



September 17, 2021

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1753-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Via online submission at www.regulations.gov

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

Dear Administrator Brooks-LaSure:

Before offering our comments to the above-referenced rule, we wish to offer our appreciation for the time and energy that you and your staff devote to meeting the challenges of the COVID-19 pandemic. The pandemic has claimed more than 670,000 American lives and wreaked enormous harm on the economy while straining our healthcare system. We now have more data on the impact of cancellations and delays to critical surgeries and screening procedures offered in ASCs, as seen in the sampling of news articles and research studies compiled in Appendix A. We look forward to working with CMS to ensure that Medicare beneficiaries have access to the care they require as this public health emergency continues and beyond.

While the calendar year (CY) 2022 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule ("Proposed Rule") (86 Fed. Reg. 42108, August 4, 2021) includes some encouraging signs that the Biden Administration is committed to improving the Medicare delivery system, it also takes some backward steps in terms of clinical discretion, access to care and adding administrative burden to our facilities with no corresponding quality improvement.

The Ambulatory Surgery Center Association (ASCA) shares the Administration's stated desire to encourage competition between high-quality healthcare providers¹ and "to protect and expand

¹ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/> (accessed September 1, 2021).

Americans' access to quality, affordable health care.”² ASCs are well-positioned to both provide high-quality care and improve efficiencies at the same time.

ASCA supports CMS in its pursuit of policies that save Medicare and its beneficiaries money without compromising quality, and this value proposition is the essence of the ASC model and can be seen in the care provided by the 6,058³ Medicare-certified ASCs nationwide. To that end, we are pleased to report that recent research⁴ shows that ASCs reduced costs to the Medicare program by \$28.7 billion in the period between 2011 and 2018. This study, which provides an update to ASC cost savings research released several years ago,⁵ indicates an increase in annual savings from \$3.1 billion in 2011 to \$4.1 billion in 2018. Importantly, if volume migration continues at the same rate as 2011–2018, ASCs are projected to reduce Medicare spending by \$74.2 billion from 2019–2028,⁶ freeing up those dollars for use on other health priorities. Adopting policies that encourage further migration will generate even greater savings than those projected.

Our comments below outline ASC payment policy proposals that would encourage the clinically appropriate migration of services into the lower-priced ASC setting—providing the Medicare program and its beneficiaries with a substantial savings opportunity while ensuring continued access to the high-quality care that ASCs provide and beneficiaries deserve. We welcome the opportunity to collaborate with CMS on the payment policy changes outlined in this letter that will assure safe and high-quality care to beneficiaries and reduce the cost of care to them and the Medicare program.

Specifically, our comments focus on the following key topics:

- **Procedures Permitted in ASCs.** ASCA opposes the sweeping proposal to remove 258 codes from the ASC Covered Procedures List (ASC-CPL) that were just added in 2021. We encourage CMS to reconsider this significant shift backward and to ensure that the appropriate site of care is determined by the clinical judgment of those providing care to beneficiaries.
- **Conversion Factor.** ASCA supports CMS' continued use of the hospital market basket as the annual update mechanism for ASC payments. However, the migration of services to ASCs will remain limited due to the siloed budget neutrality adjustments.

² <https://www.whitehouse.gov/priorities/> (accessed September 1, 2021).

³ As of September 1, 2021, according to CMS' Survey & Certification (S&C)'s Quality, Certification and Oversight Reports (QCOR), available here: <https://qcor.cms.gov/main.jsp>.

⁴ *Reducing Medicare Costs by Migrating Volume from Hospital Outpatient Departments to Ambulatory Surgery Centers*, KNG Health Consulting, LLC, September 2020. <https://www.advancingsurgicalcare.com/reducinghealthcarecosts/costsavings/reducing-medicare-costs>

⁵ *Medicare Cost Savings Tied to Ambulatory Surgery Centers*, University of California-Berkeley Nicholas C. Petris Center on Health Care Markets and Consumer Welfare, September 2013; and the US Department of Health and Human Services. Office of Inspector General. Washington: Government Printing Office, April 2014. (A-05-1200020).

⁶ *Reducing Medicare Costs by Migrating Volume from Hospital Outpatient Departments to Ambulatory Surgery Centers*.

- **ASC Weight Scalar Adjustment.** ASCA supports the discontinuation of the ASC weight scalar. With the 2019 change in the conversion factor, it is even clearer that removing this secondary scaling adjustment is necessary to truly align the payment systems and enable ASCs to capture the value of the conversion factor, which will motivate increased migration of surgery to our setting and lower the cost of care.
- **Quality Reporting Requirements.** ASCA supports a strong quality reporting program with measures that are actionable at the facility-level. We oppose ASC-11, as it is a little-used clinician measure that will create an undue burden for facilities.

Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2022

ASCA opposes the complete reversal of the 2021 decision to add 258 codes to the ASC-CPL based on revised criteria.

While ASCA was not expecting the 267 codes that were proposed – and later finalized – to be added to the ASC-CPL in 2021, we were even more surprised that one year later CMS is proposing to completely reverse course. We have serious concerns with the way this was handled and the discussion surrounding this issue included in the proposed rule.

Lack of clinical data

The same medical officers who allowed for the codes’ addition in 2021 are now claiming, without evidence, that these codes may not be safely performed in the ASC setting. To retain any of these codes, CMS is requesting “clinical evidence or literature to support commenters’ views that any of these procedures meet the proposed revised CY 2022 criteria and should remain on the ASC CPL for CY 2022.” ASCA will provide as much as we can in this short comment period window, but we would also request that CMS do the same. The rule indicates that CMS clinicians evaluated all 258 codes proposed for removal from the ASC-CPL, but there is not one data point in the rule, or citation to research, or other outcomes data indicating exactly what the safety concerns are for any of the codes.

Relying on limited claims to argue lack of adoption

CMS also indicates that based on an “internal review of preliminary claims submitted to Medicare,” the Agency does not believe ASCs have begun furnishing these procedures on Medicare patients. Because of this, CMS believes it is “unlikely that ASCs have made practice changes in reliance on the policy we adopted in CY 2021. Therefore, we do not anticipate that ASCs would be significantly affected by the removal of these 258 procedures from the ASC CPL.” This supposition ignores the reality that it takes time to add new procedures in a facility, and the data CMS would have at this point in the year is extremely limited.

In addition, CMS’ addition of codes to the ASC-CPL often opens the door for other payors to reimburse for these procedures, and as such, many facilities may have started with other patient populations before taking on any sort of significant Medicare volume. ASCA recently conducted a survey, asking facilities for input on this proposed rule. Overall, 42 percent of the respondents

(97/233) said their facility did make an investment in technology, staff or training due to the expectation that these codes would remain on the ASC-CPL.⁷

Evaluating codes based on the “typical” Medicare beneficiary

CMS acknowledges that many procedures added in CY 2021 are only appropriate for healthier Medicare beneficiaries who have less complex medical conditions than the “typical” beneficiary, and upon further review, they “believe it is appropriate to assess the safety of these procedures in the context of the typical Medicare beneficiary, whose health status is representative of the broader Medicare population.” CMS references the authority granted to the US Department of Health and Human Services (HHS) in the Social Security Act (SSA) to add codes and implies that by adding codes to the ASC-CPL Medicare has determined the procedure is safe to perform on the typical Medicare beneficiary. The SSA does **not** include any language of the sort.⁸

Medicare beneficiaries – like our country’s population at large – are not a monolith. When CMS added total knee arthroplasty (TKA) to the ASC-CPL in 2020, the Agency acknowledged that there is a “small subset of Medicare beneficiaries who may be suitable candidates to receive TKA procedures in an ASC setting based on their clinical characteristics.” If CMS is truly only allowing ASCs to perform procedures that are safe for the “average” Medicare beneficiary, you are severely limiting access to Medicare beneficiaries who are relatively young and active with few comorbidities. There would also need to be a much more detailed explanation of what constitutes an average beneficiary, because on its face this language could practically eliminate the ASC-CPL altogether.

There are certain subsets of the population who should be having surgeries performed in an inpatient hospital due to comorbidities and risk factors. It is much more reasonable to determine whether a subset of the population is suitable and allow for the clinician to then decide which of her patients are eligible for care in an ASC.

CMS indicates that “while a physician can make safety determinations for a specific beneficiary, CMS is in the position to make safety determinations for the broader population of Medicare beneficiaries.” It is insulting to physicians to insinuate that they would risk the health or life of their patients by intentionally bringing them to an inappropriate setting. The physicians who work in ASCs are much better equipped to determine which cases should be in an ASC than CMS clinicians – most of whom are not surgeons.

Incorrect assessment of the requirements for HOPDs vs ASCs

CMS argues that “while there are similarities between the ASC and HOPD settings, there are also significant differences between the two care settings.” The rule gives as examples that “hospitals operate 24/7 and are subject to EMTALA requirements, while ASCs are not,” and uses that to conclude that “a procedure that can be furnished in the HOPD setting is not

⁷ ASCA conducted a member survey between August 3 – August 13, 2021. There were 361 responses overall, but some respondents did not answer all questions.

⁸ See Social Security Act 1833(i)(1).

necessarily safe and appropriate to perform in an ASC setting simply because we make payment for the procedure when it is furnished in the HOPD setting.”

An HOPD is a department of a hospital – not a fully-functioning hospital on its own. It simply provides outpatient services, hence the name. An off-campus HOPD can be up to **35 miles** away from a hospital’s campus,⁹ is not open 24/7, and is not necessarily equipped with – or even close to – an emergency department. Although inpatient hospitals must provide 24/7 nursing services, the hospital Condition of Participation (CoP) for nursing services found at 42 CFR §482.23 (7) states, “the hospital must have policies and procedures in place establishing which outpatient departments, if any, are *not* required under hospital policy to have a registered nurse present.”

ASCs are subject to a rigorous 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 (CfCs) and further safeguards have since been implemented to enhance patient safety and quality of care in ASCs.

Technological advances increasingly drive procedures to the outpatient setting and research confirms that outcomes are very similar, even adjusting for risk, between hospital outpatient departments (HOPD) and ASCs.¹⁰ Survey and certification requirements are essentially the same in both ASCs and HOPDs, as evidenced by the table below;¹¹ indeed, the primary difference between the settings is the much higher reimbursement rate HOPDs receive over ASCs.

Medicare Health and Safety Standards	ASCs	HOPDs
Compliance with State licensure laws	§416.40	§482.11
Governing body and management	§416.41	§482.12
Surgical services	§416.42	§482.51
Quality assessment and performance improvement	§416.43	§482.21
Physical environment	§416.44	§482.41
Safety from fire	§416.44	§482.41
Building safety	§416.44	§482.41
Emergency equipment	§416.44	§482.41
Emergency personnel	§416.44	§482.55
Medical staff	§416.45	§482.22
Nursing services	§416.46	§482.23
Medical records	§416.47	§482.24
Pharmaceutical services	§416.48	§482.25
Laboratory and radiologic services	§416.49	§482.26; §482.27
Patient rights	§416.50	§482.13
Infection control	§416.51	§482.24; §482.42
Patient admission, assessment and discharge	§416.52	§482.43
Emergency preparedness	§416.54	§482.15

⁹ 42 CFR § 413.65(3)(i)

¹⁰ Elizabeth L. Munnich and Stephen Parente, “Returns to Specialization: Evidence from the Outpatient Surgery Market.” *Journal of Health Economics*, 57, 2018.

¹¹ Sources: 42 CFR 416 & 482

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

Codes that should stay on the ASC-CPL

While ASCA believes CMS should keep all 258 codes on the ASC-CPL that are proposed for removal, we recognize that the Agency may be unwilling to completely reverse course on this proposal. Attached, we highlight codes for which there is volume in the ASC setting, that ASCA has requested previously, and that our members have indicated they are performing or would like to perform in the future and believe are safe.

Ambulatory Payment Classifications

Most of the codes listed in Appendix B are in Ambulatory Payment Classification (APC) groups where the vast majority of the codes are proposed to be reimbursed in the ASC setting in 2022. According to this Proposed Rule and rules preceding it, when evaluating which codes to put in the same APC groups, CMS establishes "resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC." It makes sense then that those codes should remain payable if the other codes within the APC group are clinically similar and deemed safe for the ASC setting.

There are even several codes proposed for removal from the ASC-CPL that would be the *only* code in their APC group not payable in the ASC setting. One example is CPT 1903, which ASCA has long-requested be added to the ASC-CPL. It is in APC 5092, which has 12 codes, and the 11 other codes in the group are all on the ASC-CPL for 2022. There is significant HOPD Medicare volume for this code (4,439 cases in 2019), and it is commonly performed on non-Medicare beneficiaries in the ASC setting. This procedure, along with the others identified in Appendix B should remain on the ASC-CPL for 2022.

Lumbar Spine Fusion

In addition to the codes that should remain payable in the ASC-CPL, CPT 22633 should be added to the ASC-CPL in 2022. This procedure, along with CPT 22630 (discussed more below in the inpatient-only list section) has been commonly performed in the ASC setting for commercially insured patients for several years. So far in 2022, CPT 22633 has been performed 6,244 times in the ASC setting.¹²

¹² Definitive Healthcare (<https://www.definitivehc.com/>). Healthcare data analytics with all-claims data. (Accessed September 17, 2021).

Thanks to the Hospital Without Walls program that was established early in the COVID-19 public health emergency, we now have outcomes data¹³ for posterior lumbar inter-body fusions for Medicare beneficiaries, as the program enabled one of our facilities, Legacy Surgery Center, to enroll and perform these lumbar inter-body fusion services on Medicare patients over the last year and a half in a COVID-19 free environment. The results from this study, attached as Appendix C, demonstrate the safety, efficacy and patient satisfaction for lumbar inter-body fusion surgery performed in the ASC setting are comparable to or better than in the hospital setting. In fact, the only major difference is that the length of stay is significantly longer in the hospital; the average length of stay for Medicare patients in the ASC was less than three hours.¹⁴

Nomination Process for Additions to ASC-CPL

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

As CMS notes in the rule, stakeholders are currently able to schedule meetings with CMS and present data on codes that should be added to the ASC-CPL, but ASCA agrees that a more formal nomination process would provide greater transparency to the process. The proposed rule states that CMS would establish a nomination process for CY 2022 through which external stakeholders, such as professional specialty societies, would nominate procedures for addition to the ASC-CPL. Nominations would be due to CMS by March 1 and CMS would review and finalize procedures through annual rulemaking, beginning with the CY 2023 rule.

CMS indicates the Agency “would address in rulemaking nominated procedures for which stakeholders have provided sufficient information for us to evaluate the procedure.” More guidance as to what is deemed sufficient would be helpful. For example, whether outcomes data for individual facilities counts or peer-reviewed research is required.

Currently, CMS is not required to disclose a rationale for excluding a given procedure, so any progress on this front is much needed and long overdue. The current lack of transparency makes it difficult for clinicians to marshal the data needed to challenge these decisions since they are often not sure by what basis CMS chose to exclude the codes. In the 2022 proposed rule, CMS indicates that if the Agency were to disagree with the addition of a nominated code, the Agency would provide a rationale for exclusion in the final rule. This proposal is similar to a provision in legislation supported by ASCA, the most recent version being the *Ambulatory Surgical Center Quality and Access Act of 2019* (H.R. 4350/S. 3085), which would require CMS to disclose what criteria trigger the exclusion of the procedure from the ASC-CPL. ASCA supports a 2021 version of this legislation, and we also support CMS proactively creating a more formal and transparent process.

¹³ Schlesinger, Scott MD, Maggio, Dominic MD. A study, made feasible by the Hospitals Without Walls (HWW) waiver due to the public health emergency (PHE) of the COVID-19 pandemic, of the safety and efficacy of transforaminal or posterior lumbar inter-body fusion surgery (TLIF or PLIF) at in the ASC setting for Medicare beneficiaries. Pending publication. August 2021.

¹⁴ Schlesinger, Scott MD, et al.

CMS should eliminate the following exclusionary criteria

CMS is proposing to revert to the old exclusionary criteria, formerly under 42 CFR 416.166 (c)(1) – (5); (1) *generally result in extensive blood loss*; (2) *require major or prolonged invasion of body cavities*; (3) *directly involve major blood vessels*; (4) *are generally emergent or life threatening in nature*; (5) *commonly require systemic thrombolytic therapy*. ASCA has had success working with CMS to add codes to the ASC-CPL in the past, even using these criteria, and while we have reservations as to how they can be interpreted—they are imprecise and subjective—we do not oppose their return if they are used as guidance for exclusion as opposed to an automatic refusal to consider. Many states that look to CMS regulations when determining what to allow in their jurisdictions misinterpret the exclusionary criteria for the Conditions for Coverage (CfCs) and impose onerous limitations on ASCs based on those misinterpretations. As previously discussed, the CfCs that are in place already ensure that ***all*** ASC patients receive care in a safe and highly regulated environment, regardless of payer.

There are many procedures, for instance, that “involve major blood vessels” that are extremely safe for the outpatient setting. CMS should continue to evaluate codes on a case-by-case basis to determine whether that “involvement” leads to a heightened risk of negative outcomes.

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

Active Medical Monitoring and Care Past Midnight

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

Unlisted Codes

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

One code that is requested for addition to the ASC-payable list every year by our members is 41899 (dental surgery procedure). This is the *only* CPT code available for dental surgery. We recognize that dental services in general are not yet provided under Medicare, but we have heard from the dental community that dentists want to bring cancer patients to ASCs for certain complex procedures, such as to have teeth removed prior to radiation. While it is not significant for the Medicare population, this procedure is also frequently performed on pediatric dental patients, many of whom are covered by Medicaid. Some state Medicaid plans only reimburse ASCs for codes found on the ASC-CPL, which causes access issues.

If providers can choose to perform these procedures in HOPDs, facilities that we have already shown to be often identical to ASCs, and physician offices that are not regulated by the federal government, physicians should be able to use unlisted codes in the ASC setting. ASCA requests that CMS revise the Code of Regulations to eliminate this restriction. In the alternative, we request that CMS work with ASCA and dental community stakeholders to identify a viable billing solution that improves access to covered dental surgical services for patients and allows dentists the ability to choose to perform these procedures in ASCs for Medicare and Medicaid patients.

Proposal to Reverse the Elimination of the Inpatient-Only (IPO) List

ASCA supports this proposal, but requests several codes remain payable in the HOPD setting.

The decision in 2021 to begin the process of eliminating the inpatient-only (IPO) list was surprising, and ASCA raised some concerns with the move in our comment letter last year. However, as with the huge swing in policy regarding a complete reversal of the codes added to the ASC-CPL last year, ASCA has concerns with the proposal to completely reverse course on the IPO list. It is difficult for facilities and the clinicians who practice there to invest in new equipment and develop protocols to move new procedures to the facility if they are unsure how long those codes will remain payable in the setting. Many codes that were removed from the IPO list are currently being performed not only in HOPDs but also in ASCs on other patient populations, and CMS should not put those codes back on the IPO list. Three codes we request that CMS keep off the IPO list are (number in parenthesis is 2021 volume in the ASC setting through August): ¹⁵ CPT 23472, total shoulder arthroplasty (11,555), CPT 27702, total ankle replacement (567) and CPT 22630, lumbar spine fusion (886).

Total Shoulder Arthroplasty and Total Ankle Replacement

While total joint replacements were historically inpatient surgical procedures that required lengthy hospital stays, as CMS acknowledges in the 2020 Proposed Rule and prior rulemaking, recent innovations have enabled surgeons to perform joint replacement procedures “on an outpatient basis on non-Medicare patients (both in the HOPD and in the ASC).” Innovations such as minimally invasive techniques, improved perioperative anesthesia, alternative

¹⁵ Definitive Healthcare (<https://www.definitivehc.com/>). Healthcare data analytics with all-claims data. (Accessed September 17, 2021).

postoperative pain management, and expedited rehabilitation protocols” have made it possible for these procedures, along with other total joint replacement surgeries, to be performed in the outpatient setting. There have been more than 100 peer-reviewed articles published on the topics of outpatient joint replacement, appropriate patient selection, multi-modal pain management, rapid rehabilitation and clinical outcomes. Attached as Appendix D to this comment letter are several studies that specifically speak to outpatient total shoulder arthroplasty and total ankle replacement safety. It is backwards and counter to research on the topic to move these procedures back to the IPO-list.

Lumbar Spine Fusion

As stated above when discussing the need to add 22633 to the ASC-CPL, these spine procedures are routinely being done on other patient populations in the ASC setting and should be available to appropriate Medicare beneficiaries in the outpatient setting, as well. The HWW program provided the opportunity for these cases to be performed in ASCs on the Medicare population, and the results show what we already knew – that ASCs achieve stellar outcomes for these procedures.¹⁶ As with the joint replacement procedures, it is backwards and counter to research on the topic to move these procedures back to the IPO-list.

Device-Intensive Policy Change

ASCA strongly supports CMS’ proposed device intensive policy.

ASCA has been working with the Agency for many years to address the device offset threshold and its impact on ASC volume and we appreciate the Agency recognizing the important role that device costs can play in a facility’s ability to perform these procedures. Although we supported dropping the device threshold twice over the past several years, from 50 percent to 40 percent and then down to the current 30 percent threshold, the threshold determination was still based on the cost when performed in an HOPD. ASCA has long-requested that CMS determine the percentage the device accounts for in the ASC setting to determine device-intensive status, and we are grateful that CMS has finally acknowledged that this is a more appropriate calculation method.

ASCA encourages CMS to use the most accurate data available, including external invoices, to calculate the device-intensive threshold to ensure adequate reimbursement for procedures. This would have the effect of designating additional procedures device-intensive and allow for additional migration of procedures from the higher-cost HOPD setting.

CMS will accept invoices for the device intensive assessment if there are no available claims data. The Agency should expand its policy of using invoices for the device intensive assessment to include consideration of invoices when there are fewer than 20 single frequency claims. When there are so few claims it is functionally akin to having no available claims data and thus is a logical extension of existing policy that can facilitate appropriate payment to ASCs.

¹⁶ Schlesinger, Scott MD, et al.

As we have commented above, we support the agency's efforts to use the device-intensive policy to ensure appropriate payment rates to ASCs for these procedures. We appreciate the statement from CMS in the CY 2021 final rule that indicated that when an existing code is clinically related and similar to a new code CMS would apply the device offset percentage from the existing clinically related or similar code's claims data when computing the ASC rate for the new code. We agree that this better compensates ASCs for the resources for new codes.

In the proposed rule, though, CMS does not seem to be implementing this policy as written. CMS proposes to use a 31 percent device offset percentage for ASC rate calculations for the new MIGS procedure codes (new CPT codes 669X1, 669X2, and 0X12T) even though these procedures are clinically related and similar to CPT code 0191T, which has a device offset percentage above 55 percent. This issue was presented to the Advisory Panel on Hospital Outpatient Payment (HOP Panel), which recommended that CMS use the device offset percentage from the pertinent existing CPT codes. We agree with the HOP Panel's recommendation and request that CMS use the device offset percentages from related existing CPT codes in computing the ASC payment rates for new codes 645X1, 669X1, 669X2, and 0X12T.

The vast majority of these cases are performed in the ASC setting and are already reimbursed at about half the HOPD rate. We strongly believe that payment for the combined MIGS cataract procedures at the proposed rate, *i.e.*, approximately \$800 lower than CY 2021 reimbursement, could impede the glaucoma patient's access to these vital services in the ASC.

CMS should encourage Congress to implement an ASC co-pay cap.

While recent changes to the device-intensive threshold have increased the number of device-intensive codes on the ASC-CPL, they have also shone a spotlight on how the lack of alignment in the HOPD and ASC payment systems creates a barrier to access for Medicare beneficiaries. While there is a statutory cap on the patient responsibility when a procedure is done in a hospital, including an HOPD, that policy is not in place for the ASC setting. Even though the Medicare beneficiary's patient responsibility is capped, the hospital is made whole by the Medicare program. Perversely, the lack of a co-pay cap in the ASC setting encourages beneficiaries to receive care in the hospital, increasing costs to the Medicare program for no clinical reason.

In years past, this had not been an important issue for ASCs due to the lack of codes for which the reimbursement rate was high enough to trigger a potential cap in our setting, but this is changing as higher-cost procedures in general have been added to the ASC-CPL, and as more procedures have been identified as device-intensive. There are 150 codes on the 2022 proposed ASC-CPL for which the patient responsibility based on the national reimbursement rate would be higher in the ASC than the HOPD; all but one of those codes are device-intensive. Many orthopedic codes, such as total joint replacements, are included in that group. Beneficiaries who would otherwise have access to the high-quality, convenient ASC setting are disadvantaged by this lack of alignment in policy. As this requires a statutory fix, ASCA will be working with Congress to address this issue and we encourage CMS to advise Congress to create a co-pay cap for the ASC setting as well.

ASCA requests that CMS pay separately for additional levels of spine procedures.

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

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

ASCA requests that CMS assign a payment weight to these codes so that the ASC will be reimbursed fairly to offset the increased cost with the add-on codes that are performed in these cases.

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

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

One example of how much the wage index can impact device-intensive codes is for a knee reconstruction code, CPT code 27429. The 2022 proposed national rate for 27429 is \$10,520.50 and CMS estimates the device costs at \$9,364.15. In rural Tennessee, where the local wage index is currently 0.7159, the current reimbursement rate for 27429 is \$9,026.07, ***which is less than the device costs***. There are very few device-intensive codes for which the total reimbursement rate exceeds the device cost in rural Tennessee, and this issue impacts all communities with a lower wage index and causes access issues for Medicare beneficiaries.

Continued Divergence of Payment Rates

No matter how many codes are added to the ASC-CPL, the top 100 by volume rarely change. Until problematic payment policies that contribute to a lack of alignment between the ASC payment system and the OPPS are fixed, CMS will not realize its desired Medicare cost reductions as there will be insufficient incentive for providers to migrate services to our facilities.

Most ASCs operate as small businesses, with all the taxation that entails, and as such, must run efficiently to remain viable. As of June 2021, there were 5,998 CMS-certified ASCs¹⁷, and 4,338 (72 percent) have three or fewer operating rooms and 3,250 (54 percent) of those 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 supplies since they do not have the same purchasing power of a hospital or large health system. ASCs compete with hospitals and other health care providers for the same nurses and other staff, which has been made more challenging during the COVID-19 pandemic. ASCs still must comply with state and federal regulations¹⁸ comparable to those required of HOPDs, along with an ever-growing Medicare quality reporting program. And yet, CMS payment policies drive a growing disparity in reimbursement rates.

While ASCs pride themselves on running efficiently, being reimbursed 50 percent on average for the same procedures being provided in a similar site of service jeopardizes the ability of our facilities to perform all the Medicare cases we possibly could absorb. Medicare surgical procedures in too many markets continue 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 and the taxpayers who fund it.

Medicare is projecting a total *increase* in expenditures under the OPPS for CY 2022, compared to CY 2021, due only to the changes to the OPPS in this proposed rule, of approximately \$1.35 billion. Yet, even though CMS claims to want to drive volume to the lower-cost, high-quality ASC setting, the Agency is projecting a \$20 million *decrease* in spending in the ASC payment system in 2022. Whereas ASCs accounted for 6.63 percent of the total spend between ASCs and HOPDs in 2016, the ASC percentage between the two settings is declining. According to CMS' projections in the proposed payment rule, ASCs will account for only 5.87 percent of that spend in 2022.

While the alignment of update factors was a positive first step, the lack of alignment between payment systems, most evident in the ASC (secondary) weight scalar, as discussed later in these comments, threatens patient access to outpatient surgical care in the ASC setting.

¹⁷ 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/>.

¹⁸ <https://www.advancingsurgicalcare.com/safetyquality/federalrequirementsgoverningasc> (Accessed September 2021)

Annual Payment Update Policies

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

When CMS implemented the revised ASC payment system in 2008, the Agency's stated goal was to encourage high-quality, efficient care in the most appropriate outpatient setting and align payment policies to eliminate payment incentives favoring one care setting over another.¹⁹ Since 2008, the ASC community has urged CMS to adopt the same update factor for both the ASC and OPPOS payments and appreciates that CMS took this first, necessary step toward better alignment of the payment systems.

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

Request for Cost Data

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

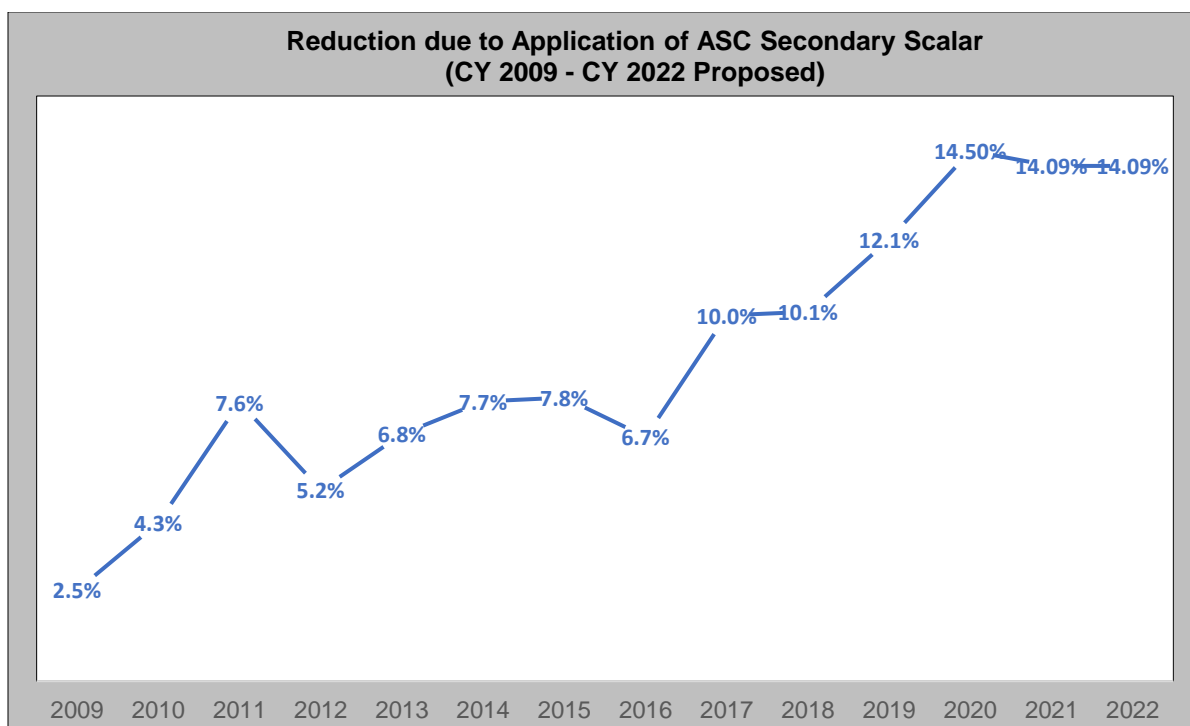
We know that many of the same types of costs incurred by hospital outpatient departments are also incurred by ASCs, but we do not know if they are weighted the same. We welcome the opportunity to discuss how we might potentially use a simple, cost-effective survey or other low-burden data collection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

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

¹⁹ CY 2007 OPPOS/ASC Proposed Rule (<https://www.cms.gov/newsroom/press-releases/cms-revises-payment-structure-ambulatory-surgical-centers-and-proposes-policy-and-payment-changes>)

ASCA encourages CMS to discontinue the ASC weight scalar.

Since the payment systems were aligned, CMS has taken the relative weights in the OPPS, which have already been scaled, and then applies a secondary weight scalar, known as the ASC weight scalar, before arriving at the ASC payment weights. In the Final Rule establishing the ASC payment system (72 Fed. Reg. 42532, August 2, 2007), CMS suggested that the scaling of the relative weights is a design element that would protect ASCs from changes in the OPPS relative weights that could significantly decrease payments for certain procedures. However, the trend in the OPPS relative weights suggests that the ASC weight scalar rarely, if ever, results in an increase in ASC relative weights. As the graph below indicates, the reduction due to application of the ASC weight scalar has increased significantly since the ASC payment system was aligned with the HOPD payment system. In 2018, the ASC weight scalar fell under 0.9000 to 0.8995, for a 10.1 percent reduction to the ASC weights, and in 2021, CMS is proposing an adjustment of 0.8591 which, if finalized, would result in a 14.09 percent reduction.



The historical trend seen in the above chart and the absence of any indication that it is likely to reverse in the future suggest that the continued application of the ASC weight scalar will exacerbate the growing divergence in ASC and HOPD rates and discourage beneficial migration.

Gastrointestinal endoscopies are among the highest-volume procedures performed in the ASC setting, accounting for six of the top 12 codes by volume in 2019. There were more than 1.8 million GI procedures performed in ASCs in 2019, just within this group of six codes.²⁰ Taking out current savings (cases already being done in ASCs instead of HOPDs), if 90 percent of these

²⁰ The six CPT codes are: 43239, 45378, 45380, 45385, G0105, and G0121.

six GI endoscopies were performed in ASCs instead of HOPDs—and many clinicians believe that percentage of beneficiaries could be safely seen in an ASC—the volume migration would represent \$775 million in additional (“new”) savings annually. The total *annual* reduction in cost to the Medicare program would be approximately \$1.55 billion *for these six codes alone*.

The current payment system does nothing to incentivize case migration to the lower cost setting, and it actually does the reverse. CMS’ antiquated cost containment mechanisms – trying to maintain budget neutrality in silos for each payment system – penalizes migration to a lower-cost setting because that shift ultimately leads to reductions in reimbursement rates for those providing the care. While ASCA realizes we cannot fix the entire Medicare program with the OPPS/ASC rule, the Agency could take a big step in at least reducing disparities between HOPD and ASC reimbursement by eliminating the ASC weight scalar.

If CMS continues to apply budget neutrality adjustments looking at the ASC payment system alone, that means that any increase in volume would lead to stagnation or a decrease in reimbursement rates. There is no evidence of a growing difference in capital or operating costs in the two settings to support this growing payment differential. By maintaining budget neutrality in silos, instead of looking at HOPDs and ASCs collectively, the positive impact of the conversion factor alignment is negated and CMS will not achieve long-term savings.

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

Under the statute that implemented 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.²¹ CMS has full authority to increase payments to ASCs (for example, by preventing the further relative deterioration of rates compared to hospitals performing identical services), particularly if it believes such policies will help constrain overall Medicare spending. CMS continued the scalar after the initial year of the new ASC payment system pursuant to its own perceived authority and not pursuant to any identified statutory requirement. As such, CMS has the authority to likewise discontinue the scalar at its discretion under the same rationale. ASCA implores CMS to encourage savings and greater access to ASCs for Medicare beneficiaries by eliminating the ASC weight scalar.

ASCA recognizes that the elimination of the ASC weight scalar would represent an initial increase in cost to the Medicare program (a cost that will only get more expensive each year that the scalar exists and continues to depress rates) until cost savings are achieved by shifting volume to the ASC setting. Alternatively, ASCA proposes that CMS refrain from applying the

²¹ 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.

“secondary scalar” to the ASC payment system. Instead, CMS could combine the OPPS and ASC utilization and mixes of services to establish a single weight scalar. In other words, CMS could apply a single budget neutrality calculation to the OPPS and ASC payment systems. By incorporating the ASC volume into the OPPS weight scalar calculations, CMS would further the alignment of the payment systems and more accurately scale for outpatient volume across both sites of service.

Payment for Non-Opioid Pain Management Treatments

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

ASCA supports the Administration’s efforts to combat the opioid epidemic, which has only been exacerbated by the COVID-19 pandemic. We support the separate payment for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting. As part of our continued desire to align the HOPD and ASC payment systems, we also encourage CMS to establish this same policy for the HOPD setting.

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

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

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

Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests

ASCA appreciates the proposal that implements Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116-260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests. CAA adopts a modified version of the *Removing Barriers to Colorectal Cancer Screening Act*, legislation that ASCA has supported for years, ensuring that if a

scheduled screening colonoscopy becomes therapeutic, the Medicare beneficiary will not face a copayment. Under the legislation, the Medicare beneficiary cost sharing for colorectal cancer screening will be phased out between January 2022 and January 2030. As the Medicare payment percentage increases, the beneficiary coinsurance percentage decreases until it is eliminated in 2030. Ultimately, this will greatly reduce patient financial burden, increase access to life-saving screening and strengthen the fight against colorectal cancer.

ASCA requests that CMS consider another policy change that would increase access to life-saving colonoscopies for Medicare beneficiaries. In 2014, CMS approved coverage for Cologuard, a multitarget stool DNA test for asymptomatic, average risk beneficiaries aged 50 to 85 years.²² While ASCA supports coverage for tools that will help with early detection of colorectal cancer, we believe that when a follow-up colonoscopy is required after use of the Cologuard screening test, Medicare should waive the copayment for that screening colonoscopy as well.

Key Comments on ASC Quality and Proposed Reporting Program Changes

ASCA appreciated that the 2021 rule did not make significant changes to the ASCQR Program, as ASCs and other healthcare providers were still in the early stages of dealing with the COVID-19 global pandemic. It is unfortunate that a year later we are in the same position, yet CMS has proposed significant changes to the ASCQR Program, including the mandatory inclusion of ASC-11, a measure that was not contemplated to be a facility measure.

The ASC community established the ASC Quality Collaboration (ASC QC) more than a decade ago to develop, test and publicly report quality measures specific to the ASC setting. We proactively requested our own quality reporting program, in no small part so that information about ASC quality would be easily accessible to the public. It is concerning, however, how difficult it is to find the ASCQR Program data that is supposed to be publicly available. If a consumer goes to the Medicare Care Compare website,²³ there is not an option to see ASC data. You have to type something in the search bar to pull up data you may be seeking. However, when typing in “colonoscopy,” even though there are measures in the ASCQR Program with colonoscopy in the title, no search results are for data from the ASCQR Program. Until CMS makes the data easily accessible, adding additional measures to our ASCQR Program simply provides additional burden on our facilities with no benefit to the public.

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

ASCA supports the resumption of ASC-1 through ASC-4 for CY 2023 and requests that similar measures be added to the HOPD quality reporting program to allow for better comparisons across sites of service.

²² <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=277> (accessed September 16, 2021).

²³ <https://www.medicare.gov/care-compare/> (Accessed on September 16, 2021).

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

These measures were reported using quality data codes on ASC fee-for-service (FFS) Medicare claims. As noted in our comments to the 2019, 2020 and 2021 payment rules, it would be more beneficial to all stakeholders if this data were submitted via QualityNet and reporting expanded to all patients served by the ASC, not just Medicare FFS patients. This would considerably expand the scope and transparency of public reporting as well as the accountability related to these measures. The ASC QC is the measure developer and steward for the measures and they attest that these measures are suitable for the type of aggregate data collection and submission in use at the QualityNet site.

We appreciate that CMS has proposed to require ASCs to report these measures via QualityNet, but there is no mention in the rule of expansion of the patient population captured. ASCA requests that CMS clarify in the final rule that data collection and reporting for this measure is expanded to cover a wider patient population than just FFS Medicare. We would also appreciate clarification as to what is meant by CY 2023 reporting period/CY 2025 payment determinations. It was always our understanding that the first year was the data *collection* year, the next year data would be reported, and in the third year payments would be impacted. This would mean that the reporting year would be CY 2024. If data reporting is truly required in 2023, ASCs would need to resume data collection in January 2022, which would be difficult given the other significant changes being proposed to the ASCQR Program. We appreciate clarification in the final rule.

ASCA is encouraged by this desire to align measures between various sites of outpatient surgery, as has been the approach from the Agency for the past few rulemaking cycles. ASCA recommends that CMS not only reestablish data reporting for *ASC-1* through *ASC-4* for all patients served, but also add similar measures for HOPDs and physicians performing surgery in their offices to provide patients with more meaningful data to compare sites of service.

ASCA has significant concerns with our facilities' ability to operationalize the proposed COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure.

ASCA has strong reservations about this measure. When a new measure is proposed for addition, particularly with such a short turnaround time for compliance, it must be clear that the benefits of the measure will outweigh the burden. This does not seem to be the case here.

ASCA understands requiring this measure in settings like nursing homes and hospitals that have more vulnerable patient populations. A new study from the Centers for Disease Control and Prevention (CDC) shows substantial increases nationally in healthcare-acquired infections (HAI) and select antibiotic-resistant (AR) infections in hospitals in 2020 compared to 2019. For most of these infections, the increases seen in 2020 present a strong contrast to the success in reducing

these infections prior to the pandemic.²⁴ The study notes that “many hospitals faced extraordinary circumstances that may have reduced the implementation of standard infection prevention and control (IPC) practices.”

There is no such evidence that ASCs have this issue or are contributing to the spread of COVID-19. As part of its mission to support the collection and reporting of quality data, the ASC QC conducted a survey of more than 700 ASCs during the early days of the COVID-19 pandemic when surgeries were limited to urgent and emergent cases. The study found that ASCs continued to perform essential outpatient surgeries safely during March and April in 2020 with patients facing virtually no heightened risk of contracting the coronavirus either during or following their procedure.

Specifically, 709 outpatient surgery centers in 8 states²⁵ were surveyed, including 3 states—New York, New Jersey and Louisiana—that were experiencing high rates of COVID-19 infection in the general population. A total of 84,446 patients were included in the survey. Only 16 of those patients tested positive for COVID-19 within 14 days after their procedure, an infection rate of just .02 percent, and no evidence any of those cases were connected to the patients’ procedures.

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

In the 2019 final rule, CMS removed ASC-8: *Influenza Vaccination Coverage Among Healthcare Personnel*, a change ASCA strongly supported. The burden associated with this measure outweighed the benefit of its continued use in the program. This measure was problematic since inception, largely because it was the only measure ASCs submitted through the Centers for Disease Control (CDC) and Prevention’s National Healthcare Safety Network (NHSN). There were significant implementation issues with NHSN. Our analysis of the 233 facilities subject to payment reductions in 2018 for failure to meet ASCQR Program reporting requirements showed that 95 of those facilities successfully reported on every measure *except* ASC-8. Removal of this measure reduced administrative burdens for facilities and improved overall compliance with our quality reporting program.

ASCA fears that inclusion of this COVID vaccination measure in the ASCQR Program will lead to even higher numbers of ASCs being penalized. While ASC-8 only required enrollment and annual reporting, this new COVID vaccination measure requires facilities to select one week every month during which to report through NHSN. If CMS finalizes this measure as proposed, we ask for some flexibility with this requirement, for instance only requiring ASCs to submit a new report during months in which there was a change in staff.

²⁴ The impact of coronavirus disease 2019 (COVID-19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network. <https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/abs/impact-of-coronavirus-disease-2019-covid19-on-healthcare-associated-infections-in-2020-a-summary-of-data-reported-to-the-national-healthcare-safety-network/8197F323F4840D233A0C62F4726287E1> (accessed September 16, 2021).

²⁵ Connecticut, Illinois, Louisiana, Massachusetts, Michigan, New Jersey, New York, Pennsylvania

In addition, reporting is proposed to begin January 2022. With all the operational issues ASCs faced previously with NHSN, ASCA is concerned that facilities will not even be registered and able to submit data that soon. ASCA respectfully requests that if CMS chooses to finalize this measure, that the Agency delay reporting until at least the second quarter of 2022.

ASCA strongly opposes making ASC-11 mandatory.

In the proposed rule, CMS indicates that “we now believe it is appropriate to require that ASCs report on ASC-11 as our earlier concerns have been allayed.” Respectfully, ours have not.

CMS implies that the *ASC-11 Cataracts: Improvement in Patient’s Visual Function within 90 Days Following Cataract Surgery* (NQF #1536) measure is “NQF-endorsed for the ASC setting,” but this is false. In fact, on the CMS Measures Inventory Tool website, it shows the NQF Endorsement Status as “Endorsement Removed.”²⁶ ASCA believes this is for good reason. This measure was never intended to measure facility performance, but rather was developed, tested and NQF-endorsed as a clinician-level measure.

The facility cannot make changes based on the results of this survey – that would be incumbent upon the physician.

The distinction between clinician-level and facility-level measures is a pivotal one, but was not acknowledged by CMS. This measure relies on the use of data obtained by the physician and recorded in the medical records housed in the physician office at two key points in time: (1) the patient’s visit(s) with the physician during which the evaluation, examination and decision regarding surgery was made, and (2) the patient’s visit(s) with the physician after surgery and during the post-operative 90-day global period. ASCs do not have access to these records. Asking ASCs to report this measure is administratively burdensome and not reflective of the attributes of the ASC facility or the actions of its staff during the patient’s time in the facility.

Importantly, there are no publicly reported results available in 2021 from the 2019 reporting period for Quality ID #303, the physician measure corresponding to ASC-11. According to the Quality Payment Program support contractor, this is because the standards for publicly reporting the measure were not met. Reporting standards were not met because fewer than 20 reporters submitted data. It will be difficult to coordinate the use of the survey between settings when physicians are not even choosing to report on this measure.

This measure places an undue burden on facilities.

This measure would pose significant implementation issues for ASCs. Instructions for Quality ID #303 indicate “the survey should be administered, collated and scored by the registry, or by a third-party intermediary, to prevent or minimize bias which might be introduced if it is an in-office paper survey with questions asked by the office staff.”²⁷ If CMS allows ASCs to conduct

²⁶ CMS Measures Inventory Tool. https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=1049 (accessed September 16, 2021).

²⁷ https://mdinteractive.com/mips_quality_measure/2020-mips-quality-measure-303 (accessed September 17, 2021).

the surveys at the facility (it is unclear in the rule), clearly that opens the door to the bias CMS wished to avoid in the past and still creates significant burden for facilities. If a third-party vendor is required, that is another financial burden being imposed at the same time CMS is mandating another survey requiring a third-party vendor, the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS).

Facilities have not familiarized themselves with the measure, as there was no indication they needed to do so.

CMS states that “at this point, ASCs have had several years to familiarize themselves with ASC-11, prepare to operationalize it, and opportunity to practice reporting the measure since the CY 2015 reporting period/CY 2017 payment determination.” Neither ASCs nor HOPDs have been “practicing” this reporting because there was never any indication in previous rulemaking that this measure may become mandatory. While other measures, such as ASC-1 through ASC-4 and adoption of the OAS CAHPS measures have been discussed in previous rules, ASC-11 has not. The most recent publicly available data shows that 42 ASCs and 28 HOPDs submitted data for this cataract measure. There are currently over 2,000 ASCs that perform ophthalmic procedures.²⁸ Ninety-eight percent of the facilities who would be required to report this measure have never “practiced,” and could be overwhelmed by this new and significant administrative burden that physicians are not even “practicing.”

ASCA requests that CMS maintain ASC-11 as a voluntary measure or simply remove it from the dataset altogether as we have previously requested, as it is not actionable by the facility and therefore of limited to no value to the patients served.

ASCA supports OAS CAHPS implementation with changes that will reduce the administrative and financial burden on our facilities.

CMS previously 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 appreciated 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.

²⁸ 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/> (June 2021 data; accessed September 2021).

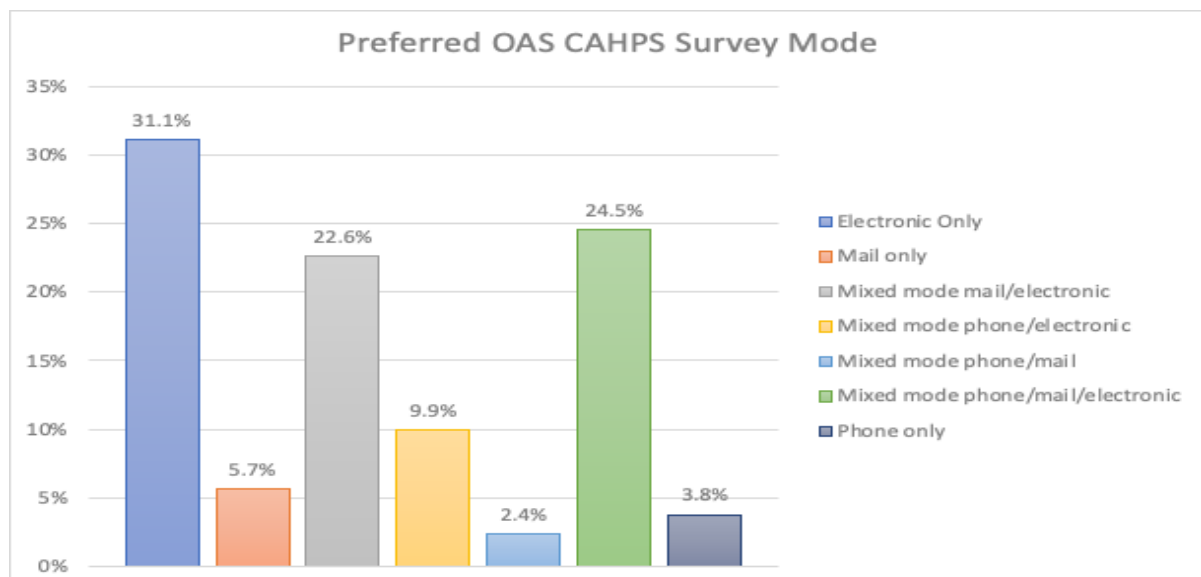
Cost to Facilities

Besides the cost of finding and securing a third-party vendor, of which there are currently 16 that are CMS-approved,²⁹ 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. ASCA appreciates the proposed addition of two new mixed mode options – electronic with phone and electronic with mail. Based on the data we have collected from vendors, an average cost per center will be at least \$3,000 per year, but this amount could be higher depending on the mode selected by the ASC. As previously mentioned, ASCs are often small businesses and as such we request that CMS make every effort to decrease the cost to our facilities. 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 for 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 inexpensive as possible. The table below shows that based on a recent ASCA member survey 31 percent (66 of 212) of respondents selected electronic administration only as their preferred survey mode.³⁰



²⁹ <https://oascahps.org/General-Information/Approved-Survey-Vendors> (accessed September 15, 2021).

³⁰ ASCA member survey, August 2021.

Implementation

In the same survey, 75 percent of facilities that responded (159 of 212) indicated they are not currently administering an OAS CAHPS survey, and many have not looked into a vendor yet.³¹ While there are 16 approved vendors, when ASCA reached out to all 16, we received bounce back emails for several, and others were not currently working with any ASC clients, and as such, seem ill-equipped to ramp up efforts quickly. With 6,000 Medicare-certified ASCs and the vast majority currently not using an OAS CAHPS survey, these vendors will be inundated shortly with facilities reaching out. ASCA believes that potentially only one – Press Ganey – is currently positioned to on-board a significant number of facilities.

Survey length

The survey should be significantly shorter, focusing on actionable aspects of patient experience in the outpatient setting and essential demographic data. 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 will help improve care as well as the patient experience. In addition, we have long supported more measures that allow beneficiaries to compare ASCs to HOPDs. We have serious concerns, however, that this 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.

Request for Comment on Potential Adoption of Future Measures for the ASCQR Program

CMS should adopt measures supported by the ASC community and included in previous rulemaking.

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

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

³¹ ASCA member survey, August 2021.

ophthalmic devices, and to cleaning and sterilization of surgical equipment.” ASCA requests that CMS reconsider adding this measure.

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

Request for Comment on Potential Future Adoption and Inclusion of an ASC-Level, Risk-Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)

CMS is seeking input on the potential future adoption of a (yet to be) re-specified version of a patient-reported outcome-based performance measure (PRO–PM) for total hip arthroplasty (THA) and total knee arthroplasty (TKA). The measure in question is NQF #3559: Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA).

According to the measure developer, the goal of having a hospital-level outcome measure is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patients’ health. This is reasonable in a hospital system that includes the full spectrum of preoperative, intraoperative and postoperative services involved in the care of THA/TKA patients under its ownership. However, we question how ASCs that are not owned or managed by a hospital system can be held accountable for the full spectrum of patient care. As you know, federal regulations governing ASCs limit the scope of ASC services and the timeframe ASCs are permitted to be involved in patient care and intentionally isolate the operations of ASCs from other providers.

We are also concerned about the patient survey instruments that provide the foundation for the measure. The appropriate survey is administered in advance of surgery and then again approximately a year after surgery - reflecting the normal timeframes for clinical workflow for THA/TKA patients. This strikes us as an even more challenging version of the survey protocol for ASC-11 (please see discussion above) and one that we believe would be very difficult for ASCs to implement.

Request for Comment on Potential Future Efforts to Address Health Equity in the ASCQR Program

Physicians, nurses and all healthcare providers must be sensitive to the biases that have fostered disparities and be committed and conscientious in rooting them out so that every patient receives

the care they need. From a community perspective, however, it is critical to recognize that regulatory limitations placed upon ASCs, such as state certificate of need restrictions, low Medicaid reimbursements and state provider taxes, all play a role in limiting the ability of the ASC model to reach into underserved areas to provide the care every community should enjoy.

Like CMS, ASCA is committed to “achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.” While we are committed to working with the Agency to determine appropriate measures or data collection initiatives, we believe that CMS, which has access to demographic information regarding Medicare beneficiaries, is best situated to identify data points to for measurement.

Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Outpatient Quality Programs – Request for Information

While we support the goal of moving to all digital quality measures (dQM) by 2025, we have serious concerns about the number of Medicare-certified ASCs that will be able to comply. While the Office of the National Coordinator of Health Information Technology (ONC) estimates that at least 86 percent of office-based physicians and 96 percent of acute care hospitals are currently using an EHR, we estimate that *at most* 50 percent of ASCs are using an EHR.³² Additionally, many of those ASCs with EHRs are likely using inpatient products that are ill-fitted to the operational needs of an ASC. ASCs did not receive any federal funding for EHR adoption in the HITECH Act of 2009 and should not be penalized for slower adoption of health information technology.

Both Congress and CMS have recognized the lack of EHR availability in ASCs. There is no federal requirement for ASCs to implement an EHR and ASC-based clinicians (those clinicians who furnish 75 percent or more of their covered services in an ASC) are exempt from the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS). While ASCs are subject to the policies finalized in the ONC’s 21st Century Cures Act Final Rule, it should be noted that it contains several exceptions for sites of service with limited access to electronically stored health information. For example, ASCs are not responsible under Information Blocking for any health information not stored in electronic format.

Given the current lack of health IT in ASCs, it is likely that a transition to FHIR-based quality reporting would provide a considerable burden for many of the 6,000 Medicare certified ASCs. It would also provide an inaccurate picture of quality in ASCs as compared to offices and hospitals that have had years to integrate health IT components into their clinical and administrative processes. ASCA has strong concerns about moving to dQMs by 2025. CMS should consider ASC stakeholder feedback before implementing policies that may penalize ASCs. ASCA has an

³² This estimate is based on a data from Definitive Healthcare, a 2021 survey of ASCA members and estimates from ASC-focused EHR vendors.

ongoing working relationship with staff at ONC that can serve as a foundation for such stakeholder discussions.

Closing Summary

The Biden Administration’s Build Back Better Agenda – which promises a “renewed commitment to protect and expand Americans’ access to quality, affordable health care”³³ dovetails perfectly with the ASC model. ASCA supports the Biden Administration’s stated desire to encourage competition between high-quality healthcare providers. However, many of the policies in this proposed rule will foster the opposite result.

In a recent blog post reflecting on your first 100 days leading CMS, you highlighted the need to “protect our programs’ sustainability for future generations by serving as a responsible steward of public funds.”³⁴ ASCA and our facilities are well-equipped to help. We welcome the opportunity to collaborate with CMS on the recommendations in this comment letter that highlight several areas where CMS can facilitate movement of outpatient procedures to the lower-cost ASC setting without compromising patient outcomes or quality of care. We appreciate the opportunity to provide feedback on the Agency’s work and welcome the opportunity to discuss 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

³³ <https://www.whitehouse.gov/priorities/> (accessed September 1, 2021).

³⁴ <https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms> (accessed September 10, 2021).

Appendix A – Impact of Surgical Delays During COVID-19

Medical Care: [Elective Surgical Delays Due to COVID-19 The Patient Lived Experience](#)

April 2021

Authors interviewed 47 individuals with delayed elective cardiac and vascular surgeries due to the pandemic. The study concludes that the emotional and psychological distress that these patients experienced due to the postponement of their procedures may also, “require additional considerations in postoperative recovery.”

The Lancet Rheumatology: [Too long to wait: the impact of COVID-19 on elective surgery](#)

February 2021

This is a paper from the UK that looked at the delays in joint replacement surgeries, the backlog caused by the pandemic and the effects of those delays on patients.

Journal of Cataract & Refractive Surgery: [COVID-19 and cataract surgery backlog in Medicare beneficiaries](#)

Nov 2020

This study of cataract surgery volumes estimates that the US may face a backlog of 1.1 million to 1.6 million cataract procedures by 2022.

PAIN Reports: [Unintended consequences of COVID-19 safety measures on patients with chronic knee pain forced to defer joint replacement surgery](#)

November 2020

Authors modeled deferring knee replacements for three months (March to May 2020) assuming a return to 100% capacity by September 2020. This would create a backlog of approximately 300,000 total knee replacements in 2020, with approximately 100,000 of those delayed for six months or longer. In the best-case scenario, it would take the U.S. surgical system 16 months to clear the backlog.

This creates health risks, as primary TKA patients are already experiencing conditions that have a substantial impact on their day-to-day functioning. Some studies report high levels of clinical depression in patients waiting for orthopedic surgery. There is some evidence that delays cause negative effects on surgical outcomes.

Journal of Bone & Joint Surgery: [SARS-CoV-2 Impact on Elective Orthopaedic Surgery](#)

July 2020

Given that elective orthopaedic surgery was able to resume in June 2020, it would take 7 months under the most optimistic scenario until the health care system is able to resume regular performance (which they describe as 90% of forecasted cases). Even so, there will be a cumulative backlog of over 1 million surgical cases even 2 years later.

Kaiser Health News: [Nearly Half Of Americans Delayed Medical Care Due To Pandemic](#)

May 2020

A survey by Kaiser Health News found that 48% of respondents had themselves or a family member postpone medical care due to coronavirus.

The Lancet: [Bariatric and metabolic surgery during and after the COVID-19 pandemic: DSS recommendations for management of surgical candidates and postoperative patients and prioritisation of access to surgery](#)

May 2020

Quote: “The delay of bariatric and metabolic surgery that is occurring due to COVID-19 will augment the burden of disease among surgical candidates. This increase will particularly affect patients with type 2 diabetes, given that metabolic surgery causes remission of hyperglycaemia in most cases.”

The Journal of Arthroplasty: [The Effect of the COVID-19 Pandemic on Electively Scheduled Hip and Knee Arthroplasty Patients in the United States](#)

April 2020

AAHKS surveyed 360 patient who had to have elective hip and knee arthroplasty cancelled between March and July 2020. Not knowing when the procedure would be rescheduled caused moderate to severe anxiety in 60% of patients, and notably was a higher cause for anxiety than becoming infected with COVID and/or spreading infection to others. 54% said that their pain increased since surgery cancellation, and 15% said they were without help at home. The patients generally agreed with the decision to stop elective procedures, but 90% replied that they would like their surgery rescheduled in the near future.

Wolters Kluwer: [The Consequences of Delaying Elective Surgery: Surgical Perspective](#)

April 2020

A 3-month surgery backlog translates to 5 million surgical cases. Delays will cause costly treatment of more advanced disease; disease progression in breast, colorectal, and lung cancer is associated with an annual increase of \$50,000 per case.

Milliman: [How will an interruption in elective medical services affect existing workers' compensation claims?](#)

April 2020

This report found that 2-month delay to elective surgery could cause an 89% increase in workers compensation indemnity payments.

The Journal of AAOS: [Orthopaedic Surgical Selection and Inpatient Paradigms During the Coronavirus \(COVID-19\) Pandemic](#)

April 2020

Quote: “We have categorized major orthopaedic surgeries by how long they can safely be delayed according to the previous studies (Table1). Deciding which surgeries to cancel may not be as simple as a binary decision (elective versus nonelective). Depending on the phase of the disease locally, orthopaedic programs may move into more of an emergency surgery situation and then move toward allowing elective surgery, then move back into an emergency surgery only situation again.”

Quote: “As major inpatient hospitals prepare to face an increased burden of COVID-19 patients, it may also be beneficial for patients to have their vital orthopaedic surgeries redirected to an ASC, where there are no COVID-19 inpatients being simultaneously cared for.”

NEWS/ARTICLES:

Advisory Board: “[Hospitals are delaying elective surgeries again. But this time, they're doing it differently.](#)”

August 18, 2021

Quote from article: “Some providers also say that, because of care disruptions over the last year, some patients now have more serious needs. For instance, surgeons at Covenant High Plains Surgery Center in Texas noted about a 10% increase in the severity of conditions among patients entering the hospital. “Patients who had delayed their procedures may have had more complex procedures or may have come in sicker as a result,” Alfonso del Granado, administrator and CEO of the center, said.”

WSHU (NPR): “[Doctors Worry Another COVID-19 Shutdown Could Further Delay Elective Surgeries](#)”

October 13, 2020

This is an interview transcript from public radio. Sumeer Sathi, MD, is interviewed and offers personal testimony of how delaying elective surgeries harmed his patients and briefly discusses furloughing staff, receiving PPP funds, and the Medicare stimulus program.

Health Affairs: “[How The COVID-19 Pandemic Has Affected Provision Of Elective Services: The Challenges Ahead](#)”

October 8, 2020

A thorough blog post/article that outlines the challenges that elective health services will face if there is another drastic spike in cases and states reintroduce elective surgery bans.

JAMA Viewpoint: “[Preserving Elective Surgeries in the COVID-19 Pandemic and the Future](#)”

October 5, 2020

Authors share experiences from the Wake Forest Baptists Health system in North Carolina. From March to June 2020 the system experienced a 27% reduction in orthopedic surgery cases.

Quote from article: “The COVID-19 pandemic has illuminated the critical importance of “elective” surgery and the path to sustaining, not stopping, surgical care based on local conditions of SARS-CoV-2 prevalence and available resources, even during times of crisis or uncertainty.”

Harvard Business Review: “[Covid-19 Created an Elective Surgery Backlog. How Can Hospitals Get Back on Track?](#)”

August 10, 2020

Authors suggest strategies that leaders can take to meet demand for current/backlogged elective surgeries as the result of the pandemic.

Quote from article: “Transitioning care from historically inpatient to outpatient settings may aid in expanding surgical capacity through decentralization of care from hospitals to less-intensive care centers or physician office settings.

Kaiser Health News: “[Avoiding Care During the Pandemic Could Mean Life or Death](#)”

July 31, 2020

This article gives a good account of the effects COVID-19 has had on all aspects of health, and the long-term effects that delaying care will have for patients and on the healthcare system.

Quote from article: “‘There will be consequences for deferring chronic disease management,’ [Farzad Mostashari, MD] said. ‘Patients with untreated high blood pressure, heart and lung and kidney diseases are all likely to experience a slow deterioration. Missed mammograms, people keeping up with blood pressure control — there’s no question this will all cause problems.’ In addition to fear? Changes in the health care system have prevented some from getting needed care.”

Lowell Sun: “[COVID-19 delayed my spinal surgery](#)”

July 18, 2020

This article is written about the author’s experience of constant pain due to a herniated disc, and provides an emotional, personal look into how delayed surgeries can drastically affect every aspect of everyday life.

Quote from article: “I’d already spent weeks laying on my living room floor in pain — while working and otherwise — and hunkered down for several more. I repeatedly tried to remind myself that the situations of those suffering from COVID-19 were much more dire. Between changing medications multiple times and the last cortisone shot wearing off, the end of March through May was probably the single most painful time of my life.”

Washington Post: “[Patients are still delaying essential care out of fear of coronavirus](#)”

July 13, 2020

This article warns leaders about the potential dangers of delaying care (whether it is screenings, appointments, or elective procedures), providing updated statistics on the volume of care being completed, and including uplifting stories of patients receiving care. The article also describes the new daily safety protocols and vigorous cleaning that are helping ensure patients are safe.

Quote from article: “At the beginning of the outbreak, ‘the last place you wanted to be was in the hospital,’ said Stephen Bello, senior vice president and eastern region executive director for Northwell Health, a large health-care system that has cared for more than 17,000 covid-19 patients and includes Syosset Hospital. ‘But we understand the virus better and have adapted. Now it’s safer to be in our hospitals than in a restaurant or grocery store.’”

Reuters: [“New US health crisis looms as patients without COVID-19 delay care”](#)

July 13, 2020

The article focuses on the risks of delayed care, especially as the number of cases continues to dramatically rise. The article focuses on cancer screenings, patients’ fear of entering hospitals, and patients’ experiences waiting for their delayed elective surgeries.

Newswise: [“COVID-related Delays in Colorectal Cancer Screening Jeopardizes Preventive Care, Early Treatment”](#)

June 17, 2020

Rush Medical Center was forced to halt 800 colonoscopies per month from mid-March to mid-May. Nationwide, two months with little or no cancer screenings could postpone diagnosis of cancer in 24,650 patients.

Quote from article: “‘We really don’t know how long the delay could last,’ Hayden said. ‘Patients may be focused on more urgent matters than preventative care and may also be nervous about coming to the hospital while the pandemic continues.’ That would reverse a positive, lifesaving trend: The rate of people over age 50 who are up to date on colorectal cancer screening has improved greatly in the past several years, from 38% in 2000 to 66% in 2018, according to the American Cancer Society.”

Washington Examiner: [“Elective surgery moratorium takes a toll on patients”](#)

May 14, 2020

The article mentions problems that are exacerbated by a delay in surgery, including the patients’ mental health and increase of opioid addiction.

WFPL: [“U of L Health Faces Four Weeks Of Backlogs For Elective Surgeries”](#)

May 12, 2020

The article explores elective procedures at University of Louisville Health.

The Buffalo News: [“Covid-19 sidelines thousands awaiting surgeries in Erie County”](#)

May 10, 2020

Article focuses on data and includes number of surgeries delayed and revenue lost at several hospitals and surgery centers in the county.

Quote from article: “Doctors collectively have canceled or postponed 1,300 elective surgeries in recent weeks, including 750 they deemed urgent or priority cases, hospital spokesman Peter Cutler said. ECMC lost \$16.8 million for lack of such surgeries since the pandemic began, accounting for more than half of its \$26.5 million in revenue generating losses, Cutler said.”

NPR: Doctor Explains Decisions to Delay Elective Surgery

May 2, 2020

Transcribed audio interview with ER doctor at Duke University Hospital on the consequences of postponing elective surgeries.

Quote: “A gallbladder surgery, if it's an emergency, can be a dangerous procedure. If it's not an emergency, the problem that's causing the pain and vomiting of an obstructed gallbladder is still there. It's just something that can be temporarily delayed by a change in diet or medications or antibiotics. But it's still going to get inflamed and obstructed pretty frequently. And that makes you have to come back to the emergency room for this temporizing treatment over and over again until it gets bad enough that it's an emergency surgery.”

CNBC: “It may take up to four months to reschedule surgeries and medical procedures”

April 29, 2020

Focuses on the resumption of elective procedures and the inevitable growing backlog of patients that still need care.

Quote from article: “It will take a while to get back on track. For those who did have their procedures delayed — whether it be hip replacement, plastic surgery or repairing a knee ligament tear — it will likely take an average of three to four months to resolve the backlog, says Jonathan Wiik, principal of health care strategy at TransUnion.”

ABC 7 (Chicago Local News): “Postponement of elective surgeries one reason Chicago area hospitals not overwhelmed during COVID-19 pandemic”

April 24, 2020

The article has quotes from several doctors about the effects of halting elective procedures, and even ponders ethical implications that might result in the future.

A quote about the term ‘elective:’ “‘I think people misinterpret the term elective surgery to mean uninsured surgery or unnecessary surgery or cosmetic surgery. But we're treating conditions that are very painful for patients are, very limiting for patients,’ said Dr. Eric Chehab, an orthopedic surgeon at Illinois Bone & Joint Institute.”

The New York Times: “The Pandemic’s Hidden Victims: Sick or Dying but Not from the Virus”

April 20, 2020

Focuses on cancer, organ donation, and surgeries conducted in hospitals; however, there are good quotes in the article from doctors and other experts on how the delay in surgery is dramatically affecting their patients.

Quote from article: “The coronavirus may be killing people who are not even infected, by depriving them of desperately needed treatment, said Dr. Bruce K. Lowell, an internist in Great Neck. ‘People are still having heart attacks, people are still having strokes,’ he said. ‘I feel as if there is no awareness of anything other than Covid.’”

ProPublica: “[Cancer Surgeries and Organ Transplants Are Being Put Off for Coronavirus. Can They Wait?](#)”

April 6, 2020

The article focuses on elective procedures scheduled for cancer patients. However, at the end of the article, the author writes about the backlog of “critical” surgeries and the ripple effects that will be felt in the health care system if elective surgeries aren’t started up again soon.

Quote from article: “Those ripple effects are only just starting to be felt. If we aren’t vigilant in taming the COVID-19 crisis, and then in quickly reinstating essential elective procedures and preventive screening, we’ll have another crisis in the making. Flattening the curve is indeed essential to save lives — and not just those of COVID-19 victims.”

The Atlantic: “[What it Really Means to Cancel Elective Surgeries](#)”

March 17, 2020

Older article, but it focuses on explaining the categorical choices that surgeons are making to determine who will receive surgical care and which surgeries will be delayed.

Quote from article: “Elective surgery does not mean optional surgery. It simply means nonurgent, and what is truly nonurgent is not always so obvious. Gerard Doherty, the chair of the surgery department at Brigham and Women’s Hospital in Boston, which began postponing elective surgeries on Friday, says surgical procedures can fall into one of three categories. About 25 percent of the surgeries performed at his hospital can be delayed without much harm. These might include joint replacements and bariatric surgeries for weight loss. Another 25 percent are for life-threatening emergencies that need to be treated right away: perforated bowels, serious heart problems, bones that have broken through the skin. The last 50 percent are the tricky ones. These cases, Doherty says, have ‘some potential for harm to delay’; they might include cancer and problems in the blood vessels of the arms and legs. Brigham and Women’s is postponing some of these surgeries now on a case-by-case basis.”

Appendix B – Codes ASCA Requests Remain on ASC-CPL

HCPCS Code	Short Descriptor	2019 ASC All-Payor Volume	2020 ASC All-Payor Volume	HOPD 2019 Medicare FFS Volume
19307	Mast mod rad	669	785	4,439
31241	Nsl/sins ndsc w/artery lig	113	81	210
43830	Place gastrostomy tube	388	349	347
49405	Image cath fluid colxn visc	52	47	821
51860	Repair of bladder wound	144	103	167
54336	Revise penis/urethra	26	9	0
54535	Extensive testis surgery	8	8	0
57285	Repair paravag defect vag	152	171	787
27006	Incision of hip tendons	382	318	360
28805	Amputation thru metatarsal	1154	1032	1,391
54650	Orchiopexy (fowler-stepkens)	110	96	4
21386	Opn tx orbit fx periorbital	108	59	41
60252	Removal of thyroid	607	621	974
60260	Repeat thyroid surgery	495	474	980
60271	Removal of thyroid	296	305	1,330
31600	Incision of windpipe	1481	1660	877
35045	Repair defect of arm artery	99	88	280
37191	Ins endovas vena cava filtr	534	417	3,633
43774	Lap rmvl gastr adj all parts	1122	832	1,321
43280	Laparoscopy fundoplasty	526	475	2,020
43281	Lap paraesophag hern repair	6119	6533	5,911
43282	Lap paraesoph her rpr w/mesh	513	597	3,759
43770	Lap place gastr adj device	211	406	96
50543	Laparo partial nephrectomy	282	263	2,096
55866	Laparo radical prostatectomy	845	824	10,648
37244	Vasc embolize/occlude bleed	173	132	1,090
59409	Obstetrical care	2509	2352	9
33244	Remove elctrd transvenously	220	151	0
39402	Mediastinoscopy w/lmph nod bx	228	231	2,455
44180	Lap enterolysis	2412	1978	2,421
44970	Laparoscopy appendectomy	11748	10605	10,148
23470	Reconstruct shoulder joint	690	703	593
23473	Revis reconst shoulder joint	378	450	265
27235	Treat thigh fracture	1831	1401	447

HCPCS Code	Short Descriptor	2019 ASC All-Payor Volume	2020 ASC All-Payor Volume	HOPD 2019 Medicare FFS Volume
29868	Meniscal trnspl knee w/scpe	212	295	4
63011	Remove spine lamina 1/2 scr1	9	13	27
63012	Remove lamina/facets lumbar	836	747	112
63015	Remove spine lamina >2 crvcl	540	438	252
63016	Remove spine lamina >2 thrc	68	51	35
63017	Remove spine lamina >2 lmbr	111	99	247
63040	Laminotomy single cervical	59	37	40
63075	Neck spine disk surgery	253	281	113
32551	Insertion of chest tube	1360	1373	683
38531	Open bx/exc inguinofem nodes	731	1054	1,979
35206	Repair blood vessel lesion	373	424	560
35903	Excision graft extremity	221	199	1,663
37193	Rem endovas vena cava filter	313	164	5,878
60512	Autotransplant parathyroid	526	491	0
63035	Spinal disk surgery add-on	2731	2538	0
63048	Lam facetec & foramot ea addl	24599	23985	0
63057	Decompress spine cord add-on	457	388	0
63076	Neck spine disk surgery	177	137	0

Appendix C – Lumbar Fusion Study

Title: A study, made feasible by the Hospitals Without Walls (HWW) waiver due to the public health emergency (PHE) of the COVID-19 pandemic, of the safety and efficacy of transforaminal or posterior lumbar interbody fusion surgery (TLIF or PLIF) in the ASC setting for Medicare beneficiaries

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ABSTRACT

We sought to evaluate the safety and efficacy of lumbar interbody fusion (TLIF) surgeries performed in Medicare-age patients in an ASC setting made possible by Legacy Surgery Center enrolling in the Hospitals Without Walls (HWW) initiative of the Centers for Medicare & Medicaid Services (CMS). In response to the Covid-19 pandemic, numerous ASCs in the US enrolled in CMS' HWW program. Numerous ASCs in the nation have regularly performed lumbar interbody fusions since 2010. However, patient access to lumbar interbody fusions at ASCs has been limited to commercially insured patients as this procedure's, codes 22633 and 22630, are not on the CMS ASC Covered Procedures List (ASC-CPL) updated annually.

Numerous prior studies have proved the safety and efficacy of minimally invasive (MIS) lumbar fusions on commercially insured patients including our study from 2020.¹⁷ We have performed 504 lumbar interbody fusions at the ASC study site since 2011 with excellent safety and efficacy. This study was conducted to demonstrate the same safety and efficacy of lumbar interbody fusion surgery in the ASC setting for CMS beneficiaries. In this report, we also compare data from our study, along with other studies, as regards key inclusion and exclusion measures from CMS' published material on its guidelines for approving a procedure for the ASC-CPL. Prior to the HWW ASC paradigm, there was no way to provide CMS with good data to show that the outpatient ASC setting was safe and effective for Medicare-age patients. With the data from this study and other studies reported on commercially insured patients, CMS should add 22633 and 22630 to the ASC-CPL for 2022. Doing so will be significantly advantageous to CMS and its

beneficiaries in both cost, risks and experience. This study will show that these codes meet every single CMS published criteria for the ASC-CPL and that there is zero downside and tremendous upside potential gains for addition of these codes as ASC covered procedures.

INTRODUCTION

Over the past several years, a shift toward the migration of spinal surgery to the ASC setting versus traditional hospital setting has occurred across the world. For commercially insured patients in the US, this includes TLIF surgery. Advances in technology of spine surgery approaches and implants have made this feasible.

Several authors have reported on their experiences of operative and perioperative (30-day) safety of TLIF surgery in the ASC site of service.^{1-15.}

In our prior ASC TLIF report, we demonstrated the safety and efficacy of lumbar interbody fusion in a study comparing 50 patients in the ASC group versus 50 in the hospital group and found data similar to the current study.^{17.} We have nonpublished data of our 504 TLIF cases since 2011 that shows the same safety and efficacy data and is pending completion of this publication. However, no patient required supervised care or services anywhere near midnight on the day of surgery nor experienced any complications. All cases have met or exceeded the conditions for coverage as a ASC CMS covered procedure. The issue as regards the ASC-CPL is none of these prior to the current study were on CMS beneficiaries.

Unfortunately, CMS has not yet added the primary CPT codes for TLIF or PLIF, 22633 or 22630, to the ASC-CPL. The presumed reason is that while the safety and efficacy have been well demonstrated for this procedure in non-Medicare patients in the ASC setting, there has been no way to show this in Medicare beneficiaries as it has not been a covered service in the ASC. This was a Catch 22. You must show outcome data on CMS beneficiaries in the ASC setting, yet you could not obtain such data as the procedure was not covered in this setting for CMS beneficiaries. Addition of these codes for the ASC-CPL has been suggested repeatedly in comments to CMS proposed rules. Despite good clinical data from numerous studies and the fact that these codes meet all criteria for inclusion on the ASC-CPL CMS has failed to approve their addition.

The PHE HWW program has given ASC spine centers a unique opportunity to, once and for all, provide proof of the safety and efficacy of lumbar interbody fusions in an ASC setting in Medicare-age patients.

This allowed the study of 23 consecutive Medicare beneficiaries having lumbar fusion surgery at one ASC that enrolled as a temporary hospital. In our prior ASC TLIF report we demonstrated the safety and efficacy of lumbar interbody fusion in a study comparing 50 patients in the ASC group versus 50 in the hospital group and found data similar to the current study.¹⁷

The intent of the study was to prove that Medicare beneficiaries could safely undergo a lumbar interbody fusion surgery in the ASC setting and to compare our data to inclusion and exclusion criteria to demonstrate that CMS should act to include these codes in the 2022 ASC-CPL.

The ASC in the study was technically a “temporary” hospital that had to have 24-hour nursing available when patients were onsite as well as laboratory, respiratory, dietary services onsite. None of these extra services required for participation in the HWW plan were needed for any of the 23 patients in the study and none as well for the additional 56 non-CMS TLIF patients who we cared for during the same time but were not part of the study.

All the patients in this study were discharged well before midnight of the day of the procedure, and none required any care needs beyond what is otherwise available in our traditional ASC setting. The extra requirements for participation as a temporary hospital in the HWW program were simply not needed nor utilized for any of these patients. This is true as well for the 504 total patients we have operated on for lumbar interbody fusion surgery since 2011 when our fusion program started, including the 56 patients in the HWW timeframe.

Therefore, the data from this study, albeit technically at a “temporary hospital,” proves the safety, efficacy of lumbar interbody fusions in the ASC setting and demonstrates that these codes meet all of the criteria for inclusion in the CMS ASC-CPL.

Methods

Single-level lumbar fusion Medicare beneficiaries were retrospectively identified and enrolled from Legacy Surgery Center and the same number of Medicare beneficiaries that were performed at a single hospital prior to the PHE- CHI St Vincent Little Rock, AR. The data was obtained retroactively from the medical records for each procedure. All cases were performed by a single, community neurosurgeon who has been performing ASC lumbar fusion cases since 2011. Records were evaluated beginning in 2020, and the first 23 CMS beneficiary patients in the ASC- HWW cohorts were included for analysis. All underwent a one-level decompression and interbody fusion through a MIS TLIF approach using the operating microscope. All patients were implanted with an expandable, standalone titanium interbody with or without pedicle screw fixation or other posterior fixation through a MIS approach with use of the operating microscope. For comparison, a 23-patient cohort of CMS beneficiary patients undergoing a single level lumbar interbody fusion were reviewed who underwent the same procedure at a local hospital in the months prior to the PHE by the same neurosurgeon. All Medicare beneficiaries operated on for lumbar fusion surgery at the ASC HWW center were included in the study. There were no exclusions.

The operative technique for all patients in both cohorts was the same. All cases were single-level interbody fusion combined with posterior lateral fusion and involved either a standalone threaded expandable interbody device (Varilift) using a MIS approach +/- the addition of posterior fixation with pedicle screws and/or other forms of posterior fixation.

With the patient in the prone position on a radiolucent table and using standard fluoroscopy, the side for decompression was selected based on the patient’s primary symptoms. The appropriate level was identified utilizing a spinal needle and fluoroscopic imaging. Most of the cases were done through a roughly 3-centimeter incision made approximately 4 centimeters off midline in a paramedian fashion. Once the facial layer was incised, a tubular retractor system was used and sequential dilation of the paraspinous soft tissue was completed in a Wiltse fashion. Microscopic

technique was used and neural decompression was performed by bilateral or unilateral laminectomy as indicated for neural decompression. This was then followed by a complete annulotomy and discectomy and preparation of the disc space for the inter body implant and bone fusion.

An expandable distraction device was inserted into the disc space and expanded to determine the optimal size for the interbody device. The appropriately sized interbody distractor and obturator was then inserted into the disc space in a neutral orientation then rotated 90 degrees to distract the vertebral bodies to the previously determined spacing. The obturator was then removed and the nerve root protector was placed and employed to retract the traversing nerve root medially. The threaded trial/tap was advanced in conjunction with fluoroscopic imaging to confirm proper sizing of the interbody device and to prepare the vertebral body endplates for the permanent device. The appropriately sized interbody device (from VariLift-LX Wenzel Spine, Austin, Texas) device was then placed with fluoroscopic guidance and expanded. After placement and expansion of the interbody, the device was filled with morselized autograft from the harvested lamina and/or allograft bone product or demineralized bone matrix (DBM). The end cap was then placed on the interbody device and the distraction instrument removed. Appropriate placement was confirmed via fluoroscopic imaging. Finally, a complete foraminotomy was performed at this level. In some cases, additional fixation with pedicle screw instrumentation was included in a usual manner under fluoroscopic control and with the use of navigation in some cases. Following this a posterior lateral fusion was performed using either autograft or allograft or both. The surgical site was then irrigated and closed in the standard technique over a drain.

Postop Protocol

Patients typically had the drain removed between postop days one and three. Those with durotomies had the drain in place for five days and it was attached to a bile bag not a hemovac drain.

Patients were instructed to wear their lumbar brace for five months when up and ambulating. Patients typically returned on the day after surgery for postop drain removal and then had a follow up visit at two weeks, six weeks, three months and six months postop. Postop X-rays were obtained on the third and sixth months.

Results

Records from 46 patients were evaluated with 23 performed at the ASC-HWW and 23 performed in the traditional hospital setting.

Table 1:

[illegible]

Average Age

The average age of the ASC-HWW cohort was 73 years with a range of 65 to 85. The average age of the traditional hospital setting was 73.9 years with a range of 67 to 86. Thus, the age distribution of the two groups was equivalent.

Gender

The gender distribution in the ASC-HWW group was 14 females and nine males while the traditional hospital group was 13 females and 10 males. Thus, the gender distribution was equivalent.

BMI

The average BMI of the ASC-HWW group was 28.1. The average BMI of the traditional hospital group was 29.4. Thus, the average BMI of the two cohorts were similar.

Blood Loss

Average blood loss in both groups was less than 170 cc and neither group had patients needing a blood transfusion. There was no clinically significant blood loss at either site of service.

ASA

[illegible]

ER Postop Visits

No patient in either group had an ER visit within 24 hours of discharge. Two patients in the ASC HWW group were seen in the ER between day two and seven and one in the CHI SVI group. One of the ASC HWW patients was treated for pain control and had a known intolerance to pain. They were treated appropriately and released. The other ASC HWW patient was seen for urinary retention and constipation. This was treated with an indwelling foley catheter and medications. The CHI SVI patient was seen due to a fever. The patient was examined, and an MRI was performed to rule out evidence of any abscess. The patient was then followed by his primary care for work up of his fever of uncertain etiology. No adverse complications developed in any of these patients. None required admission to the hospital in either group.

Hospital Admission

No patient required hospital re-admission in either group in the first 24 hours after discharge. One patient in the traditional hospital group was admitted to a hospital within the first seven days and none in the ASC HWW group. One patient in the ASC HWW group was admitted to the hospital after the first week but up to 30 days and none in the traditional hospital group. This patient was admitted due to fever and chills. An MRI of the lumbar spine was performed and showed no evidence of abscess. She was started on oral antibiotics due to positive beta strep in her blood and superficial surgical wound. No complications developed.

Re-operation

No patient was re-operated on in the first seven days in either group.

Infection

No patient in either group developed post-operative infections requiring surgical care.

ICU

No patient needed ICU care in either group.

DVT/PE

No patient in either group developed DVTs or PEs.

Thrombolytic Therapy

No patient in either group needed systemic thrombolytic therapy.

The surgery was not performed for emergency reasons on any patient in any group.

No body cavity was entered in either group.

Neither the nature of the condition nor the surgery was life-threatening in either group.

No major blood vessels were involved with any surgery in either group.

DISCUSSION:

One of our objectives was to prove the safety and efficacy of lumbar interbody fusion in CMS beneficiaries in an ASC setting.

In 2014, two different author groups reported their experiences with outpatient lumbar fusion.^{7, 8} Chin *et al.* reviewed medical records from 16 patients who had undergone single-level PLIF or TLIF with posterior supplemental fixation operated in an ASC.⁷ Eckman *et al.* reviewed 728 patients who were eligible and chose to go home on the same day as fusion and compared them to a group of 277 patients who were required to stay at least overnight due to their age (65 and over) or due to comorbid medical conditions.⁸

In 2016, Emami *et al.* reported on their experience with MIS-TLIF outpatient surgery.⁹ These authors retrospectively reviewed 32 patients who were discharged in less than 24 hours compared to 64 patients who were admitted and considered inpatient. The authors concluded that comparable clinical and safety outcomes were found between the groups and therefore MIS-TLIF may be safely performed as an outpatient procedure.

In 2016, Chin *et al.* again reported on outpatient lumbar fusions and compared a patient series to a hospital counterpart.¹⁰ The authors reported no major complications and no unplanned post-operative admissions for the ASC group. Their mean operative time for the surgery center patients compared closely to our experience of outpatient surgery (mean of 138 minutes versus 127 minutes). Overall, the authors concluded a demonstration of successful conversion from hospital to surgery center lumbar fusions based on their less exposure technique due to the implementation of cortical bone trajectory pedicle screws.

Bovonratwet *et al.* interrogated the ACS-National Surgical Quality Improvement Program (NSQIP) database for the years 2005–2015 to evaluate possible differences in outpatient posterior fusions versus inpatient posterior fusions by defining inpatient as a length of stay greater than 0 days.¹¹ Their query returned an outpatient sample of 360 cases with statistical differences in age, gender and ASA status pre-operatively compared to inpatient. They then employed propensity score matching to evaluate inpatient versus outpatient differences for matched groups and found all statistically significant differences vanished. The same was true for 30-day perioperative events except blood transfusion, which remained statistically higher in the inpatient group. They report unadjusted proportions of 3.6 percent versus 5.4 percent readmission and 1.1 percent versus 2.3 percent return to the OR (outpatient versus inpatient).

In 2019, Basques *et al.* reviewed the literature on outpatient lumbar fusion surgery. They concluded that outpatient lumbar fusion surgery has similar functional outcomes, complication rates and readmission rates to inpatient cohorts.

In our prior study, Schlesinger S. *Et al.*, Thirty-Day Outcomes from Stand-alone Minimally Invasive Surgery- Transforaminal Lumbar Interbody fusion Patients in an Ambulatory Surgery Center vs Hospital Setting,¹⁷ we reviewed these various studies, both direct research and

database reviews, to benchmark the present experience of a single, community neurosurgeon who is performing the same MIS-TLIF procedure both at a hospital and in a surgery center environment. We studied the potential differences in perioperative baseline characteristics, operative efficiency and 30-day safety events for 50 patients undergoing MIS-TLIF in a hospital versus 50 patients in an ambulatory surgery center setting for non-CMS patients. Our 30-day readmission proportion of 2 percent for the ASC setting and 6 percent for the hospital setting is well aligned both with direct retrospective series as well as on a population-based view of these procedures. There were no re-admissions within the first 24 hours of surgery in either group. The same is true for the re-operation proportions found in our ASC and hospital cohorts of 2 percent each. Our data was further stratified and reported compared to previous accounts and we found that seven patients (five ASC and two hospital) presented to an emergency room in the first 30 days postop with only two of these incidents being directly related to their surgery (continued pain), yet with unremarkable findings on labs or imaging. The only difference noted between our ASC and hospital patients of significance was the length of stay: three hours versus 1.8 days. Our results of this current study, therefore, confirms that just like the published data on commercially insured patients, lumbar interbody fusion surgery can be safely and efficaciously performed on CMS beneficiaries in the ASC setting for patients on ASA levels 1-3.

In addition to the CMS beneficiaries treated during this same period of time, an even greater number of commercially insured patients (481) have successfully undergone the same fusion procedures at the same ASC setting and had no complications and had a length of stay in the same range as our CMS beneficiary patients.

While the ASC is technically a “temporary hospital,” the clinical environment for surgical care, the requisite postop care needed and length of stay did not necessitate utilization of any of the CMS requirements beyond the normal ASC requirements for these cases. Therefore, this study validates the safety and efficacy of these procedures at a typical spine-focused ASC once the PHE is over and the clinical supportive documentation that these two fusion codes should be added to the ASC-CPL for CY 2022.

ASC-CPL

Another one of our objectives was to demonstrate that the CPT codes 22633 and 22630 meet all CMS published criteria for inclusion to the ASC Covered Procedures List (ASC-CPL). Inclusion in the ASC-CPL does not mean all patients must have such a covered procedure in an ASC. It only means that CMS believes that the procedure has met all of its published criteria for safe and effective ASC site of service and will be covered by CMS for payment in the ASC setting. CMS defers to the physician to make a medical judgment for an individual patient on the most appropriate site of service for their condition. Being on the ASC-CPL simply means that CMS will pay for the ASC site of service for the covered CPT code if a surgeon performs this service in an ASC setting.

Excerpts from CMS follows.

“As previously stated in the discussion of the CY 2018 OPPTS/ASC final rule (82 FR 59383), we continue to believe that the decision regarding the most appropriate care setting for a given

surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary”.

(b) General standards. Subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the Federal Register and/or via the Internet on the CMS Website that are separately paid under the OPPTS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

The experience with ASCs for several years performing non-CMS patient lumbar fusion surgery along with the data from the ASCs enrolled in the HWW program clearly demonstrates that this procedure does not pose any additional safety risk to a Medicare beneficiary when performed in an ASC, and also demonstrates that such patients did not require active medical monitoring and care beyond midnight following the procedure. Our data on Medicare beneficiaries shows an average length of stay of less than three hours.

The excerpt below is from CMS published information and outlines CMS ASC covered services inclusion criteria: “Calendar Year (CY) 2008 Revised Ambulatory Surgical Center (ASC) Payment System.”¹⁸

“CMS uses many of the existing clinical criteria under the pre-2008 ASC payment system to evaluate the safety risk associated with each procedure. These clinical criteria include those procedures that generally result in extensive blood loss; require major or prolonged invasion of body cavities; directly involve major blood vessels; are emergent or life-threatening in nature; or commonly require systemic thrombolytic therapy.”

(C) General exclusions. Notwithstanding paragraph (b) of this section, covered surgical procedures do not include those surgical procedures that—

- (1) Generally result in extensive blood loss;*
- (2) Require major or prolonged invasion of body cavities;*
- (3) Directly involve major blood vessels;*
- (4) Are generally emergent or life-threatening in nature;*
- (5) Commonly require systemic thrombolytic therapy;*
- (6) Are designated as requiring inpatient care under §419.22(n) of this subchapter;*
- (7) Can only be reported using a CPT unlisted surgical procedure code; or*
- (8) Are otherwise excluded under §411.15 of this subchapter.*

The excerpt below is from CMS published information: “Calendar Year (CY) 2008 Revised Ambulatory Surgical Center (ASC) Payment System Questions and Answers”.

18. How does CMS determine which surgical procedures can be performed safely in an ASC under the revised ASC payment system?

First, CMS excludes from consideration for payment under the revised ASC payment system all surgical procedures that are included on the inpatient list used in the OPPS and those that only can be reported by using one of the CPT unlisted codes. CMS determined that procedures that were deemed to be unsafe for performance in any but the hospital inpatient setting were not safe for performance in ASCs and that procedures for which there is no specifically descriptive code could not be evaluated for safety risk and so should be excluded from consideration.

CMS uses many of the existing clinical criteria under the pre-2008 ASC payment system to evaluate the safety risk associated with each procedure. These clinical criteria include those procedures that generally result in extensive blood loss; require major or prolonged invasion of body cavities; directly involve major blood vessels; are emergent or life-threatening in nature; or commonly require systemic thrombolytic therapy.

19. The ASC final regulation for the revised ASC payment system says that CMS excludes from coverage procedures that are expected to require an overnight stay. What does that mean?

If a patient has to stay overnight for a procedure that is on the list of covered ASC surgical procedures, does that mean the claim for the procedure will be denied?

CMS excludes any surgical procedure for which standard medical practice dictates that the beneficiary typically would be expected to require active medical monitoring and care at midnight following the procedure (i.e., an overnight stay). CMS does not certify ASCs to provide overnight care to Medicare beneficiaries and determined that any surgical procedure for which the post-operative period of active medical monitoring is expected to extend to midnight is not appropriate for Medicare beneficiaries in ASCs. Thus, “overnight stay,” for purposes of ASCs, means the patient recovery generally requires active monitoring by qualified medical personnel, regardless of whether it is provided in the ASC, beyond 11:59 P.M. of the day on which the surgical procedure was performed.

This does not mean that a beneficiary cannot remain in an ASC beyond midnight or that ASCs only should perform procedures on “typical” patients that would not be expected to require an overnight stay. CMS’ use of “overnight stay” only applies to determinations about procedures for inclusion on the ASC list and should not be used to dictate care in individual cases.

Our study demonstrates that the CPT codes 22633 and 22630 meet all criteria for inclusion and none for exclusion in the ASC-CPL.

The posterior interbody lumbar fusions we are recommending be covered in the surgery center setting do not involve extensive blood loss. The average blood loss is 345 cc per case in various studies, which is comparable to other procedures that are commonly performed in the ASC setting. Advancements in minimally invasive techniques and surgical instruments have allowed surgeons to utilize smaller incisions resulting in less tissue disruption and, therefore, less blood loss during surgery. In our commercially insured publication¹⁷ and in our current study, 0 percent of CMS beneficiaries experienced any clinically significant quantity of blood loss and none required blood transfusions. This is consistent with numerous other publications on ASC lumbar interbody fusions.

PLIFs do not require invasion of any body cavities. The incision is typically a 1-3 inch incision directly above or lateral to the spinous process of the vertebral interspace that is being fused. The only anatomy affected is the vertebral interbody space, the epidural space, the ligamentum flavum and the posterior annulus of the disc. This is the identical anatomy encountered in currently ASC-approved procedures, such as 63030, 63047 and 22612. The intervertebral disc space fusion portion of the procedure for the cervical spine has been covered in the ASC by CMS for the cervical spine CPT Code 22551 for several years.

The procedures do not involve any major blood vessels and thus the risk to injury of major vessels is low. The risk to major blood vessels is the same for lumbar interbody fusion as it is for existing ASC-covered spine procedures above.

Lumbar inter body fusions are performed for elective conditions of the spine, not for life-threatening or emergent conditions.

Patients undergoing lumbar fusions do not require systemic thrombolytic therapy and, in fact, this would be contra-indicated for any lumbar fusion patient due to risk of hemorrhage. The codes for lumbar interbody fusions are on the hospital outpatient list and do not require inpatient care only.

There are specific CPT Codes for the two procedures we are proposing to be added to the ASC-CPL. The two codes are 22630 – Posterior Lumbar Interbody Fusion and 22633 – Combined Posterior Lumbar and Posterior Lumbar Interbody Fusion. These codes are specific and the procedure will never be reported with an unlisted CPT code.

This study shows that length of stay for performance of these lumbar interbody fusion services on CMS beneficiaries meets and exceeds the requirements as regards length of stay.

CMS excludes from payment only those procedures that pose a significant safety risk to beneficiaries or are expected to require an overnight stay when furnished in ASCs. CMS excludes any surgical procedure for which standard medical practice dictates that the beneficiary typically would be expected to require active medical monitoring and care at midnight following the procedure (i.e., an overnight stay). From CMS Update for CY 2008: Thus, “overnight stay” for purposes of ASCs, means the patient recovery generally requires active monitoring by qualified medical personnel, regardless of whether it is provided in the ASC, beyond 11:59 P.M. of the day on which the surgical procedure was performed. This does not mean that a beneficiary cannot remain in an ASC beyond midnight or that ASCs only should perform procedures on “typical” patients that would not be expected to require an overnight stay. CMS’ use of “overnight stay” only applies to determinations about procedures for inclusion on the ASC list and should not be used to dictate care in individual cases.

This study has demonstrated that like commercially insured patients per many publications, Medicare beneficiaries undergoing lumbar interbody fusion did not require an overnight stay nor active medical monitoring and care beyond midnight of the day of care. This study also demonstrates that not only did the “typical” patients not need close monitoring and Medicare

care after midnight on the date of service, none of the patients required such and all patients were discharged well before the midnight timeline.

Without question there are many patients whose procedures are on the ASC-CPL that may have underlying conditions that might reasonably be expected to require active medical monitoring and care beyond midnight. This would include any patient with severe heart disease, lung disease, etc. that would render them as an ASA 4 or higher. These medically infirm patients are not suited to ASC care for any ASC-CPL procedure. However, for purposes of CMS definition above we have shown the CPT codes 22633 or 22630 (lumbar interbody fusion) do not qualify for exclusion from the ASC-CPL as regards the length of stay regulation. We have proven that the CMS beneficiary typically would not be expected to require active medical monitoring and care at or after the midnight following the procedure.

Benefits of ASC Site of Service

During the COVID-19 pandemic, being able to care for non-COVID elective surgical patients in an ASC setting has been life-saving to the patients by reducing or eliminating their risk of nosocomial acquisition. Numerous studies have pointed out the high risk of nosocomial transmission of COVID-19 to healthcare workers and patients seeking care at a hospital treating COVID patients. The same is true for bacterial nosocomial infection, including Methicillin-Resistant Staphylococcus Aureus MRSA and risks outside of COVID 19. Prior reports suggest a rate of postop bacterial infection in the ASC setting to be <0.13 percent versus 5 percent in the hospital setting. The cost for a postop spine deep infection is staggering both directly and indirectly. Mortality from a deep spine infection has been estimated to be 11 percent.

Many studies have shown the reduced risk of numerous complications for ASC patients and the higher patient satisfaction rate for ASC care versus hospital care for surgery.

Cost savings would be substantial for both CMS and CMS beneficiaries if these codes were included in the ASC-CPL. This is due to direct reimbursement difference between hospital and ASC sites of service for the identical procedure and indirectly due to cost savings of the reduced infection rate and other complications rate at the ASC.

CONCLUSIONS

As expected, and in line with prior reports on non-Medicare patients, lumbar interbody fusion was shown to be equally safe and efficacious in the ASC HWW group versus in the traditional hospital group. All measured factors and variables were comparable with one exception: the length of stay. The length of stay for the identical procedure and identical demographics and age was 10 times the length of stay for the same procedure in the traditional hospital setting versus in the ASC-HWW setting. All ASC-HWW patients were discharged well before midnight of the day of surgery.

All prior ASC lumbar interbody fusion studies were of non-Medicare beneficiaries as CMS has not yet covered this procedure at an ASC. Therefore, there was no way to collect data on the safety and efficacy of the Medicare patient population for the ASC site of service until the PHE

waivers allowed enrollment of ASCs as temporary hospitals. None of our CMS beneficiaries in this study and none of the non-CMS patients in the same time frame nor the 420 cases performed in the ASC setting prior to the PHE starting when we added TLIF surgeries to our center in 2011 required any services or care beyond what is accessible in a regular non-HWW ASC. All have been discharged well before the midnight of the day of surgery. The average length of stay of all our 504 cases has been around 2.25 hours. No patient in this series nor the 504 total cases required transfer to a hospital nor were admitted to a hospital for care within 24 hours. In our experience, since 2011 and in this current study, no patient has required blood transfusions, none were emergent surgeries, none involved body cavities and none involved system thrombolytics.

The return of the ASC enrolled in the HWW as temporary hospitals when the PHE is over will have no impact on their ability to continue to provide this lumbar fusion service if it gets added to the ASC-CPL.

Our report shows that the codes for lumbar interbody fusion (22630) and lumbar interbody combined with posterior lateral fusion (22633) meet all published criteria for inclusion on the ASC-CPL and meet no exclusion criteria. Our report proves the safety and efficacy of this procedure in the ASC setting. Our report and our review of the literature outlines numerous advantages to CMS and CMS beneficiaries of inclusion of these codes in the 2022 final rule for ASC coverage and zero disadvantages to the same.

No disclosures.

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Appendix D – Total Shoulder and Ankle Research

Safety of Outpatient Total Ankle Arthroplasty vs Traditional Inpatient Admission or Overnight Observation

Foot & Ankle International

Published: August 2017

Results: Eighty-one patients underwent TAA who met inclusion criteria, and 8 had a complication (10%). A significant difference in complication rate was seen among groups ($P = .01$) but not rate of readmission or reoperation. Of 16 patients, 5 (31%) who were admitted for 2 or more nights following surgery had a complication, as opposed to 3 of 65 (5%) who were outpatient or admitted overnight ($P = .01$). There were no differences in frequency of postoperative phone calls, narcotic refills, or visual analog scale pain scores at the first postoperative visit. There were no adverse medical events.

Outpatient total shoulder arthroplasty in an ambulatory surgery center is a safe alternative to inpatient total shoulder arthroplasty in a hospital: a matched cohort study

The Journal of Shoulder and Elbow Surgery

Published: February 2017

Finding: Comparing two samples (30 patients matched for age/comorbidity) of patients undergoing total shoulder arthroplasty at an ASC and an inpatient hospital, there was no significant difference in 90-day episode-of-care complication rates such as hospital admission/readmission.

Safety of Outpatient Shoulder Surgery at a Freestanding Ambulatory Surgery Center in Patients Aged 65 Years and Older: A Review of 640 Cases

Journal of the American Academy of Orthopaedic Surgeons

Published: January 2018

Finding: Our findings are consistent with currently reported outpatient hospital-based data and illustrate the safety of outpatient shoulder procedures at a freestanding ambulatory surgery center in Medicare-age patients.

Outpatient Shoulder Arthroplasty at an Ambulatory Surgery Center Using a Multimodal Pain Management Approach

Journal of the American Academy of Orthopaedic Surgeons

Published: October 2018

Results: No major complications, readmissions, revision surgeries, or deaths occurred in the outpatient cohort. The rate of 90-day complications was 9.5% and 17.5% for the outpatient and inpatient cohorts, respectively. All patients who had their shoulder arthroplasty as an outpatient were discharged home the day of surgery. No complications related to the outpatient protocol were observed.