correct this oversight, since these are the replacement codes for 22851 that CMS proposed to add to the ASC list.

While ASCA appreciates the addition of these spine codes, these procedures bring additional cost, such as those incurred from insertion of a cage, instrumentation and allografts, and we have serious concerns with the fact that none of these codes will be separately payable. The instrumentation codes proposed (22840, 22842, 22851 & 22845) are usually billed in conjunction with a cervical or lumbar fusion. Some cervical fusions are done without instrumentation, but most cases require instrumentation. These codes represent the staff time and work involved in placing the plates, rods and screws to stabilize the spine during fusion surgery as well as the cost of these implants.

Additional level cervical and lumbar decompression and discectomy surgeries performed at the time of the original level are very commonly needed and performed to treat the patient's condition. The additional level CPT Codes for these procedures are 63035, 63048 and 63057. These cases require additional operating room time, staff time and supplies for surgery centers compared to a single level laminectomy (cervical or lumbar) surgery reflected in the primary codes (63020, 63030, 63056, 63045, 63046 and 63047)

If these additional codes are not reimbursed, it will not be financially feasible for an ASC to perform anterior cervical discectomies (22551) and fusions (22612 and 22614) on Medicare patients. The cost of the instrumentation and cages alone often exceeds the reimbursement rates established on the current rate schedule.

In addition, CPT 22552 indicates a second level ACDF. The current Medicare payment system makes it economically unfeasible for these procedures to be performed in an outpatient setting. CPT 22552 must be reimbursed separately to cover the additional implant cost, not to mention increased costs of time in the operating room and increased staff time. CMS will not see volume migrate out of the inpatient setting and into the ASC without providing adequate reimbursement for these codes.

***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 328 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. ASCs are often on the cutting edge of new

treatments. 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 ASCs are allowed to perform.

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 which 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, and particularly with off-campus HOPDs, 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 codes to be performed in either an HOPD or an ASC.

***High Volume in HOPD Setting***

Recognizing that eliminating the distinction between the ASC and HOPD approved codes may be too large a step for CMS to take this late in the rulemaking process, CMS should at least consider those codes with high volume in the HOPD setting. Table B highlights procedures with high Medicare volume (which we are defining as 1,000 services or more a year) in the HOPD setting, indicating these codes are performed safely and effectively in the outpatient setting on the Medicare population. For all of these procedures, ASCA members report positive outcomes when performed on non-Medicare patients in ASCs, and indicate the procedures would not raise any of the specific safety concerns when performed on Medicare beneficiaries that would bar a procedure from being added to the ASC list of covered procedures.

**Table C. High Volume HOPD Codes not on ASC-Payable List**

| HCPCS Code | Short Descriptor | Specialty | HOPD Volume 2015 | Unlisted Code |
|---|---|---|---|---|
| C9600 | Perc drug-el cor stent sing | HCPCS codes - drug eluting stents | 76,185 | |
| 44970 | Laparoscopy appendectomy | Digestive | 7,869 | |
| C9604 | Perc d-e cor revasc t cabg s | HCPCS codes - drug eluting stents | 6,661 | |
| 41899 | Dental surgery procedure | Digestive | 6,014 | * |
| 19307 | Mast mod rad | Dermatology | 5,311 | |
| 37191 | Ins endovas vena cava filtr | Cardiovascular | 4,803 | |
| 37193 | Rem endovas vena cava filter | Cardiovascular | 4,753 | |
| 53899 | Urology surgery procedure | Urinary | 4,317 | * |
| C9602 | Perc d-e cor stent ather s | HCPCS codes - drug eluting stents | 4,193 | |

| HCPCS Code | Short Descriptor | Specialty | HOPD Volume 2015 | Unlisted Code |
|---|---|---|---|---|
| 29999 | Arthroscopy of joint | Orthopedics | 4,039 | * |
| 38207 | Cryopreserve stem cells | Hemic/lymphatic system | 3,799 | |
| 57282 | Colpopexy extraperitoneal | Female genital | 3,407 | |
| 37799 | Vascular surgery procedure | Cardiovascular | 3,010 | * |
| C9607 | Perc d-e cor revasc chro sin | HCPCS codes - drug eluting stents | 2,903 | |
| 17999 | Skin tissue procedure | Dermatology | 2,678 | * |
| 64999 | Nervous system surgery | Neurology | 2,509 | * |
| 43281 | Lap paraesophag hern repair | Digestive | 2,279 | |
| 28899 | Foot/toes surgery procedure | Orthopedics | 2,251 | * |
| 32551 | Insertion of chest tube | Respiratory | 2,224 | |
| 57425 | Laparoscopy surg colpopexy | Female genital | 2,155 | |
| 29799 | Casting/strapping procedure | Orthopedics | 2,140 | * |
| 47379 | Laparoscope procedure liver | Digestive | 2,093 | * |
| 43999 | Stomach surgery procedure | Digestive | 1,833 | * |
| 44799 | Unlisted px small intestine | Digestive | 1,757 | * |
| 33244 | Remove elctrd transvenously | Cardiovascular | 1,602 | |
| 43280 | Laparoscopy fundoplasty | Digestive | 1,553 | |
| 38214 | Volume deplete of harvest | Hemic/lymphatic system | 1,535 | |
| 49329 | Laparo proc abdm/per/oment | Digestive | 1,508 | * |
| 43499 | Esophagus surgery procedure | Digestive | 1,489 | * |
| 20999 | Musculoskeletal surgery | Orthopedics | 1,465 | * |
| 31599 | Larynx surgery procedure | Respiratory | 1,319 | * |
| 49999 | Abdomen surgery procedure | Digestive | 1,300 | * |
| 46999 | Anus surgery procedure | Digestive | 1,266 | * |
| 55899 | Genital surgery procedure | Male genital | 1,196 | * |
| 57283 | Colpopexy intraperitoneal | Female genital | 1,175 | |
| 38999 | Blood/lymph system procedure | Hemic/lymphatic system | 1,104 | * |
| C9606 | Perc d-e cor revasc w ami s | HCPCS codes - drug eluting stents | 1,052 | |
| 44180 | Lap enterolysis | Digestive | 1,034 | |
| 23470 | Reconstruct shoulder joint | Orthopedics | 1,001 | |

Source: Cost Statistics File, CY 2017 OPPS Proposed Rule

***Unlisted Codes***

The Code of Federal Regulations §416.166 - Covered surgical procedures, states that "covered surgical procedures do not include those surgical procedures that…can only be reported using a CPT unlisted surgical procedure code." There is no clear safety rationale for this provision, and commercial payers commonly provide ASCs the needed flexibility to use unlisted CPT codes to

report procedures. Facilities must document why they need to use the unlisted code and receive approval from the payer to be reimbursed. This is a practice CMS permits for HOPDs and physician's offices, but not for ASCs, and is yet another example of an area where CMS could derive savings for both the Medicare program and beneficiaries. By making a simple change in policy.

One of the codes requested for addition to the ASC-payable list by our members, 22899 (spine surgery procedure), is proposed to be included in APC 5111 for 2017. The *only* codes within that APC that are not payable in the ASC setting are unlisted codes. Unlisted codes represent 60 of the 328 codes (including 19 of the high-volume codes above) that are reimbursed in the HOPD but not the ASC. If physicians have the ability to choose to perform these procedures in HOPDs, outpatient facilities that are often identical to ASCs, physicians should also be able to utilize unlisted codes in the ASC. ASCA requests that CMS revise the Code of Regulations to eliminate this restriction.

***Facility-Recommended Codes***

ASCA surveyed its membership to determine common codes being performed safely and effectively in the ASC on non-Medicare patient populations that members believe should be added to Medicare's ASC-payable list. The addition of the codes below (in Table D), which are often clinically similar to codes already on the ASC-payable list, would allow beneficiaries and the Medicare system to realize substantial savings.

**Table D. Codes Requested to be Added to ASC-payable List**

| CPT | Short Descriptor |
|---|---|
| 00142 | Anesth lens surgery |
| 00170 | Anesth procedure on mouth |
| 00810 | Anesth low intestine scope |
| 20936 | Sp bone agrft local add-on |
| 21196 | Reconst lwr jaw w/fixation |
| 21470 | Treat lower jaw fracture |
| 22558 | Lumbar spine fusion |
| 22585 | Additional spinal fusion |
| 22600 | Neck spine fusion |
| 22630 | Lumbar spine fusion |
| 22632 | Spine fusion extra segment |
| 22633 | Lumbar spine fusion combined |
| 22634 | Spine fusion extra segment |
| 22830 | Exploration of spinal fusion |
| 22846 | Insert spine fixation device |
| 22849 | Reinsert spinal fixation |
| 22850 | Remove spine fixation device |

| CPT | Short Descriptor |
|---|---|
| 22852 | Remove spine fixation device |
| 22856 | Cerv artific diskectomy |
| 22858 | Second level cer diskectomy |
| 22864 | Remove cerv artif disc |
| 22899 | Spine surgery procedure |
| 23472 | Reconstruct shoulder joint |
| 27130 | Total hip arthroplasty |
| 27176 | Treat slipped epiphysis |
| 27412 | Autochondrocyte implant knee |
| 27447 | Total knee arthroplasty |
| 27457 | Realignment of knee |
| 27477 | Surgery to stop leg growth |
| 27485 | Surgery to stop leg growth |
| 27486 | Revise/replace knee joint |
| 27535 | Treat knee fracture |
| 27540 | Treat knee fracture |
| 27702 | Reconstruct ankle joint |
| 28805 | Amputation thru metatarsal |
| 29867 | Allgrft implnt knee w/scope |
| 29868 | Meniscal trnspl knee w/scpe |
| 37244 | Vasc embolize/occlude bleed |
| 43280 | Laparoscopy fundoplasty |
| 43775 | Lap sleeve gastrectomy |
| 44180 | Lap enterolysis |
| 44705 | Prepare fecal microbiota |
| 44950 | Appendectomy |
| 44970 | Laparoscopy appendectomy |
| 47600 | Removal of gallbladder |
| 49329 | Laparo proc abdm/per/oment |
| 49659 | Laparo proc hernia repair |
| 54411 | Remov/replc penis pros comp |
| 54417 | Remv/replc penis pros compl |
| 57282 | Colpopexy extraperitoneal |
| 58300 | Insert intrauterine device |
| 60252 | Removal of thyroid |
| 60260 | Repeat thyroid surgery |
| 63035 | Spinal disk surgery add-on |
| 63048 | Remove spinal lamina add-on |

| CPT | Short Descriptor |
|---|---|
| 63057 | Decompress spine cord add-on |
| 63081 | Remove vert body dcmprn crvl |
| 67904 | Repair eyelid defect |
| 90870 | Electroconvulsive therapy |
| 91110 | Gi tract capsule endoscopy |
| 0232T | Njx platelet plasma |
| C9600 | Perc drug-el cor stent sing |
| C9601 | Perc drug-el cor stent bran |
| C9604 | Perc d-e cor revasc t cabg s |
| C9605 | Perc d-e cor revasc t cabg b |
| G0455 | Fecal microbiota prep instil |
| L8699 | Prosthetic implant nos |

Procedures are grouped in APCs with clinically-similar codes. One of the requested codes, 22856, is proposed to be in APC 5116. It is currently the only code in that APC group that is not reimbursed in the ASC and CMS should rectify this in the final rule. In addition, we highlight several other codes below that should be added because they are within APCs with high ASC volume or have high volume in the HOPD setting.

***Codes in APCs with High ASC Volume.*** There are several codes listed above that fall within three APC groups that have CPT codes within them that were performed at least 10,000 times in the ASC setting in 2014. Since APCs represent clinically-similar codes, these codes should be given special consideration.

*APC 5113*. CPT codes 27477, 27485 and 28805 are proposed to be included in APC 5113 for 2017. There are several codes within that APC group that experienced significant volume in the ASC setting in 2014 (volume is in parenthesis): 28285 (30,477), 29824 (14,482), 29880 (22,320) and 29881 (26,374).

*APC 5114:* CPT codes 27412 and 29868 are proposed to be included in APC group 5114 for 2017. CPT code 29827, another code in that APC group, was performed 21,235 times in the ASC setting in 2014.

*APC 5301:* CPT code 91110 is proposed to be included in APC 5301 for 2017. There are four codes within that APC group that experienced significant volume in the ASC setting in 2014 (volume is in parenthesis): 43235 (68,985), 43239 (526,052), 43248 (48,864) and 43450 (35,753).

As previously mentioned, codes within an APC are considered clinically similar, and the six codes listed above fall within APCs that include other codes with very high volume in ASCs. CMS should add 27477, 27485, 28805, 27412, 29868 and 91110 to allow for the agency and its beneficiaries access to these procedures, and the savings they will enjoy, by having these procedures done in ASCs.

***Facility-recommended with high volume in the HOPD setting.*** Six of the above codes are also on the HOPD high-volume list: 44180, 44970, 49329, 49659 (all in APC 5361), 43280 (APC 5362) and 57282 (APC 5416).

***Inpatient-only codes clinically-similar to codes done in ASCs.*** While not currently allowable in HOPDs, CMS should also remove CPT 22630 and 22633 from the inpatient-only list, and subsequently add them to the ASC-payable list. These two lumbar spinal fusion codes are commonly performed on an outpatient basis. They are clinically similar, if not identical in most respects, to the anterior discectomy and interbody fusion (CPT 22551) and the posterior lumbar fusion (22612) which are both covered by CMS in ASCs. CPT 22633 is billed when a 22630 and 22612 are performed together.

## Solicitation of Comments on Removing Total Knee Arthroplasty from the IPO List

***CMS should remove total knee arthroplasty (TKA) from the Medicare inpatient-only list.***

Total knee arthroplasty (TKA), or total knee replacement, CPT code 27447, was historically an inpatient surgical procedure that required a lengthy hospital stay. As CMS acknowledges in the proposed rule, "innovations in TKA care include minimally invasive techniques, improved perioperative anesthesia, alternative postoperative pain management, and expedited rehabilitation protocols" have made it possible for this procedure, along with other total joint replacement surgeries, to be performed in the outpatient setting. There have been over 100 peer-reviewed articles published on the topics of: outpatient joint replacement, appropriate patient selection, multi-modal pain management, rapid rehabilitation and clinical outcomes.

One such study entitled, "Patient Selection in Outpatient and Short-Stay Total Knee Arthroplasty"[9] compared the results of two selected matched cohorts of 64 patients who underwent total knee arthroplasty during the same time period. One cohort, with no severe medical conditions but who had post-operative follow up care available at home, were all discharged within 23 hours of surgery. The other cohort followed a standard inpatient protocol "with a mean hospital stay of 2.3 days (range, 2-4 days)." There were no perioperative complications in either cohort and none of the patients who followed the outpatient protocol returned to the hospital for any reason. The study authors asserted that "outpatient total knee arthroplasty may be a safe procedure in certain selected patients, with similar outcomes to a traditional protocol."

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 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

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[9] *Patient selection in outpatient and short-stay total knee arthroplasty*. Lovald S, Ong K, Lau E, Joshi G, Kurtz S, Malkani A. J Surg Orthop Adv. 2014 Spring; 23(1):2-8.

readmission or ER visits post-operatively. As CMS mentions in the proposed 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 in an outpatient setting in order to prevent comingling with patients with infections requiring IV AB therapy or other inpatient conditions/treatments.

As with any other procedure that a surgeon is contemplating performing in an ASC, patient selection is paramount. Our facilities that perform total joint replacements on commercially-insured patients develop and follow strict protocols 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.

Recent innovations have enabled surgeons to perform TKA on an outpatient basis on non-Medicare patients (both in the HOPD and in the ASC). In this context, ''outpatient'' services include both same day outpatient surgery (that is, the patient goes home on the same day that the outpatient surgery was performed) and outpatient surgery that includes one overnight hospital stay for recovery from the surgery. These innovations in TKA care include minimally invasive techniques, improved perioperative anesthesia, alternative postoperative pain management and expedited rehabilitation protocols. Patients generally benefit from a shorter hospital stay. Such benefits 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.

Like most surgical procedures, TKA must to be tailored to the individual patient's needs. Patients with a relatively low anesthesia risk and without significant comorbidities, and who have family members at home who can assist them post-operatively, would likely 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 possibly 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 TKA outcomes.

ASCA strongly supports the removal of TKA from the inpatient-only list and recommends that CMS also reimburse for these procedures when done in the ASC setting. With the assistance of several of our facilities currently performing outpatient total joint replacements, we provide answers below to the questions outlined in the rule.

1. **Are most outpatient departments equipped to provide TKA to some Medicare beneficiaries?**

   If a hospital is performing TKA in its facility, it is our understanding that there is typically little variation between an "outpatient department" and the inpatient facility. They are typically co-mingled. 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 a 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. As with all procedures performed in the ASC, the physicians, nurses, other clinicians and staff work closely together to ensure each procedure is performed efficiently and safely. Also, as with any procedure on the ASC-payable list, the physician, in coordination with the anesthesiologist in the case of total joint replacements, must work together to determine patient eligibility. 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.

In order to be in-network, many payers require the facility to be accredited. The Joint Commission, one of the largest ASC accrediting bodies, has recently established an "Advanced Certification for Total Hip and Total Knee Replacement" that facilities (including ASCs) can pursue to indicate they are equipped to handle these types of procedures. As discussed later, unilateral knee replacements (CPT 27446) are on the ASC-payable list, and are clinically similar, if not more complex, than TKAs. Since there are some Medicare patients for whom 27446 is appropriate, there are certainly Medicare patients who could have TKA performed in the outpatient setting.

2. **Can the simplest procedure described by CPT code 27447 be performed in most outpatient departments?**

   If the facility can answer "yes" to question 1 that it is equipped to handle these cases for some segment of the Medicare population, the answer will also be yes to this question. As long as the patient meets appropriate selection criteria for outpatient total joint replacement. This should not be determined simply 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 on commercially-insured patients and some have been doing so for several years. Facilities that have decided to perform total 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 established by the operating surgeon and anesthesiologist.

3. **Is the procedure described by CPT code 27447 sufficiently related to or similar to the procedure described by CPT code 27446 such that the third criterion listed at the beginning of this section for identifying procedures that may be removed from the IPO list, that is, the procedure under consideration for removal from the IPO list is related to codes that we have already removed from the IPO, is satisfied?**

   Yes, the only difference between a partial knee replacement and a total knee replacement is about 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 utilized,

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.

4. **How often is the procedure described by CPT code 27447 being performed on an outpatient basis (either in an HOPD or ASC) on non-Medicare patients?**

While we do not have firm numbers, we know that an increasing number of our facilities are performing these procedures. A few years ago, there were only a couple of dozen facilities performing total joint procedures, but we now conservatively estimate between 150-200 ASCs nationwide are performing them. This number will continue to increase as more patients require these procedures. A recent article indicated that by 2030, total knee replacements are estimated to grow by 673 percent to 3.48 million procedures annually, and total hip arthroplasties (THA) are expected to increase by 174 percent to 572,000 procedures annually.

At Mississippi Valley Surgery Center in Davenport, Iowa, Dr. John Hoffman has performed over 1,100 total joint replacement procedures in his ASC since 2007, 804 TKAs and 357 THA. He now performs between 150-175 outpatient total hips and total knees per year. Extensive review by insurance providers was required with eventual approval only after review of his outcomes data. An analysis of 1,010 of these cases last year indicated extremely positive patient outcomes, as evidenced in the slide below.

Strong Quality Metrics

| Outcome | Incidence | Total Cases | Incidence Rate |
|---|---|---|---|
| Surgical Site Infections | 3 | 1010 | 0.0029 |
| Hospital Admission/Transfers | 3 | 1010 | 0.0029 |
| Hospitalizations within 48 hours of discharge | 3 | 1010 | 0.0029 |
| Wound Dehiscence | 0 | 1010 | 0.00 |
| Patient Fall | 1 | 1010 | 0.0001 |

SCA 17

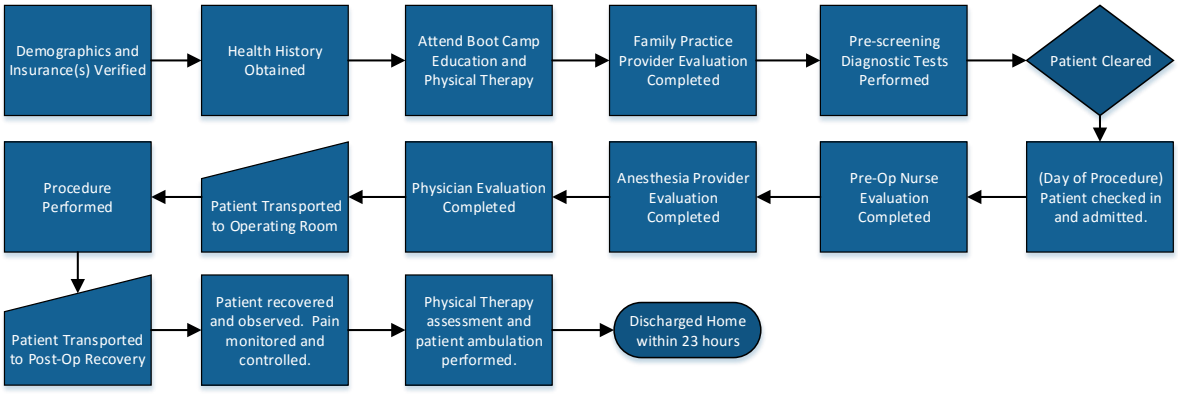
As presented by Dr. Sohrab Gollogly to the Advisory Panel on Hospital Outpatient Payments (HOP) at their August meeting, Monterey Peninsula Surgery Center in Monterey, CA, and a sister facility in Carlsbad recently conducted a retrospective study of 100 patients. The patients ranged in age from 38 to 84, with an average age of 59 years old. Of those patients, there were zero infections reported, and zero admissions within

five days of discharge. Further, there were zero hospital admissions within 5 days, and only one emergency room visit for uncontrolled pain. The results also showed very high patient satisfaction scores (>99%). Monterey alone anticipates performing over 200 joint replacements in 2016 on private payer patients.

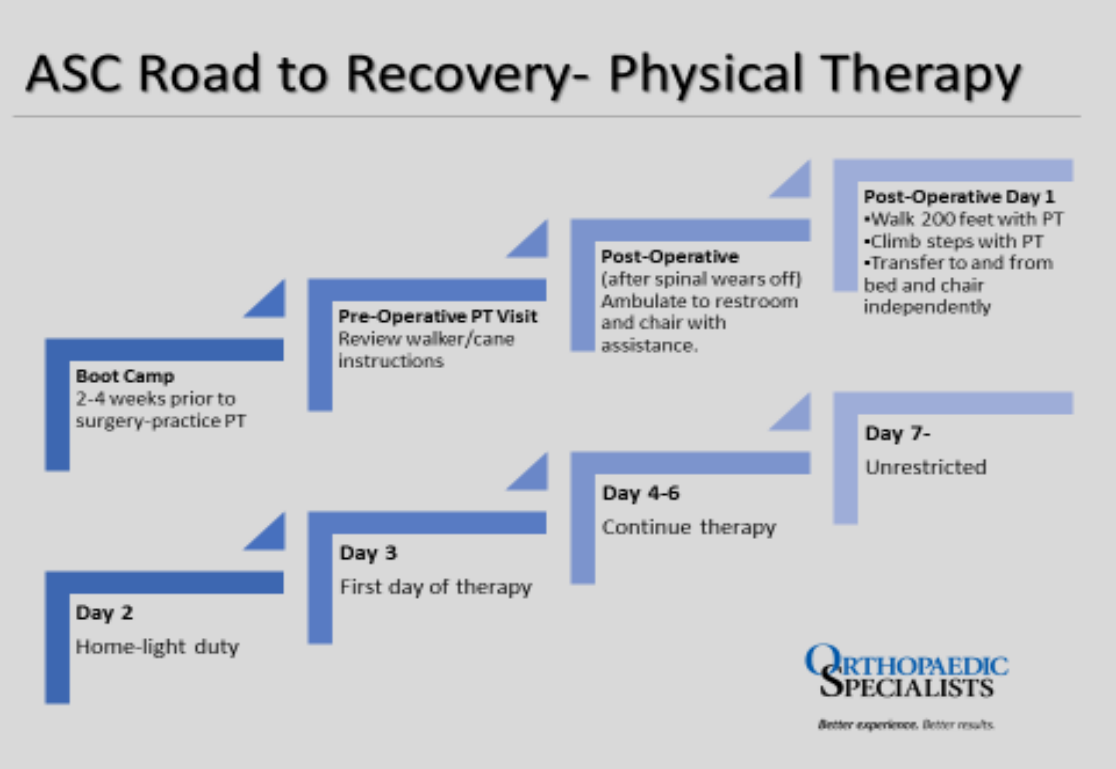
5. **Would it be clinically appropriate for some Medicare beneficiaries in consultation with his or her surgeon and other members of the medical team to have the option of a TKA procedure as a hospital outpatient, which may or may not include a 24-hour period of recovery in the hospital after the operation?**

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 who have family members at home who can assist them would likely be excellent candidates for an outpatient TKA procedure. Having options allows the physician and patient to determine the most appropriate setting of care.

Surgeons who perform outpatient TKA procedures know the importance of careful patient selection and strict protocols to optimize outpatient TKA 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 TKA is selected as the appropriate course of action.




Physical therapy is a critical element in the success of outpatient joint procedures. The slide below outlines the physical therapy protocols from Mississippi Valley. While all of these protocols are specific to one facility, every facility has in place strict criteria that must be followed in order to perform these procedures in the ASC setting.




Many inpatient hospitals are even starting to tout their ability to perform same-day total joint replacements. There have been several news stories recently on these procedures, including an article describing the same day total hip replacement surgery performed on a 76-year-old man.[10] Due to advances in technology and pain management, the patient was up and walking within a couple of hours, and discharged from the hospital the same day.

Dr. Hoffman, for example, performs the majority of his Medicare total joint replacements as outpatients at Trinity Bettendorf hospital. These are not billed as outpatient procedures because they are on the inpatient-only list, and procedures on the inpatient-only list are guaranteed as covered inpatient procedures regardless of the length of stay. Effectively, these patients are treated in the same manner as commercially-insured outpatient patients when done in the ASC setting. Medicare patients are treated at the hospital and are typically discharged the next morning.

If the agency continues to classify these procedures as inpatient-only, Medicare and its beneficiaries are forced to pay higher rates. By not only moving TKA off the inpatient-only list but also onto the ASC-payable list, CMS would be providing physicians and their patients the ability to choose, when appropriate, a high-quality, lower-cost outpatient alternative.

[10] *To Your Health: Same-day hip replacement*. http://www.doverpost.com/news/20160621/to-your-health-same-day-hip-replacement. (Posted on June 21, 2016).

The decision of where and when a TKA should take place should be between the patient and his or her surgeon. There are three options – hospital inpatient, hospital outpatient and ASC. If Medicare allowed 27447 to be performed at an ASC, that would allow patients and surgeons more flexibility in making this decision. Ultimately, the patient should be treated in the appropriate setting based on health status, not by a rule that dictates where a patient has to 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. On August 22nd, the Advisory Panel on Hospital Outpatient Payment unanimously recommended that CMS remove TKA from the inpatient-only list. ASCA strongly urges CMS to follow the recommendation of this panel and remove TKA from the inpatient-only list; this as an important first step to ultimately seeing ASCs reimbursed by Medicare for TKA and eventually other joint replacement procedures.

## Implementation of 603 of the Bipartisan Budget Act of 2015

***CMS should operationalize section 603 of the Bipartisan Budget Act of 2015 as intended by Congress to ensure continued Medicare patient access to outpatient surgery.***

The Bipartisan Budget Act of 2015 (Pub. L. 114–74) became law on November 2, 2015, and included Section 603 entitled, "Treatment of Off-Campus Outpatient Departments of a Providers." Effective January 1, 2017, unless the facility was billing as a department of a hospital prior to the date of enactment (November 2, 2015), payment for items and services furnished at an off-campus HOPD "shall be made under the applicable payment system under this part if the requirements for such payment are otherwise met." ASCA interpreted the applicable payment system as whichever system the facility was being reimbursed through prior to becoming an HOPD. For instance, an HOPD that used to be a physician's office would be paid under the Medicare Physician Fee Schedule (MPFS), and HOPDs that were previously ASCs would be reimbursed under the ASC fee schedule. We believe this was the intent of the legislation.

In this rule, CMS proposes the MPFS as the ''applicable payment system'' for the majority of the items and services furnished by nonexcepted HOPDs. CMS states that it intends "that this payment proposal would be a transitional policy, applicable in CY 2017 only" while CMS explores operational changes to allow a nonexcepted off-campus HOPD to bill Medicare under an applicable payment system." In this statement, CMS seems to be admitting that while the MPFS is not always the applicable payment system, it does not know how to accurately implement the provision.

While ASCA is sympathetic to the work it will require on the part of CMS, it is the duty of the Agency to operationalize the policy as Congress conceived in the statute. This means that CMS should use the ASC fee schedule to reimburse for codes in HOPDs that were previously ASCs, and the MPFS for procedures performed in HOPDs that were previously physicians' offices.

CMS acknowledges that there are limited instances in which a nonexcepted HOPD could reimburse under other payment systems. If a hospital were to enroll the HOPD as the provider it wishes to bill as (for instance, enroll as an ASC), that facility could be paid under another payment system. Basically, CMS is saying that the facility needs to convert back to an ASC in

order to be reimbursed as such. Practically speaking, this is not feasible under the current process required to convert from an HOPD to an ASC. When ASCs convert to HOPDs, they simply become a department of the hospital, and essentially an ASC could shut down on a Friday and reopen as an HOPD on Monday. However, the same is not true in reverse.

The HOPD can only remain part of the hospital and bill for services as such until the point it is no longer part of the hospital. It cannot seek status as an ASC as long as it is part of the hospital. Therefore, the hospital must first spin off the HOPD by creating a separate entity. Once it is not part of the hospital, the location (no longer an HOPD) can begin the process to become a separately-certified ASC. Once the location is "spun off" from the hospital, the location is not a location of the hospital nor is it any type of Medicare-participating entity. No services provided in that location are eligible for hospital payment. Further, since it is not a certified ASC until it is relicensed, no services provided in the location are eligible for Medicare ASC payment. During the time between disassociating from the hospital and the effective date of Medicare participation there is no eligibility for Medicare hospital or ASC payment. There is also no retroactive payment eligibility. With today's certification backlog, it is not uncommon for this process to take six to twelve months.

If CMS were to fix this process and allow HOPDs to be converted into ASCs more easily, ASCA might support this policy. However, as of now, we see the only viable option under the proposed rule is nonexcepted facilities being reimbursed under the MPFS, no matter what type of procedures are done or what type of facility the HOPD was prior to conversion. This is unacceptable. ASCA worries that HOPDs that were previously ASCs will stop performing certain surgical procedures, causing patient access issues. ASCA respectfully requests that if the facility was previously reimbursed as an ASC, that covered procedures in the nonexcepted HOPD will continue to be reimbursed at the ASC payment rate.

## Changes to the Quality Reporting Program

### *May 15 Deadline for all Web-Based Measures*

ASCA appreciates the work the agency has done to implement the ASC Quality Reporting (ASCQR) Program. Although still in its infancy, the ASCQR Program is already complex, featuring different data collection time frames, data submission deadlines and data submission methodologies.

The ASC community coalesced behind a group of stakeholders a decade ago to develop, test and seek endorsement of measures specific to the ASC setting. This group, the ASC Quality Collaboration (ASC QC), is preparing and will submit detailed comments on the specific measures proposed for inclusion in the ASCQR Program. 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," and ASCA strongly supports the ASC QC's comments regarding the quality reporting sections of this rule. In addition, we have highlighted below a few major areas of interest to ASCA regarding quality reporting to emphasize the concerns of our membership on some of the proposed policies.

In the 2017 payment rule, CMS has proposed to align the reporting deadlines for all web-based measures. If finalized, the reporting deadline for all web-based measures submitted via QualityNet (*ASC-6: Safe Surgery Checklist Use, ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures, ASC-9: Endoscopy/Poly Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients and ASC-10: Endoscopy/Poly Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use)* would be May 15 in 2017 and beyond, which would align the reporting deadline with the current deadline for reporting *ASC-8: Influenza Vaccination Coverage among Healthcare Personnel.*

While ASCA supports efforts to simplify the process for our facilities, we have concerns with the proposed May 15 deadline. Two of the measures were reported for the first time in 2015, *ASC-9* and *ASC-10*, and there were technical issues with QuailtyNet, such that any facility entering zeroes (meaning they did not perform these procedures) was unable to report until mid-April. The deadline was then extended, which was just as confusing for facilities. ASCA worries that when new measures are added in the future (such as when the seven proposed measures are reported in 2019) there will be technical difficulties and the deadline will need to be extended. We respectfully request that CMS keep the current deadline of August 15 for *ASC-6, ASC-7, ASC-9* and *ASC-10.*

***Measures Developed by the ASC QC that are Under Consideration***

The ASC QC has worked diligently to develop facility-level measures that are meaningful for the ASC setting and actionable for facility clinicians and staff. Two of these measures are proposed for inclusion in the ASC Quality Reporting Program for payment determination year 2020 and beyond: *ASC-13: Normothermia Outcome* and *ASC-14: Unplanned Anterior Vitrectomy.* ASCA applauds the work that has been done by the ASC QC, and supports the addition of both *ASC-13* and *ASC-14* to the ASCQR Program.

CMS has also requested more information on another ASC QC measure, toxic anterior segment syndrome (TASS). ASCA echoes the comments provided by the ASC QC, and supports this measure's future inclusion in the ASCQR Program.

***Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) Survey***

CMS has also proposed for payment determination year 2020 and beyond the addition of five new measures based on the use of the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) survey:

(1) *ASC-15a: OAS CAHPS – About Facilities and Staff*;

(2) *ASC- 15b: OAS CAHPS – Communication About Procedure*;

(3) *ASC-15c: OAS CAHPS – Preparation for Discharge and Recovery*;

(4) *ASC-15d: OAS CAHPS – Overall Rating of Facility*; and

(5) *ASC-15e: OAS CAHPS – Recommendation of Facility*.

While many ASCs and HOPDs conduct their own patient satisfaction surveys, there is currently no single instrument that assesses patient experience in both outpatient surgical settings. CMS is proposing the adoption of the OAS CAHPS survey, which would measure patient experience of care within ASCs and HOPDs. CMS is proposing to make this survey mandatory for both settings beginning in 2018, impacting 2020 payment determinations and beyond.

The OAS CAHPS survey instrument contains questions about the patient's overall rating of the outpatient surgery facility, experience with the check-in process, facility environment, communication with administrative staff and clinical providers, attention to comfort, pain control, provision of pre-and post-surgery care information, overall experience and patient characteristics. If this measure is finalized, ASCs will be required to select and contract with a CMS-approved third-party vendor who will collect survey data for eligible patients at the ASCs on a monthly basis and report that data to CMS on the ASC's behalf by quarterly deadlines established for each data collection period. The data may be collected by mail survey, telephone survey, or mixed mode (mail survey with telephone follow-up of non-respondents). ASCs may elect to add up to 15 supplemental questions to the OAS CAHPS survey.

ASCs would be required to survey a random sample of eligible patients on a monthly basis and collect at least 300 completed surveys over a 12-month reporting period. Smaller ASCs that cannot collect 300 completed surveys over a 12-month reporting period would only be required to collect as many completed surveys as possible during that same time period, by surveying all eligible patients.

Under the proposed rule, ASCs that treat fewer than 60 survey-eligible patients during the year preceding the data collection period can submit a request to be exempt from performing the OAS CAHPS survey. However, for all ASCQR Program requirements, facilities are exempt from participation if they bill fewer than 240 Medicare primary and secondary claims in a year. It is difficult to identify a scenario in which a facility would have fewer than 60 survey-eligible patients, but not also fall under the 240 Medicare claim threshold. This will be confusing to facilities, who may wonder if they need to submit a request to be exempt, even though they are already exempt from the entirety of the ASCQR Program requirements. ASCA requests that CMS clarify in what situations a facility may have to apply for the exemption, or use the 240 claims threshold to exempt all small facilities.

***CMS should refine the OAS CAHPS survey and the proposed measures based on the survey to ensure that the data collected by facilities is meaningful and actionable.***

The ASC QC has been extremely involved since the beginning of the survey development process and proposed ways to shorten the survey and make its administration less burdensome for our facilities. The ASC QC and ASCA are aligned in our desire to promote a patient satisfaction survey that provides meaningful data to patients, ASCs and CMS. As such, it is important that CMS address some of the industry's key concerns to alleviate burden and encourage participation.

***Lack of electronic survey option.*** Internet access and email accounts are common in today's society, and should be at least allowed as one option for data collection. Survey vendors already

offer electronic survey options to their customers. Particularly if facilities would like to include their own measures, making the survey even longer, it is important that the means by which they complete the survey is as user-friendly as possible. The inability of CMS to provide an electronic survey option increases burden and cost unnecessarily. ASCA implores CMS to add an electronic mode as an option for conducting the OAS CAHPS survey.

***Required number of completed surveys.*** The expected number of 300 completed surveys may be overly burdensome for facilities. As previously mentioned, ASCs are more often than not small businesses, with two or fewer operating rooms. When inpatient hospitals were first required to use the HCAPHS survey, they only had to achieve 100 completed surveys. Setting higher expectations from the start for smaller providers like ASCs is unreasonable, and ASCA requests that the initial requirement be set at 100 completed surveys.

***Survey length.*** The survey should be significantly shortened, 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. Only those items that are required by law or that would actually be used in patient-mix adjustment for public reporting purposes should be included. Based on our review of the factors used in the patient-mix adjustment for CAHPS® surveys, only the items that identify self-reported health status (item 25), age (item 27), education (item 29), primary language other than English (item 33) and a proxy respondent (item 36) should be retained. Federal data collection requirements regarding sex, race, ethnicity, and primary language can be met with items 28, 30, 31, 32 and 33. The other four items (26, 34, 35 and 37) are not essential. In fact, the US Office of Minority Health clearly identifies items 34 and 35 as optional in its implementation guidance. It is not reasonable to ask ASCs to shoulder the additional cost of items that are optional. Optional and non-essential items in this should be removed.

In addition, 24 questions regarding the patient's experience is needlessly high. If a facility chooses to add its own questions to collect information to enhance the patient experience in their facility, 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 responses rates.

ASCA strongly supports quality reporting measures that speak to the quality of care being provided by the facility and will help improve care as well as 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.

## Summary

While ASCA appreciates the stated efforts of CMS leadership to achieve cost-savings, the agency must do a better of job ensuring that the annual ASC payment rule allows Medicare beneficiaries continued access to the high-quality, lower-cost care that ASCs provide. The current regulatory framework that governs ASC payments is based on an outdated perspective of how ASCs operate and a limited understanding of the many benefits to Medicare and its

beneficiaries that ASCs can provide. The ASC community serves an integral role in the healthcare delivery system and we implore CMS to consider policies that encourage these providers to continue to serve Medicare patients.

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 happy to discuss any of these issues further.

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