September 13, 2022

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1772-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; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Dear Administrator Brooks-LaSure:

We applaud the Centers for Medicare & Medicaid Services' (CMS) ambitious strategic plan,[1] and appreciate the Agency's stated desire to "ensure that the public has a strong voice through CMS' policymaking, operations, and implementation process." As high-quality, lower-cost facilities for outpatient surgical care, ambulatory surgical centers (ASCs) are well-positioned to help CMS achieve success on the Agency's strategic pillars.

The Ambulatory Surgery Center Association (ASCA) supports CMS in its pursuit of policies that save Medicare and its beneficiaries money without compromising quality, and this value proposition is the essence of the ASC model. While there are some promising policies in the calendar year (CY) 2023 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule ("Proposed Rule") (87 Fed. Reg. 44502, July 26, 2022), there is still significant work to be done to increase access to care for Medicare beneficiaries.

One of CMS' strategic pillars that we will focus on in these comments is the Agency's need to protect its "programs' sustainability for future generations by serving as a responsible steward for public funds." ASCs help accomplish this, with recent research[2] showing that ASCs reduced costs to the Medicare program by $28.7 billion in the period between 2011 and 2018. This study, which provided an update to ASC cost savings research released several years ago,[3] found there

[1] https://www.cms.gov/files/document/cms-strategic-plan-infographic.pdf (accessed August 2, 2022).
[2] *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
[3] *Medicare Cost Savings Tied to Ambulatory Surgery Centers*, University of California-Berkeley Nicholas C. Petris Center on Health Care Markets and Consumer Welfare, September 2013, and the US Department of Health and

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was 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 modest rate as 2011–2018, ASCs can reduce Medicare spending by $74.2 billion from 2019–2028,[4] freeing up funds for use on other health priorities. Adopting policies to increase migration will generate even greater savings than those projected.

Most ASCs operate as small businesses, and as such, must run efficiently to remain viable and continue to provide savings to Medicare and its beneficiaries. As of June 2022, there were 6,088 CMS-certified ASCs.[5] Of those, 4,383 (72 percent) have three or fewer operating rooms and 3,289 (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.

The past few years especially have been challenging, beginning with COVID-19 restrictions starting in early 2020 and supply chain issues and increased costs that persist today. ASCs are also absorbing higher labor costs as they continue to compete with hospitals and other health care providers for the same nurses and other staff, an area where shortages already exist and are projected to grow over the next few years.[6] ASCs must comply with state and federal regulations[7] 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 the ASC model relies on running efficiently, receiving 50 percent of the reimbursement on average for the same procedures being provided in a similar site of service at much higher rates jeopardizes the ability of our facilities to provide care to all of the Medicare beneficiaries we could serve. Medicare surgical procedures in too many markets continue to be performed predominantly in hospitals, which we attribute in part 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.

We welcome the opportunity to collaborate with CMS on the payment policy proposals outlined in this letter that would encourage the clinically appropriate migration of services into the ASC setting—providing the Medicare program and its beneficiaries with a substantial savings opportunity while ensuring continued access to the high-quality care that ASCs provide and beneficiaries deserve.

Specifically, we make the following recommendations:

Human Services. Office of Inspector General. Washington: Government Printing Office, April 2014. (A-05-1200020).

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

[5] 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/.

[6] *Staff Shortages Choking U.S. Health Care System*, U.S. News & World Report. July 28, 2022. https://www.usnews.com/news/health-news/articles/2022-07-28/staff-shortages-choking-u-s-health-care-system.

[7] https://www.advancingsurgicalcare.com/safetyquality/federalrequirementsgoverningascs (Accessed September 2022).

- **Update Factor.** CMS should use the hospital market basket as the annual update mechanism for ASC payments indefinitely. The Agency should extend the five-year trial given that Medicare volume data has been skewed the past two years due to the COVID-19 pandemic.

- **ASC Weight Scalar Adjustment**. CMS must discontinue the ASC weight scalar. With the 2019 change in the update 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 the ASC setting and lower the cost of care.

- **Procedures Permitted in ASCs.** CMS should add the codes ASCA clinicians have requested for addition to the ASC Covered Procedures List (ASC-CPL) for 2023 or explain why the Agency chooses not to allow surgeons to perform these procedures in the ASC setting.

- **Complexity Adjustment.** CMS should finalize its proposal to provide complexity adjustments for combinations of certain service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

- **Quality Reporting.** CMS should finalize its proposal to suspend mandatory implementation of ASC-11 as it is a little-used clinician measure that will create an undue burden for facilities.

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.[8] Since 2008, the ASC community has urged CMS to adopt the same update factor for both the ASC and OPPS payments and appreciates that CMS took this first, necessary step toward better alignment of the payment systems.

ASCs have been increasing their share of commercial outpatient surgical volume for years. As we have consistently reported to CMS, that growth has been hampered with regard to Medicare volume by a lack of parity in reimbursement between hospital outpatient and ASC payment increases. The alignment of update factors was a promising sign and, increased confidence in the ASC community that CMS recognizes the need for a more level playing ground between ASC and hospital outpatient reimbursements.

[8] CY 2007 OPPS/ASC Proposed Rule (https://www.cms.gov/newsroom/press-releases/cms-revises-payment-structure-ambulatory-surgical-centers-and-proposes-policy-and-payment-changes).

Unfortunately, the COVID-19 pandemic arose during the second year of CMS' five-year pilot for aligning the ASC and HOPD update factors, limiting both ASCA and the Agency's ability to fully assess the success of the policy. COVID-19 impacted volume so dramatically in 2020 that CMS decided not to use it in 2022 rulemaking. ASCA appreciates that CMS has proposed to continue to use the hospital market basket to update ASC rates in 2023, and we ask that the Agency extend the policy into FY 2024 and beyond.

ASCA has remained steadfast in its support for the alignment of update factors, even though under the Consumer Price Index for All Urban Consumers (CPI-U), which was previously used for ASC updates, our facilities would have seen a higher update than what we received using the HMB last year. That difference is even greater today. However, ASCA believes that since the ASC payment system is directly tied to the OPPS, the same update factor should be used.

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 Medicare beneficiaries' access to outpatient surgical care in ASCs.

Request for Cost Data

CMS 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 applies 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 (HOPD) 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, to find out. As a starting point, we suggest 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 ASCs and that the cost experience can differ greatly depending on factors such as specialties served, size of the facility and geographic location. To meet current regulations, ASC staff already face excessive administrative burdens, and requiring formal cost reports from ASCs would run counter to the Agency's desire to establish policies that allow facilities to maintain efficiency in the Medicare program. We welcome the opportunity to collaborate on this endeavor.

ASCA Requests Clarification that 340B Policies do not Impact ASCs

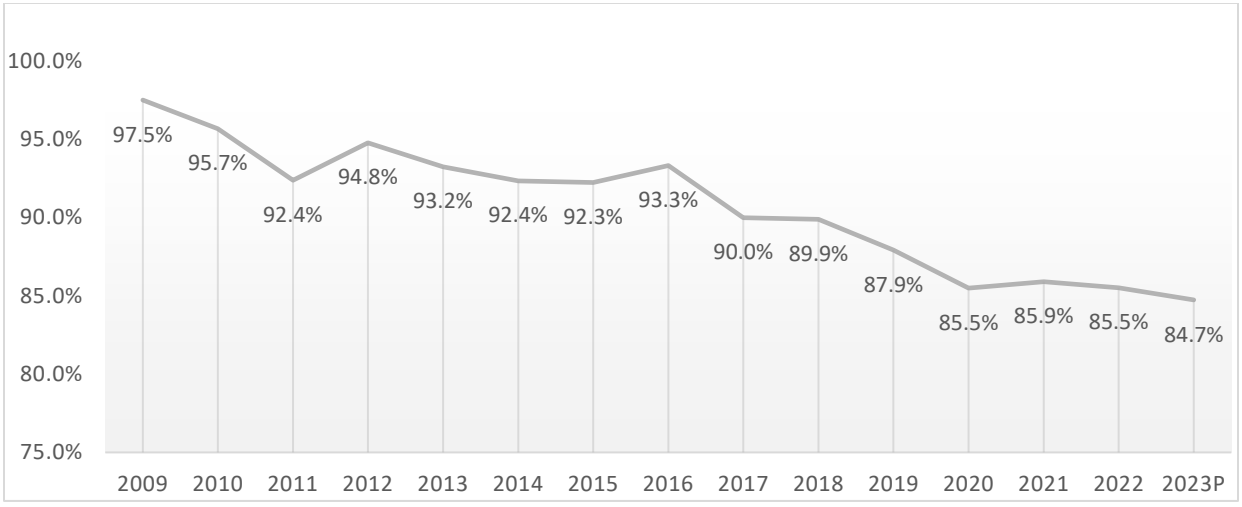
We understand that when CMS adopted its 340B payment policy for covered outpatient drugs in hospitals in the 2018 final OPPS rule, the policy did not affect the ASC conversion factor because the agency did not apply the ASC budget neutral scalar to covered outpatient drugs. *See* 82 Fed. Reg. 52496; 52558 (Nov. 13, 2017). As a result, the ASC conversion factor, in every

year since 2018, should not have been affected by the CMS 340B policy for the payment of covered outpatient drugs in hospitals. We ask CMS to confirm that ASC reimbursement in 2023 and beyond will not be affected by whatever policy CMS implements to address the Supreme Court's decision in *AHA v. Becerra* (June 2022).

CMS must 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 that established the current 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 clearly shows 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 grown more severe since the ASC payment system was aligned with the HOPD payment system.

Application of ASC Weight Scalar (CY 2009 – CY 2023 Proposed)



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 2023, CMS is proposing an adjustment of 0.8474 that, if finalized, would result in a devastating 15.26 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 ASCs, accounting for six of the top twelve codes by volume in 2019. In that single year, ASCs performed more than 1.8 million of these GI procedures, and CMS saves approximately $900

million, just within this group of six codes.[9] Even though the current savings are significant, there is room for growth, as more than 50 percent of these procedures are still performed in the HOPD setting instead of the ASC. Taking out current savings (cases already being done in ASCs instead of HOPDs) as the baseline, if 90 percent of these six GI endoscopies were performed in ASCs instead of HOPDs—the percentage of beneficiaries that many clinicians believe could be safely seen in an ASC—the volume migration would represent $710 million in additional ("new") savings annually. **The total annual savings to the Medicare program would be approximately $1.61 billion for these six codes alone.**

The current payment system disincentivizes case migration to the lower cost setting. 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 can at least take a big first step by reducing disparities between HOPD and ASC reimbursement through elimination of the ASC weight scalar.

If CMS continues to apply budget neutrality adjustments looking at the ASC payment system alone, any increase in volume will 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.

The Agency is needlessly increasing Medicare program costs by making it financially untenable for ASCs to perform 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, and that the Agency serves as a responsible steward of public funds, CMS must discontinue use of the ASC weight scalar.

Under the statute that implemented the new ASC payment system in 2008, CMS was required to apply budget neutrality only in the first year of implementation of the new payment system.[10] 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 statutory requirement. Under the same rationale, CMS also has the authority to discontinue the scalar at its discretion. ASCA implores CMS to encourage savings and greater access to ASCs for Medicare beneficiaries by eliminating the ASC weight scalar.

[9] The six CPT codes are: 43239, 45378, 45380, 45385, G0105, and G0121.

[10] 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.

ASCA recognizes that discontinuing application of the ASC weight scalar would result in an initial increase in cost to the Medicare program (a cost that only gets 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, 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.

We are now 15 years into alignment of the OPPS and ASC payment systems, and at the very least, CMS must undertake an analysis of what is causing the rising trend in the OPPS scalar and whether those factors should or should not be offset in the ASC setting. As more procedures are performed in the ASC setting, it is important to understand the impact of the ASC weight scalar and the factors driving the rising OPPS scalar and to assess whether these factors are appropriately being offset by the ASC scalar.

Proposed Addition to the List of ASC Covered Surgical Procedures

While we support the addition of CPT 38531 to the ASC Covered Procedures List (ASC-CPL) for 2023, we are extremely disappointed that this is the only code proposed for addition from the 47 codes ASCA submitted to CMS for consideration in March 2022 (full list in Appendix A).

In this rule, CMS acknowledges the importance of volume data, stating, "recent studies suggest that while larger facility surgical procedure volume does not alone lead to better outcomes, it may be associated with better outcomes due to having characteristics that improve care (for example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications), making volume an important component of quality."

Yet CMS ignored the volume data provided by ASCA, as many of the procedures requested are performed in significant volume on an outpatient basis (including HOPD and ASC volume). In fact, 41 of the 47 codes ASCA requested are performed most of the time on an outpatient basis. Research confirms that outcomes are remarkably similar, even adjusting for risk, between HOPDs and ASCs.[11] Survey and certification requirements are also essentially the same in both settings;[12] indeed, the primary difference between the settings is the much higher reimbursement rate HOPDs receive over ASCs.

Evaluating codes based on the "typical" Medicare beneficiary

In this rule, CMS indicates that "while expanding the ASC CPL offers benefits, such as preserving the capacity of hospitals to treat more acute patients and promoting site neutrality, we also believe that any additions to the CPL should be added in a carefully calibrated fashion to ensure that the procedure is safe to be performed in the ASC setting for a typical Medicare

[11] Elizabeth L. Munnich and Stephen Parente, "Returns to Specialization: Evidence from the Outpatient Surgery Market." *Journal of Health Economics*, 57, 2018.
[12] Sources: 42 CFR 416 & 482.

beneficiary." There is no clear guidance, however, as to what this "typical" Medicare beneficiary looks like. In the 2022 proposed rule, CMS referred to the "typical" beneficiary, "whose health status is representative of the broader Medicare population." CMS referenced 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.[13]

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 allowing ASCs to perform only procedures that are safe for an "average" Medicare beneficiary, the Agency is severely limiting access to younger, more active Medicare beneficiaries with few comorbidities. Medicare would also need to develop a much more detailed explanation of what constitutes an "average beneficiary" because, on its face, this language could practically eliminate the ASC-CPL altogether—an obviously absurd result.

We agree there are certain subsets of the population who should have their surgeries performed in an inpatient hospital due to comorbidities and risk factors. However, there are also significant percentages of the Medicare population who are younger and healthier, with 49 percent of Medicare beneficiaries now younger than 75 years old[14] and 31.09 percent nationally having zero or only one chronic condition.[15] Accordingly, the only reasonable approach is to determine whether a subset of the beneficiary population is suitable for a given procedure and allow for the clinician to decide which of her patients are eligible for care in an ASC. The Medicare program both overspends and underdelivers by relying on this short-sighted policy to exclude from consideration any code that may not be appropriate for the "typical" Medicare beneficiary – whoever that may be.

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. With any procedure that a surgeon is contemplating performing in an ASC, qualified patient selection is paramount. Our facilities develop and follow strict protocols to ensure that only appropriate patients are considered, which results in consistent and predictable successful outcomes. The physicians who work in ASCs are much better equipped to determine which cases should be performed in an ASC than CMS clinicians – most of whom are not surgeons.

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

[13] See Social Security Act 1833(i)(1).
[14] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Beneficiary-Snapshot/Downloads/Bene_Snaphot.pdf (Accessed August 26, 2022).
[15] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CCDashboard (Accessed August 26, 2022).

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. Physicians who invest in ASCs not only have their medical license to worry about, but the viability of their facility and the livelihoods of all who they employ. Physicians must be deliberate and careful when determining the appropriate site of service for each patient, and CMS should trust this nation's surgeons to know best what is required for each individual patient.

Ambulatory Payment Classifications

According to this Proposed Rule and rules preceding it, when evaluating which codes to put in the same Ambulatory Payment Classification (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. Most of the codes ASCA requested CMS add to the ASC-CPL for 2023 are in APC groups where the vast majority of the codes are already on the ASC-CPL. For instance, total shoulder arthroplasty (23472), the code most frequently requested for inclusion on the ASC-CPL by ASCA members, is one of only a handful of codes in APC 5115 that ASCs are not allowed to perform on Medicare beneficiaries. It is a procedure that has been performed on non-Medicare patients for years, and so far in 2022, there have been 5,178 total shoulder replacements performed in the ASC setting.[16]

There are even codes ASCA has requested for addition to the ASC-CPL that represent the *only* code in their APC group not payable in the ASC setting. One example is CPT 19307, which ASCA has long-requested be added to the ASC-CPL. It is in APC 5092, which has twelve codes, and the eleven other codes in the group are all currently on the ASC-CPL. 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 A should be added to the ASC-CPL in 2023. ASCA highlights a few codes below that were the most requested by our members.

Total Shoulder Arthroplasty (CPT 23472) and Total Ankle Replacement (27702)

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 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.

[16] Definitive Healthcare (https://www.definitivehc.com/). Healthcare data analytics with all-claims data. (Accessed August 26, 2022).

Attached as Appendix B to this comment letter are several studies that specifically speak to outpatient total shoulder arthroplasty and one study focused on total ankle replacement safety. These procedures are being performed on other patient populations as outpatient procedures. In 2021, approximately 70,000 total shoulder replacements were performed in outpatient settings, and about 4,500 total ankle replacements were performed outpatient.

Lumbar Spine Fusion

CPT 22630 and CPT 22633 should also be added to the ASC-CPL in 2023. These procedures, both payable in the HOPD setting, have been commonly performed in the ASC setting for commercially insured patients for years. So far in 2022, CPT 22633 has been performed 1,374 times in the ASC setting.[17]

Thanks to the Hospital Without Walls program that was established early in the COVID-19 public health emergency, we now have outcomes data[18] for posterior lumbar inter-body fusions for Medicare beneficiaries. 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.[19]

CMS exclusionary criteria

In 2022 rulemaking, CMS reverted to the old exclusionary criteria, *(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 using these criteria. While we have reservations as to how they can be interpreted—they are imprecise and subjective—we do not oppose their use so long as they are used as guidance for exclusion rather than as an automatic refusal to consider. States that look to CMS regulations when determining what to allow in their jurisdictions often misinterpret the exclusionary criteria for the Conditions for Coverage (CfCs) and impose onerous limitations on ASCs based on those misinterpretations. The CfCs that are in place ensure that ***all*** ASC patients receive care in a safe and highly regulated environment, regardless of payer.

[17] Definitive Healthcare (https://www.definitivehc.com/). Healthcare data analytics with all-claims data. (Accessed August 26, 2022).

[18] 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.

[19] Schlesinger, Scott MD, et al.

There are 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 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 HCPCS 41899 (dental surgery procedure). This is the *only* CPT code available for dental surgery and was performed 71,686[20] times on non-Medicare populations in the 492 CMS-certified ASCs that perform dental surgery.[21] This procedure is often 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.

For HOPDs, this procedure is currently assigned to APC 5161, but in the CY 2023 proposed rule, CMS is making a positive step toward access to dental surgery in the outpatient space, proposing to reassign HCPCS code 41899 to clinical APC 5871, which is the only APC group that specifically describes dental procedures. This change in APC group will significantly

[20] Definitive Healthcare (https://www.definitivehc.com/). Healthcare data analytics with all-claims data. (Accessed August 30, 2022).
[21] https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities/data (Q2 2022 data).

increase the reimbursement rate for HCPCS 41899 when performed in HOPDs. Whereas the current national OPPS reimbursement for HCPCS 41899 is $216.07, under its new APC group, the reimbursement rate for this dental code in 2023 is proposed at $1,956.32. That significant jump will certainly provide greater outpatient access to dental procedures.

If providers can choose to perform these procedures in HOPDs, which we have already shown are often identical to ASCs, and physician offices. which are not regulated by the federal government, physicians should be able to use unlisted codes such as HCPCS 41899 in the ASC setting. ASCA requests that CMS revise the Code of Regulations to remove this restriction.

Additional dental code considerations

The 2023 proposed Medicare Physician Fee Schedule (MPFS) proposes to expand the dental procedures eligible for Medicare coverage and suggests that further expansion may be forthcoming. If this expanded dental coverage is finalized, it is critical that there be sufficient access for those Medicare patients who need general anesthesia for the safe performance of their newly covered dental procedures.

Besides the unlisted code issue outlined in the section above, dental procedures have also been excluded from the ASC-CPL because CMS generally excludes services that are "otherwise excluded under § 411.15 of this chapter."[22] This includes: "coverage for dental procedures performed "in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth" with the exception of certain procedures requiring inpatient hospitalization. If the 2023 MPFS Proposed Rule is finalized, there will be a significant (and potentially expanding) number of dental procedures that will be covered by Medicare that are not performed "in connection with the care, treatment filling, removal or replacement of teeth" but rather "in connection with" the performance of other Medicare-covered services (such as transplantation). Under these circumstances, 42 CFR § 411.15 should no longer preclude the inclusion of dental procedures on the CPL.

The 2023 MPFS Proposed Rule implicitly supports an approach that would make individual CDT codes payable under the OPPS and add them to the ASC-CPL, since it notes that the expanded dental coverage may include numerous CDT codes that are listed in the preamble to the Proposed Rule. The CDT list includes CDT codes used to report restorative dental services to eradicate infections when performed to facilitate organ transplantation, which are often also used to perform dental surgical rehabilitation.[23]

We recognize that including all applicable CDT codes to report newly covered dental procedures may require additional consideration by CMS. Considering the urgency of the situation,

[22] 42 CFR 416.166(c)(8).

[23] The 2023 MPFS Proposed Rule preamble specifically provides that Medicare cover the following types of dental procedures in conjunction with organ transplants: pulling of teeth (CDT D7140, D7210), removal of the infection from tooth/actual structure, such as fillings (e.g., CDT D2000-2999), periodontal therapy for removal of the infection that is surrounding the tooth, such as scaling and root planning (e.g., CDT D4000-4999, and more specifically D4341, D4342, D4335 and D4910), or endodontic therapy for removal of infection from the inside of the tooth and surrounding structures, such as root canal (e.g., CDT D3000-3999).

however, and as an interim solution, we urge CMS to consider including a single CDT code on the ASC-CPL list to be used to report covered dental procedures in ASCs. Specifically, CMS should consider including CDT D9420 on the ASC-CPL on an interim final basis. This interim solution provides a way to ensure that any patients whose dental treatment are eligible for coverage under the 2023 MPFS Final Rule and whose treatment cannot be performed safely without general anesthesia, can access needed dental treatment in a timely manner. This approach also provides CMS with the opportunity to further consider whether to add individual CDT procedures to the ASC-CPL to facilitate access to Medicare-certified ORs for patients whose dental treatment qualifies for coverage under the 2023 MPFS final rule.

Proposed Name Change and Start Date of Nominations Process

ASCA prefers the title "Nominations Process" to "Pre-Proposed Rule CPL Recommendation Process." CMS indicates that the current name "may suggest a formality or limitation that we did not intend – one that implies the nominations process is the preferred, primary, or only means by which interested parties may submit recommendations – we believe this proposed new name would not." However, ASCA does view this new process as the more legitimate and preferred process because it is the avenue through which CMS must show its work and respond to requests for additions to the ASC-CPL presented to the Agency.

Currently, CMS does not have 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 on what basis CMS chose to exclude the codes. In the 2022 rulemaking cycle, CMS indicated that if the Agency were to disagree with the addition of a nominated code, it would supply a rationale for exclusion in the final rule. As noted earlier, ASCA submitted 47 codes for consideration earlier this year but we have no idea whether the Agency considered any of those codes for addition. Transparency and a clear deadline for submission make this a better process for CMS, its stakeholders, and the public.

As we view the nomination process as the superior method through which CMS will collect potential codes for consideration for the ASC-CPL, we are extremely disappointed that the Agency intends to delay implementation until CY 2025 rulemaking. Until the new process is established, CMS should include language in the final rule indicating that if stakeholders submit codes to the email address referenced on the CMS website for ASC-CPL inquiries (ASCPPS@cms.hhs.gov) by March 1, 2023, the Agency will acknowledge and consider these codes in the CY 2024 rulemaking.

Proposed Changes for CY 2023 to Covered Surgical Procedures Designated as Office-Based

The office-based policies that CMS applies to ASCs shed light on how more holistic payment policy changes are urgently needed to save the Medicare program and its beneficiaries money. While we cannot argue with the fact that CPT 15275 now meets the criteria for being permanently office-based, as it is performed more than 50 percent of the time in physicians' offices, that policy is flawed because it only looks at ASC and physicians' office volume data.

Fee-for-service volume for CPT 15275 was 50,337 cases in physicians' offices in 2019 compared to only 3,258 cases in the ASC setting. However, the bulk of the volume for CPT 15275 remains in the most expensive setting, as it was performed 55,778[24] times on Medicare fee-for-service beneficiaries in HOPDs in 2019. If CMS really wants to serve as responsible stewards of public funds, it will look closer at ASC designated office-based procedures when those same procedures are performed in HOPDs and consider an office-based procedure policy that extends to the HOPD setting.

Staying with CPT 15275 as an example, CMS has identified this as a service "of a level of complexity consistent with other procedures performed routinely in physicians' offices." For 2023, the office-based rate – which ASCs would also receive – is set at $89.97. The 2022 reimbursement rate for ASCs is $886.26. No ASC will perform these procedures at 10 percent of the previous rate.

Conversely, the 2023 proposed reimbursement rate for CPT 15275 under the OPPS is $1761.64, $1,671.67 ***more than*** the physicians' office and ASC rate. Based on 2019 volume data, CMS will waste more than $93 million ***on this code alone*** by allowing an office-based procedure to be reimbursed at such exorbitant rates in the HOPD setting. CMS should take a more holistic approach to office-based codes, evaluating the volume across all three outpatient sites of service.

Device-Intensive ASC Covered Surgical Procedures

ASCA has been working with the Agency for years to address the device offset threshold and its impact on ASC volume, and we appreciate the Agency last year recognizing the key role that device costs can play in a facility's ability to perform these procedures. ASCA has long-requested that CMS determine the percentage that the device accounts for in the ASC setting to determine device-intensive status, and we are grateful that CMS agrees that this is a more appropriate calculation method.

CMS will accept external invoices for the device intensive assessment if there are no available claims data. This is particularly important for new procedure codes, and ASCA encourages CMS to reevaluate the device offsets for new procedures that were also deemed device-intensive to ensure adequate reimbursement which will allow for beneficiary access to the ASC setting.

In addition, 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 this is a logical extension of existing policy that can facilitate appropriate payment to ASCs.

[24] Definitive Healthcare (https://www.definitivehc.com/). Healthcare data analytics with all-claims data. (Accessed August 26, 2022).

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 a prominent 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 have been added to the ASC-CPL and more procedures have been identified as device-intensive. There are 158 codes on the 2023 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 ask that CMS also encourage Congress to create a co-pay cap for the ASC setting.

ASCA asks CMS to refrain from adjusting the device portion of payments by the 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. Rural communities have lower volumes, so they do not receive the discounts from vendors based on volume that hospitals or ASCs in larger communities may receive. The cost of delivery can also be greater which adds to the cost of accessing implants and devices.

One example of how significantly the wage index can affect device-intensive codes is for a cardiology code, CPT code 33240. The 2023 proposed national rate for 33240 is $22,908.80 and CMS estimates the device costs at $18,210.21. In rural Tennessee, where the local wage index is currently 0.7199, the 2023 proposed reimbursement rate for 33240 is $17,684.42, ***which is less than the device costs.*** This issue impacts all communities with a lower wage index and causes access issues for Medicare beneficiaries.

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 impacted codes include:

- 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

We strongly support the new complexity adjustment policy, which does not currently – but potentially could – help with situations like the above. We look forward to working with CMS to determine if there is a way to expand that policy to include the code combinations listed above in the future so that the ASC will be reimbursed fairly to offset the increased cost with the add-on codes that are performed in these cases.

Proposed ASC Payment for Combinations of Primary and Add-On Procedures Eligible for Complexity Adjustments under the OPPS

ASCA strongly supports this proposed policy and commends CMS for providing an opportunity for better access to Medicare beneficiaries and significant cost savings to the Medicare program. This proposed policy clearly advances CMS' strategic pillar to serve as a responsible steward of public funds and protect Medicare's sustainability for future generations.

As CMS notes in this rule, while add-on codes (N1) do not receive additional reimbursement (packaged into primary code), the addition of the add-on codes to a primary procedure code often changes the complexity of the procedure, making it more costly to perform. Under the OPPS, Medicare provides a "complexity adjustment," adjusting the payment rate for certain primary procedures to account for the cost of also performing certain add-on procedures.

Whereas CMS generally estimates that ASC services were paid approximately 55 percent of the HOPD rate for similar services in CY 2021, when comparing the HOPD complexity-adjusted payment rate of primary procedure and add-on code combinations to the ASC payment rate for the same code combinations, they found that the average rate of ASC payment as a percent of HOPD payment for these code combinations was only 25 to 35 percent. It is not economically viable for ASCs to perform these code combinations at such a deep discount from the OPPS rate.

In one example, the lack of reimbursement for fractional flow reserve and instantaneous wave-free ratio (FFR/iFR) with the primary diagnostic cardiac procedure inhibits physicians' ability to perform percutaneous coronary intervention (PCI) procedures in an ASC. FFR/iFR (CPT 93571 and 93572) is an important physiology tool that guides physicians' PCI treatment decisions. The use of FFR/iFR to diagnose and document ischemia is supported by the most recent Society of Cardiac Angiography and Interventions (SCAI)/American College of Cardiology (ACC)

Appropriate Use Criteria and is associated with improvements in quality of care and measurable Medicare cost savings.

Despite these benefits, physicians are disincentivized from performing FFR/iFR in an ASC since Medicare's packaged payment policy does not appropriately account for the cost of the FFR/iFR procedure and is significantly lower than the Medicare outpatient rate where payment for FFR/iFR is also packaged but a "complexity adjustment" is applied. The ASC payment rate when FFR/iFR is performed is currently three and a half times lower than the outpatient rate ($1,437.45 in the ASC and $5,061.89 in the HOPD). By finalizing the complexity adjustment proposal, Medicare will make it economically feasible for ASCs to perform these procedures, allowing for better access to care in the ASC setting.

CMS is proposing to assign each eligible code combination a new C code that describes the primary and the add-on procedure(s) performed. C codes are unique temporary codes and are only valid for claims for HOPD and ASC services and procedures. Under this proposal, CMS would add these C codes to the ASC-CPL. We have received questions as to which code combinations correspond to the proposed C codes. While we believe this information is the same as that in OPPS Addendum J, it is difficult to understand, particularly for those new to this policy. ASCA recommends that when finalizing this policy, CMS add a worksheet to the ASC payment rates addenda specifying which CPT codes are included in each C code.

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 worsened during 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 also reimburse for other peri-operative non-opioid pain management tools, such as pain blocks represented by CPT codes 64415, 64416, 64417, 64445, 64446, 64447, 64448, 64450, that decrease use of post-op opioids. 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. CMS could apply the same OPPS drug packaging threshold for consideration of these codes, which is proposed at $135. If applied to the codes above, 64415, 64416, 64417, 64446 and 64448 would be eligible for reimbursement, as they all have rates well above $135.

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.

Key Comments on ASC Quality and Proposed Reporting Program Changes

ASCA appreciates that the 2023 rule does not seek to add significant burden to our facilities and that CMS is interested in continuing to cultivate a quality reporting program that includes actionable measures to help facilities provide the highest quality of care for our patients.

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. The ASC QC will submit detailed comments on the aspects of the rule pertaining 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 strongly supports CMS' decision to delay mandatory reporting of ASC-11.

ASCA appreciates CMS' recognition that implementing *ASC-11 Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery* would represent an undue burden due to the continued impact of COVID-19 on facilities. However, we continue to assert that this measure would place an undue burden on our facilities regardless of the presence of a public health emergency (PHE) in this country.

This measure was developed, tested and previously endorsed by the National Quality Forum (NQF) as a clinician-level measure (NQF #1536), and was never intended to measure facility performance. In addition, the measure was retired and the endorsement for NQF #1536 was removed during the fall cycle 2017.[25] ASCA believes this was for good reason.

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.

[25] https://www.qualityforum.org/QPS/qpstool.aspx (accessed August 26, 2022).

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.[26] If CMS allows ASCs to conduct 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 Survey (OAS CAHPS).

ASCA supports CMS' decision to maintain ASC-11 as a voluntary measure. We once again make the request that it simply be removed from the dataset altogether as it is not actionable by the facility and is, therefore, of limited to no value to the patients served.

ASCA has significant concerns with ASC-20 and its implementation.

As ASCA feared, and raised concerns about in our 2022 proposed rule comments, *ASC-20: COVID-19 Vaccination Coverage Among HCP*, has placed a needless and time-consuming burden on our facilities. Last year we wrote that "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." One year later, the benefits are even less clear, while the burden has been made abundantly so. We have facilities who have indicated it took them upwards of 24 hours to get set up to begin entering data for this measure. That is multiple days' worth of work that could have been directed to patient care.

In the 2019 final rule, CMS removed *ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel*, a change ASCA strongly supported. The burden associated with *ASC-8* outweighed the benefit of its continued use in the program. The 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 (NSHN). 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.

Unfortunately, the implementation issues that existed in 2018 are still present today. NHSN does not have a phone number to call, so facilities must email a general inbox to try to receive assistance. ASCA staff were inundated with communications from panicked staff at facilities who either never received responses to their emails to NHSN or received canned replies that were unresponsive to their questions. There were staff members at the CDC who were helpful and responsive to ASCA staff, so when we reached out directly, we were often able to get ASCs

[26] https://mdinteractive.com/mips_quality_measure/2020-mips-quality-measure-303 (accessed September 13, 2022).

the assistance they needed that way. It is unclear, however, how many other ASCs were unable to report due to NHSN's unresponsiveness.

In addition to the lack of an adequate help desk, the CDC made the data collection and reporting itself more burdensome over the past year. While vendors were not included in the original reporting requirements, the CDC changed this mid-stream, requiring ASCs to collect the vaccination status of vendors within their facilities, ***regardless of whether those individuals were involved in direct patient care.*** The expanded requirements meant ASCs had to report on individuals like cleaning staff who arrive after hours and UPS drivers who are in the front of the facility for only a few minutes.

Then, when the CDC changed the definition of "up-to-date" for individuals over age 50 to require a second booster, but not individuals under 50, healthcare facilities had to start adding date of birth information when they collected data to ensure they had the right numbers for various personnel depending on their age. But CMS is not publicly reporting booster status at this time, so that data is being collected and must be reported to the CDC with no value to the public.

This measure is overly burdensome for our facilities and unnecessary from a public welfare perspective because CMS-certified ASCs must already comply with the requirement in the Code of Federal Regulations at § 416.51 that states "***Standard: COVID-19 vaccination of staff.*** The ASC must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19." There is a complete disconnect between what the CDC wants that data for – surveillance purposes – and the requirements under the ASCQR Program measure. We respectfully request that this measure be removed from the ASCQR Program.

In the absence of complete removal from the program, CMS should refrain from penalizing facilities who were unable to report data through the NHSN but were successful in reporting data on all other measures in the ASCQR Program. We have heard from facilities who had been reaching out to NHSN for months and were still unable to report. Those facilities should not be penalized.

Request for Comment: A Potential Future Specialty Centered Approach for the ASCQR Program

ASCA would like to see a more robust program with actionable facility measures. However, before we get into comments specifically speaking to the requests in the rule, we would like to point out that there are still measures that have been endorsed by the ASC community and tested in our space that have been ignored in recent years by CMS.

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

In the 2018 OPPS/ASC proposed rule, CMS proposed to adopt *ASC-16: Toxic Anterior Segment Syndrome (TASS)* for CY 2021 payment determination and subsequent years. This measure is maintained by the ASC QC, and as indicated in the 2018 proposed rule, it is an appropriate

measure for the ASCQR Program because ophthalmic procedures are commonly performed in ASCs and "the inflammatory response associated with TASS can cause serious damage to patients' vision, but TASS is also preventable through careful attention to solutions, medications, ophthalmic devices, and to cleaning and sterilization of surgical equipment." ASCA requests that CMS reconsider adding this measure.

CMS also solicited public comment on the Ambulatory Breast Procedure Surgical Site Infection (SSI) Outcome measure (NQF #3025) in the 2018 proposed rule, and ASCA supported this measure's inclusion in the ASCQR Program. Of the healthcare acquired infections, SSIs are those that are most applicable to the ASC setting and important for ASCs to 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.

Specialty-specific measure sets

ASCA has consistently pushed back against simply adding physician-level measures to the ASCQR Program and will continue to do so. If data is being collected by physicians for their quality reporting program, CMS should figure out a way to add a site of service modifier instead of requiring ASCs to collect data on the same exact measures.

If CMS intends to move forward on specialty-specific measure sets, the Agency will need to work very closely with the ASC QC and ASCA to ensure the measures are appropriate. On the list of gastroenterology measures CMS references as potentially suitable for the ASC setting, CMS includes Anastomotic Leak Intervention Outcome, which measures the "percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery." There are no gastric bypass or colectomy CPT codes on Medicare's ASC Covered Procedures list, and these procedures are not performed in high volume on non-Medicare patients, either. Therefore, this would not be a good measure for an ASC specialty-specific measure set.

Potential Future Reimplementation of ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC –7) Measure or Other Volume Indicator

In past rulemaking, CMS adopted *ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures* for inclusion in the ASCQR Program. After several years, the agency removed the measure, believing that outcome measures on specific types of procedures such as *ASC-17, ASC-18, and ASC-19,* which include hospital visits after orthopedic, urology and general ASC procedures, respectively, would provide patients with more valuable information as to the quality of care in the facility.

Volume data for *ASC-7* was collected and reported in six broad categories: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary services. The categories of services

CMS established were too large and diverse to provide meaningful consumer information. How would a consumer planning a corneal transplant determine if a facility performed a high or low volume of that operation by reviewing the data in the "Eye" category?

This is just one example to demonstrate that aggregate volume data from very broad procedure categories is not helpful. Even if more specificity is provided, however, we still do not believe there is meaningful consumer information to be derived from this type of data, nor do we think it advances quality of care. We do not support the reimplementation of *ASC-7* or similar volume measures, and would like to see CMS continue to focus on outcome measures.

Request for Comment: Interoperability Initiatives in ASCs

While we support the stated 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. 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, but we estimate that ***at most*** 50 percent of ASCs are using an EHR.[27]

Additionally, many of those ASCs with EHRs are likely using inpatient products that are ill-fitted to the operational needs of an ASC since there are no products certified by ONC specifically for the ASC setting. ASCs did not receive any federal funding for EHR adoption in the HITECH Act of 2009, and are not currently contemplated by federal efforts. As such, we 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 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 systems in ASCs, it is likely that a transition to Fast Healthcare Interoperability Resources (FHIR)-based quality reporting would be burdensome for many of the 6,088 CMS-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 ongoing working relationship with staff at ONC that can serve as a foundation for such stakeholder discussions.

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

Conclusion

In comments[28] celebrating the 57th anniversary of Medicare and Medicaid earlier this year, HHS Secretary Xavier Becerra said that CMS "will continue to strengthen and expand these programs to ensure all Americans – no matter who they are or where they live – have access to high-quality, affordable health care." In your comments, Administrator Brooks La-Sure, you reiterated that the "Biden-Harris Administration is committed to…expanding coverage, increasing access to care, and improving the quality of care that people receive." ASCA supports these stated goals but fear there are policies in this proposed rule that will foster the opposite result.

We appreciate the opportunity to provide feedback on the Agency's work and welcome the opportunity to collaborate with CMS on the recommendations in this comment letter that ensure our facilities can continue to provide outstanding care to Medicare beneficiaries at a lower cost to the Medicare program.

Please contact Kara Newbury at knewbury@ascassociation.org or (703) 836-8808 if you have any questions or need additional information.

Sincerely,

William Prentice
Chief Executive Officer

[28] https://www.hhs.gov/about/news/2022/07/30/statement-hhs-secretary-xavier-becerra-cms-administrator-chiquita-brooks-lasure-on-57th-anniversary-medicare-medicaid.html (accessed August 25, 2022).

Appendix A – Codes Requested for Addition to the ASC-CPL

CPT Codes	Short Descriptor	ASC	HOPD	Inpatient	Total	ASC %	HOPD %	Inpatient %
19307	Mast mod rad	444	11,419	1,174	13,037	3.4%	87.6%	9.0%
22630	Arthrd pst tq 1ntrspc lum	571	3,894	5,969	10,434	5.5%	37.3%	57.2%
22633	Arthrd cmbn 1ntrspc lumbar	2,334	15,813	40,309	58,456	4.0%	27.1%	69.0%
23472	Reconstruct shoulder joint	8,822	61,711	23,400	93,933	9.4%	65.7%	24.9%
27702	Reconstruct ankle joint	528	4,028	1,065	5,621	9.4%	71.7%	18.9%
37183	Remove hepatic shunt (tips)	0	854	393	1,247	0.0%	68.5%	31.5%
37191	Ins endovas vena cava filtr	63	4,614	13,541	18,218	0.3%	25.3%	74.3%
37192	Redo endovas vena cava filtr	0	22	13	35	0.0%	62.9%	37.1%
37193	Rem endovas vena cava filter	62	9,193	713	9,968	0.6%	92.2%	7.2%
38531	Open bx/exc inguinofem nodes	1,124	7,264	778	9,166	12.3%	79.2%	8.5%
43281	Lap paraesophag hern repair	3,865	17,678	15,747	37,290	10.4%	47.4%	42.2%
43282	Lap paraesoph her rpr w/mesh	360	10,351	3,307	14,018	2.6%	73.8%	23.6%
43774	Lap rmvl gastr adj all parts	501	5,077	1,823	7,401	6.8%	68.6%	24.6%
44180	Lap enterolysis	948	8,400	6,755	16,103	5.9%	52.2%	41.9%
44970	Laparoscopy appendectomy	2,598	151,351	38,349	192,298	1.4%	78.7%	19.9%
60252	Removal of thyroid	381	4,779	1,008	6,168	6.2%	77.5%	16.3%
60260	Repeat thyroid surgery	397	3,016	223	3,636	10.9%	82.9%	6.1%
60502	Re-explore parathyroids	51	1,248	83	1,382	3.7%	90.3%	6.0%
63040	Laminotomy single cervical	16	106	103	225	7.1%	47.1%	45.8%
63267	Excise intrspinl lesion lmbr	1,336	6,719	4,617	12,672	10.5%	53.0%	36.4%
92652	Aep thrshld est mlt freq i&r	420	16,592	900	17,912	2.3%	92.6%	5.0%
92924	Prq card angio/athrect 1 art	17	1,422	821	2,260	0.8%	62.9%	36.3%
92933	Prq card stent/ath/angio	122	6,208	6,869	13,199	0.9%	47.0%	52.0%
92960	Cardioversion electric ext	1,001	199,623	42,599	243,223	0.4%	82.1%	17.5%
92961	Cardioversion electric int	2	349	228	579	0.3%	60.3%	39.4%
93306	Tte w/doppler complete	39,159	3,775,944	1,586,208	5,401,311	0.7%	69.9%	29.4%
93312	Echo transesophageal	2,178	222,916	152,649	377,743	0.6%	59.0%	40.4%
93318	Echo transesophageal intraop	1	1,421	4,848	6,270	0.0%	22.7%	77.3%
93600	Bundle of his recording	0	690	378	1,068	0.0%	64.6%	35.4%
93602	Intra-atrial recording	2	384	218	604	0.3%	63.6%	36.1%
93603	Right ventricular recording	2	448	240	690	0.3%	64.9%	34.8%
93610	Intra-atrial pacing	2	305	182	489	0.4%	62.4%	37.2%
93612	Intraventricular pacing	2	400	442	844	0.2%	47.4%	52.4%
93615	Esophageal recording	0	243	43	286	0.0%	85.0%	15.0%
93616	Esophageal recording	0	87	77	164	0.0%	53.0%	47.0%
93618	Heart rhythm pacing	0	179	107	286	0.0%	62.6%	37.4%
93619	Electrophysiology evaluation	4	790	233	1,027	0.4%	76.9%	22.7%
93620	Electrophysiology evaluation	46	10,361	2,337	12,744	0.4%	81.3%	18.3%

CPT Codes	Short Descriptor	ASC	HOPD	Inpatient	Total	ASC %	HOPD %	Inpatient %
93624	Electrophysiologic study	0	116	98	214	0.0%	54.2%	45.8%
93642	Electrophysiology evaluation	19	724	218	961	2.0%	75.3%	22.7%
93650	Ablate heart dysrhythm focus	48	8,694	2,626	11,368	0.4%	76.5%	23.1%
93653	Compre ep eval tx svt	259	49,810	6,434	56,503	0.5%	88.2%	11.4%
93654	Compre ep eval tx vt	48	10,650	2,044	12,742	0.4%	83.6%	16.0%
93656	Compre ep eval abltj atr fib	455	90,865	5,203	96,523	0.5%	94.1%	5.4%
C9602	Perc d-e cor stent ather s	163	5,417	57	5,637	2.9%	96.1%	1.0%
C9604	Perc d-e cor revasc t cabg s	125	3,867	39	4,031	3.1%	95.9%	1.0%
C9607	Perc d-e cor revasc chro sin	21	3,294	27	3,342	0.6%	98.6%	0.8%

Definitive Healthcare (https://www.definitivehc.com/). Healthcare data analytics with all-claims data for 2021. (Last accessed August 26, 2022).

Appendix B – Total Shoulder and Ankle Research

Trends in outpatient vs inpatient TSA over time

Journal of Shoulder and Elbow Surgery (JSES)

Published: January 2022

Result: Authors found that 44.9 percent of outpatients in the late cohort (12,401 patients who underwent TSA between 2017 and 2019) were over 70. Overall the complication rate for outpatients in the late cohort was much lower (1.38 percent) than the inpatients (3.9 percent).

Comparison of outpatient vs. inpatient anatomic TSA

Journal of Shoulder and Elbow Surgery (JSES)

Published: January 2022

Conclusion: When compared with a propensity score–matched cohort of inpatient counterparts, the present study found outpatient anatomic TSA (aTSA) was associated with significantly reduced severe adverse events and similar readmission rates. These findings support the growing use of outpatient aTSA in appropriately selected patients.

COVID-19 as a Catalyst for Same-Day Discharge Total Shoulder Arthroplasty

Journal of Clinical Medicine

Published: December 2021

Result: Authors looked at TSA performed in two periods, before March 2020 and after May 2020. They found a higher rate of same-day discharge in the post-COVID era (87.3 percent vs 79.1 percent pre-COVID) and no change in 90-day readmission, reoperation, ED visits. "…outpatient shoulder arthroplasty is safe in not only selected patients, but in the majority of cases based on the findings of the current study."

The Safety of Outpatient Total Shoulder Arthroplasty

International Orthopedics

Published: January 2021

Conclusion: This study highlights that outpatient TSA could be a safe and effective alternative to inpatient TSA in appropriately selected patients. It was evident that outpatient TSA does not lead to increased readmissions, complications, or revision rates.

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.

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 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 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.

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:

	COMPARISON OF DATA BETWEEN LUMBAR INTER-BODY FUSIONS AT ASC-HWW AND SVI HOSPITAL									
	Age	BMI	ASA	Prior laminectomy at same site of this fusion	Adjacent level fusion	Intraoperative complications.	Transfusion	Estimated blood loss (cc)	Operative time in minutes	Length of stay in minutes
Legacy ASC HWW	73	28.1048	2.4	8	3	3	0	169	116	146
St Vincent Hospital	74.9	29.4304	2.6	12	5	3	0	127	139	1819

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

The ASA distribution of the two cohorts was similar: 2.4 (ASC-HWW) versus 2.6 (traditional hospital).

Operative Time

Operative time in both cohorts was less than 2.5 hours in all cases.

Intra-operative complications

The only complication intra-operatively in both groups was three incidental durotomies in both groups that was repaired at the time of surgery directly with suturing. None developed any post-operative complications nor impairment in outcomes. Length of stay from these durotomies was not affected in either group. The only difference in these patients was their drain was left in for five days and the drain was attached to a bile bag not a hemovac.

Prior surgery

Both groups had cases of prior surgery at the site of the current surgery and had prior adjacent level fusions.

Length of Stay

The average length of stay in minutes for the ASC-HWW group was 146 minutes or 2.4 hours. One patient in this cohort had a length of stay of 969 minutes (15 hours) and no patient stayed longer than this time. If this one 969 minute patient was removed from the average time then the cohort average would be 109 minutes or 1.8 hours. The average length of stay in the traditional hospital group was 1,770 minutes or 29.5 hours. This difference was over 10 times the length of stay for the traditional hospital group vs the ASC HWW**.**

	COMPARISON OF DATA BETWEEN LUMBAR INTER-BODY FUSIONS AT ASC-HWW AND SVI HOSPITAL											
	Post op er visits in 24 hours	Post op er visits in 7 days	Post op er visits in 30 days	Post op re-admit same facility in 24hours	Post op re-admit same in 7 days	Post op re-admit 30 days	Post o admit other hospital 24 hours	Post op admit other 7 days	Post op admit other 30 days	Re-operation at same site 24 hours`	Re-op same site 7 days	Re op same site 30 days
Legacy ASC HWW	0	2	1	0	0	1	0	0	1	0	0	1
St Vincent Hospital	0	1	0	0	0	0	0	1	0	0	0	0

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 OPPS/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 OPPS, 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 publication[17] 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 my 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, inclusions 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.

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REFERENCES

1. de Kunder SL, van Kuijk SM, Rijkers K, Caelers I, *et al*. Transforaminal lumbar interbody fusion (TLIF) versus posterior lumbar interbody fusion (PLIF) in lumbar spondylolisthesis: a systematic review and meta-analysis. 2017 *Spine J* 17:1712-1721

2. Liu J, Deng H, Long X, Chen X, *et al*. A comparative study of perioperative complications between transforaminal versus posterior lumbar interbody fusion in degenerative lumbar spondylolisthesis. 2016 *Eur Spine J* 25:1575-1580

3. Lee HJ, Kim JS, and Ryu KS. Minimally invasive TLIF using unilateral approach and single cage at single level in patients over 65. 2016 *Biomed Res Int* Article ID 4679865

4. Lan T, Hu SY, Zhang YT, Zheng YC, *et al*. Comparison between posterior lumbar interbody fusion and transforaminal lumbar interbody for the treatment of lumbar degenerative diseases: a systematic review and meta-analysis. 2018 *World Neurosurg* 112:86-93

5. Levin JM, Tanenbaum JE, Steinmetz MP, Mroz TE, *et al.* Posterolateral fusion (PLF) versus transforaminal lumbar interbody fusion (TLIF) for spondylolisthesis: a systematic review and meta-analysis. 2018 *Spine J* 18:1088-1098

6. Wong AP, Smith ZA, Nixon AT, Lawton CD, et al. Intraoperative and perioperative complications in minimally invasive transforaminal lumbar interbody fusion: a review of 513 patients. 2015 *J Neurosurg Spine* 22:487-495

7. Chin KR, Coombs AV, and Seale JA. Feasibility and Patient-Reported Outcomes After Outpatient Single-Level Instrumented Posterior Lumbar Interbody Fusion in a Surgery Center 2015 *Spine* 40(1):E36-42

8. Eckman WW, Hester L, and McMillen M. Same-day Discharge After Minimally Invasive Transforaminal Lumbar Interbody Fusion: A Series of 808 Cases 2014 *Clin Orthop Relat Res* 472(6):1806-1

9. Emami A, Faloon M, Issa K, Shafa E, *et al*. Minimally Invasive Transforaminal Lumbar Interbody Fusion in the Outpatient Setting 2016 *Orthopedics* 39(6):e1218-e1222

10. Chin KR, Pencle FJ, Coombs AV, Brown MD, *et al*. Lateral Lumbar Interbody Fusion in Ambulatory Surgery Centers: Patient Selection and Outcome Measures Compared With an Inhospital Cohort *Spine* 2016 41(8):686-692

11. Bovonratwet P, Ottesen TD, Gala RJ, Rubio DR, *et al*. Outpatient Elective Posterior Lumbar Fusions Appear to Be Safely Considered for Appropriately Selected Patients 2018 *Spine J* 18(7):1188-1196

12. Garcia RM, Khanna R, Dahdaleh NS, Cybulski G, *et al*. Thirty-Day Readmission Risk Factors Following Single-Level Transforaminal Lumbar Interbody Fusion (TLIF) for 4992 Patients From the ACS-NSQIP Database 2017 *Global Spine J* 7(3):220-226

13. Arshi A, Park HY, Blumstein GW, Wang C, *et al*. Outpatient Posterior Lumbar Fusion: A Population-Based Analysis of Trends and Complication Rates 2018 *Spine* 43(22):1559-1565

14. Katz AD, Mancini N, Karukonda T, Greenwood M, *et al*. Approach-based Comparative and Predictor Analysis of 30-day Readmission, Reoperation, and Morbidity in Patients Undergoing Lumbar Interbody Fusion Using the ACS-NSQIP Dataset. 2019 *Spine* 44(6):432-441

15. Hartman C, Hemphill C, Godzik J, Walker CT, *et al*. Analysis of Cost and 30-Day Outcomes in Single-Level Transforaminal Lumbar Interbody Fusion and Less Invasive, Stand-Alone Lateral Transpsoas Interbody Fusion 2019 *World Neurosurg* 122:e1037-e1040

16. Basques B, Ferguson J, Kunze K, Phillips F. Lumbar spinal fusion in the outpatient setting: an update on Management, surgical approaches and planning. J Spine Surg. 2019m Sept; 5(Suppl 2): Si74-S180

17. Jeffrey E Arle, Kimberly A Krugman, Diana L Abbott, Scott M Schlesinger. 30-day Outcomes from MIS-TLIF Patients in an ASC versus Hospital Setting.

18. CMS published information: “Calendar Year (CY) 2008 Revised Ambulatory Surgical Center (ASC) Payment System