

September 13, 2022

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1772-P
P.O. Box 8010
Baltimore, MD 21244-1850

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 (CMS-1772-P)

Dear Administrator Books-LaSure:

On behalf of the over 84,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2023 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule published in the *Federal Register* on July 26, 2022.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Since a large portion of surgical care is furnished in hospital outpatient departments (HOPDs) and ASCs, the College has a vested interest in CMS' coverage, reimbursement, and quality reporting requirements applicable to these settings. With our 100-year history in developing policy recommendations to optimize the delivery of surgical services, lower costs, improve program integrity, and make the U.S. healthcare system more effective and accessible, we believe that we can offer insight to the Agency's proposed modifications to the hospital outpatient and ASC payment systems for CY 2023. Our comments below are presented in the order in which they appear in the rule.

OPPS PAYMENT AND CHANGES FOR DEVICES, DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS

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Key Objectives/Roadmap for Consistent Treatment of Skin Substitutes

CMS proposes a change to the nomenclature of skin substitute products, effective January 1, 2024. Specifically, CMS proposes to change the terminology describing these products from "skin substitutes" to "wound care management products." In the CY 2023 Medicare Physician Fee Schedule (MPFS) proposed rule, CMS makes the same

nomenclature proposal, but additionally proposes significant changes to the reimbursement paradigm for skin substitutes in the physician office setting. The ACS provided extensive feedback on these proposals in response to the CY 2023 MPFS, but limit our comments herein to the terminology proposal in this rule.

CMS proposes the terminology change for skin substitutes because, in the Agency’s view, the term *skin substitutes* is so broad as to constitute a “misnomer.” However, the proposed terms *wound care management* and *wound care management products* fail to provide any additional specificity. First, the term *wound care management* does not describe a supply, but instead describes a service or procedure. Second, the term *wound care management product* suggests that skin substitutes could be the same as bandages, as these are also commonly used in and associated with wound care management. As CMS notes, skin substitutes are not themselves technically a substitute for skin, but they can stimulate the host to generate lost tissue through a variety of mechanisms of action—something a bandage or most dressings cannot do. Although CMS expressly acknowledges that skin substitutes are not bandages or wound dressings and believes that *wound care management* would not sweep in standard dressings, we are concerned that the proposed term would do exactly that: the sweeping term *wound care management products* functionally places these currently distinct families of products into the same definitional category. **The ACS urges CMS to maintain use of the term “skin substitutes” until such time that—if appropriate—clear and uniform coding and billing guidelines can be developed by the Current Procedural Terminology (CPT) Editorial Panel.**

PROPOSED OPPTS AMBULATORY PAYMENT CLASSIFICATION (APC) GROUP POLICIES

Proposed OPPTS Treatment of New and Revised HCPCS Codes

CMS proposed APC, relative weight, and payment rate assignments for a set of eight new anterior abdominal hernia repair codes that are not included on the Inpatient Only (IPO) list. The prior CPT codeset for reporting these anterior abdominal hernia repair operations included separate codes for procedures performed via an open approach versus a laparoscopic approach. In addition, some of these codes included placement of mesh as inherent, and others allowed for placement of mesh to be separately reported.

The CY 2022 APC, relative weight, and payment rate for the CPT codes that will be deleted for CY 2023 are provided in Table 1 below. The highlighted rows indicate services that have historically had different APCs based on the typical resources used.

Table 1: Addendum B – CY 2022 APC Assignments

CPT Code	Descriptor	APC	Relative Weight	Payment Rate
49560	Repair initial incisional or ventral hernia; reducible	5341	38.6014	\$3,249.35
49561	Repair initial incisional or ventral hernia; incarcerated or strangulated	5341	38.6014	\$3,249.35
49565	Repair recurrent incisional or ventral hernia; reducible	5361	61.3908	\$5,167.69

Table 1: Addendum B – CY 2022 APC Assignments

CPT Code	Descriptor	APC	Relative Weight	Payment Rate
49566	Repair recurrent incisional or ventral hernia; incarcerated or strangulated	5361	61.3908	\$5,167.69
49570	Repair epigastric hernia (eg, preperitoneal fat); reducible (separate procedure)	5341	38.6014	\$3,249.35
49572	Repair epigastric hernia (eg, preperitoneal fat); incarcerated or strangulated	5341	38.6014	\$3,249.35
49580	Repair umbilical hernia, younger than age 5 years; reducible	5341	38.6014	\$3,249.35
49582	Repair umbilical hernia, younger than age 5 years; incarcerated or strangulated	5341	38.6014	\$3,249.35
49585	Repair umbilical hernia, age 5 years or older; reducible	5341	38.6014	\$3,249.35
49587	Repair umbilical hernia, age 5 years or older; incarcerated or strangulated	5341	38.6014	\$3,249.35
49590	Repair spigelian hernia	5341	38.6014	\$3,249.35
49652	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); reducible	5361	61.3908	\$5,167.69
49653	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated	5361	61.3908	\$5,167.69
49654	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible	5362	108.0635	\$9,096.46
49655	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	5362	108.0635	\$9,096.46
49656	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); reducible	5362	108.0635	\$9,096.46
49657	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	5362	108.0635	\$9,096.46

For CY 2023, CMS proposes the identical APC, relative weight, and payment rate for all new anterior abdominal hernia repair codes that are not on the IPO list, as shown in Table 2 below. Based on historical APC assignment for these procedures, APC 5341 assumes that all of these new codes will be performed via an open approach and not require placement of mesh.

Table 2: Addendum B – Proposed CY 2023 APC Assignments

CPT Code	Descriptor	APC	Relative Weight	Payment Rate
49X01	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial including placement of mesh or other prosthesis, when performed total length of defect(s); less than 3 cm, reducible	5341	37.2839	\$3,235.68
49X02	less than 3 cm, incarcerated or strangulated	5341	37.2839	\$3,235.68
49X03	3 cm to 10 cm, reducible	5341	37.2839	\$3,235.68
49X04	3 cm to 10 cm, incarcerated or strangulated	5341	37.2839	\$3,235.68
49X05	greater than 10 cm, reducible	5341	37.2839	\$3,235.68

Table 2: Addendum B – Proposed CY 2023 APC Assignments

CPT Code	Descriptor	APC	Relative Weight	Payment Rate
49X07	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed total length of defect(s); less than 3 cm, reducible	5341	37.2839	\$3,235.68
49X08	less than 3 cm, incarcerated or strangulated	5341	37.2839	\$3,235.68
49X09	3 cm to 10 cm, reducible	5341	37.2839	\$3,235.68

We do not agree with the proposed CY 2023 APC assignments for this set of codes.

The typical patient as described in the physician work summary of recommendation forms submitted to CMS for the CY 2023 MPFS clearly differentiate the procedures that typically will be performed via an open approach versus a laparoscopic approach. This is based on the estimated distribution of the prior codes to the new codes and current practice standards. The new codes will also include placement of mesh or other prosthesis as typical, which adds to the cost of the procedure.

APC 5341 had previously been assigned to codes that were performed via an open approach. In addition, the codes assigned to APC 5341 did not include mesh placement, as that work was separately reported with a different CPT code. APC 5362 was assigned to laparoscopic codes including inherent mesh placement that was not separately reportable. APC 5361 was assigned to codes that had variation in approach and use of mesh. Moving forward, all new anterior abdominal hernia repair codes include placement of mesh or other prosthesis as typical, but not all new codes will typically be performed via a laparoscopic approach. As previously noted, the typical patient description for each procedure code was provided to CMS in support of the physician work and time recommendations—this information clearly identified whether a new code would typically be performed via an open approach or a laparoscopic approach.

None of the new anterior abdominal hernia repair codes would typically be performed via an open approach without placement of mesh. **As such, APC 5341 does not apply to any of these new codes (i.e., open approach with no mesh).** CPT codes 49X01 and 49X02 will typically require placement of mesh and will typically be performed via an open approach. **Therefore, APC 5361 would apply and is appropriate for these services (i.e., open approach with mesh).** CPT codes 49X03, 49X04, 49X05, 49X07, 49X08, and 49X09 will typically require placement of mesh and will typically be performed via a laparoscopic approach. **Therefore, APC 5362 would apply and is appropriate for these services (i.e., laparoscopic approach with mesh).**

We understand that annual cost data will inform future decisions about APC assignment. **However, in the interim, we urge CMS to adopt the ACS’ recommendations for APC assignments presented in Table 3 below.** It would be disingenuous for the Agency to assign an APC consistent with an open procedure not requiring mesh to any of the new anterior abdominal hernia repair codes listed in this table.

Table 3: ACS APC Recommendations for CY 2023

CPT Code	Descriptor	APC	Relative Weight	Payment Rate
49X01	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial including placement of mesh or other prosthesis, when performed total length of defect(s); less than 3 cm, reducible	5361	61.3908	\$5,167.69
49X02	less than 3 cm, incarcerated or strangulated	5361	61.3908	\$5,167.69
49X03	3 cm to 10 cm, reducible	5362	108.0635	\$9,096.46
49X04	3 cm to 10 cm, incarcerated or strangulated	5362	108.0635	\$9,096.46
49X05	greater than 10 cm, reducible	5362	108.0635	\$9,096.46
49X07	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed total length of defect(s); less than 3 cm, reducible	5362	108.0635	\$9,096.46
49X08	less than 3 cm, incarcerated or strangulated	5362	108.0635	\$9,096.46
49X09	3 cm to 10 cm, reducible	5362	108.0635	\$9,096.46

PROPOSED SERVICES THAT WILL BE PAID ONLY AS INPATIENT SERVICES

Proposed Changes to the Inpatient Only List

For CY 2023, CMS will continue to apply its policy making considerations on a case-by-case basis to determine whether the codified criteria suggest that a procedure should be removed from the IPO list. **The ACS appreciates that CMS will continue its CY 2022 policy and that the Agency did not return to its proposal to eliminate the IPO list.** We continue to believe that CMS will find great value in coordinating with the surgical community to identify which specific procedures on the existing IPO list may be safely provided in an outpatient setting. We agree with CMS’ approach and pledge to continue to respond to proposals to amend the IPO list to ensure the Agency has access to the valuable clinical input that the surgical community can provide on these issues.

CPT Code 16036

For CY 2023, CMS proposes to remove CPT code 16036 (*Escharotomy; each additional incision (list separately in addition to code for primary procedure)*) from the IPO list. The Agency notes that, based on a review of the clinical characteristics of the service described by CPT code 16036, this procedure meets IPO list removal criteria because the simplest procedure described by this code may be performed in most outpatient departments and is related to codes that CMS has already removed from the IPO list. CPT code 16036 is an add-on code that is typically billed with primary procedure CPT code 16035 (*Escharotomy; initial incision*), which was removed from the IPO list in CY 2007. For CY 2023, CMS proposes to assign CPT code 16036 to status indicator “N.” The Agency is seeking public comment on their conclusion that the service described by CPT code 16036 meets criteria for removal from the IPO list, along with its proposal to assign this service to status indicator “N” for CY 2023.

CPT code 16036 is an urgent surgical procedure that involves incising through areas of burnt skin to release the eschar and its constrictive effects, restore distal circulation, and allow adequate ventilation. **This procedure is typically provided in the operating room, but can also be provided in the emergency department if required—it would never be performed in an ASC and is not widely performed in numerous hospitals on an outpatient basis.** We note that for 2020, 84% of Medicare claims for this service had inpatient hospital status. Another 8% of claims for this service were outpatient, which could represent patients undergoing emergency treatment at a hospital who are then sent to an outpatient burn center after stabilization.

Although CMS finalized removal of CPT code 16035 from the IPO list for CY 2007, it recognized that CPT code 16036 represented a patient with multiple burns requiring significantly more care. We are concerned that general practitioners are submitting claims for CPT codes 16035 and 16036 in non-facility settings (e.g., home or assisted living), and note that there are two general practitioners that make up almost all of such claims. **This clear miscoding can result in a false impression that these services can safely be performed in an outpatient or non-facility setting and should therefore be removed from the IPO list. Based on the above information, we recommend maintaining CPT code 16036 on IPO list, along with its status indicator “C,” for CY 2023.**

CY 2023 IPO List Proposals

CMS proposes to add eight procedure codes to the IPO list. Of those, one code describes implantation of mesh for delayed closure of a large defect, and six codes describe anterior abdominal hernia repair newly established for CPT 2023. These include:

- **CPT 157X1** (*Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (ie, external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma*)
- **CPT 49X06** (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated*)
- **CPT 49X10** (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated*)
- **CPT 49X11** (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible*)
- **CPT 49X12** (*Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated*)
- **CPT 49X13** (*Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; reducible*)

- **CPT 49X14** (*Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; incarcerated or strangulated*)

Given the IPO list-related history of anterior abdominal hernia repair codes prior to the development of new codes for CY 2023, and in light of the clinical characteristics of such procedures, the ACS supports CMS' proposal to add these six new anterior abdominal hernia repair codes to the IPO list for CY 2023. Furthermore, the patient undergoing the procedure described by CPT code 157X1 will have been admitted to the hospital due to soft tissue infection or trauma and this procedure will assist with closure of large defect. **Therefore, we agree that CPT code 157X1 should be added to the IPO list.**

NONRECURRING POLICY CHANGES

Direct Supervision of Certain Cardiac and Pulmonary Rehabilitation Services by Interactive Communications Technology

CMS finalized a policy on an interim basis during the COVID-19 public health emergency (PHE) to allow for direct supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services to be provided using interactive audio and video technology. This direct supervision requirement could be met by the supervising physician being immediately available to observe in real-time via audio/video communications technology throughout the performance of the procedure. This year, CMS is seeking input on whether to allow direct physician supervision of these services to include presence of the supervising practitioner physician via two-way, audio/video communication technology through the end of CY 2023. In addition, the Agency asks whether stakeholders believe there are safety or quality of care concerns if the Agency were to adopt this policy beyond the PHE.

The ACS supports direct supervision using audio/video technology as a provisional policy effective for the duration of the PHE to reduce exposure risks associated with the COVID-19 pandemic. However, upon termination of the PHE, we oppose continued use of audio/video technology to provide direct supervision due to patient safety concerns. For instance, in complex, high-risk surgical, interventional, endoscopic, or anesthesia procedures, a patient's health status can quickly change, and we believe it is necessary for such services to be furnished or supervised **in person** to allow for rapid on-site decision-making in the event of an adverse clinical situation. It may not be possible for a supervising physician to recognize or meet these urgent clinical needs while being present for the service, and potentially other services at the same time, only through audio/video interactive communications technology.

We urge CMS to first consider additional guardrails to ensure patient safety/clinical appropriateness beyond typical clinical standards, as well as restrictions to prevent fraud or inappropriate use, before proceeding with any virtual supervision policies outside of the PHE. For example, we urge the Agency to limit the number of clinicians a supervising physician may simultaneously engage with—as well as the number of

incident-to relationships a supervising physician may be involved in at a given time—via audio/video technology.

PROPOSED UPDATES TO THE AMBULATORY SURGICAL CENTER PAYMENT SYSTEM

Proposed ASC Treatment of New and Revised Codes

CMS is soliciting public comments on proposed payment indicators for new CPT Category I and III codes that will be effective January 1, 2023. The CY 2022 payment indicators, payment weights, and payment rates for the anterior abdominal hernia repair CPT codes that will be deleted for CY 2023 are provided in Table 4 below. The highlighted rows indicate services that have historically had different payment weights based on the typical resources used.

Table 4: Addendum AA – CY 2022

CPT Code	Descriptor	2022 Payment Indicator	2022 Payment Weight	2022 Payment Rate
49560	Repair initial incisional or ventral hernia; reducible	A2	29.2568	\$1,465.12
49561	Repair initial incisional or ventral hernia; incarcerated or strangulated	A2	29.2568	\$1,465.12
49565	Repair recurrent incisional or ventral hernia; reducible	A2	47.8062	\$2,394.04
49566	Repair recurrent incisional or ventral hernia; incarcerated or strangulated	A2	47.8062	\$2,394.04
49570	Repair epigastric hernia (eg, preperitoneal fat); reducible (separate procedure)	A2	29.2568	\$1,465.12
49572	Repair epigastric hernia (eg, preperitoneal fat); incarcerated or strangulated	A2	29.2568	\$1,465.12
49580	Repair umbilical hernia, younger than age 5 years; reducible	A2	29.2568	\$1,465.12
49582	Repair umbilical hernia, younger than age 5 years; incarcerated or strangulated	A2	29.2568	\$1,465.12
49585	Repair umbilical hernia, age 5 years or older; reducible	A2	29.2568	\$1,465.12
49587	Repair umbilical hernia, age 5 years or older; incarcerated or strangulated	A2	29.2568	\$1,465.12
49590	Repair spigelian hernia	A2	29.2568	\$1,465.12
49652	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); reducible	G2	47.8062	\$2,394.04
49653	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated	G2	47.8062	\$2,394.04
49654	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible	G2	78.7902	\$3,945.66
49655	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	G2	78.7902	\$3,945.66

Table 4: Addendum AA – CY 2022

CPT Code	Descriptor	2022 Payment Indicator	2022 Payment Weight	2022 Payment Rate
49656	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); reducible	G2	78.7902	\$3,945.66
49657	Laparoscopy, surgical, repair, recurrent incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated	G2	78.7902	\$3,945.66

For CY 2023, CMS proposes the identical payment weight of 28.7365 for all new anterior abdominal hernia repair CPT codes that are not on the IPO list, as shown in Table 5 below. Based on historical payment weight assignment, this assumes that all of the new codes will be performed via an open approach and not require placement of mesh. **We disagree with this assignment, as it does not account for the historical differential for codes typically performed via a laparoscopic approach and/or for placement of mesh.**

Table 5: Addendum B – Proposed for CY 2023

CPT Code	Descriptor	Proposed Payment Indicator	Proposed Payment Weight	Proposed Payment Rate
49X01	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial including placement of mesh or other prosthesis, when performed total length of defect(s); less than 3 cm, reducible	G2	28.7365	\$1,474.61
49X02	less than 3 cm, incarcerated or strangulated	G2	28.7365	\$1,474.61
49X03	3 cm to 10 cm, reducible	G2	28.7365	\$1,474.61
49X04	3 cm to 10 cm, incarcerated or strangulated	G2	28.7365	\$1,474.61
49X05	greater than 10 cm, reducible	G2	28.7365	\$1,474.61
49X07	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed total length of defect(s); less than 3 cm, reducible	G2	28.7365	\$1,474.61
49X08	less than 3 cm, incarcerated or strangulated	G2	28.7365	\$1,474.61
49X09	3 cm to 10 cm, reducible	G2	28.7365	\$1,474.61

The typical patient, as described in the physician work summary of recommendation forms submitted to CMS for the CY 2023 MPFS, clearly identifies the procedures that typically will be performed via an open approach versus a laparoscopic approach. This is based on the estimated distribution of the prior codes to the new codes and current practice standards. The new codes will also include placement of mesh or other prosthesis as typical, which adds to the cost of the procedure.

CPT codes 49X01 and 49X02 will typically be performed via an open approach and will typically require placement of mesh. Therefore, although the payment weight of 28.7365 appears accurate with respect to approach, it fails to recognize the placement of mesh or other prosthesis, and there is no allowance for an ASC device offset. **CPT codes 49X03, 49X04, 49X05, 49X07, 49X08, and 49X09 will typically be performed via a laparoscopic approach and typically require placement of mesh. Therefore, the relative weight should be 48.4566, which is the same as other laparoscopic procedures (e.g., CPT codes 47562-47564).**

We understand that annual cost data will inform future decisions about payment weight assignment. **However, in the interim, we urge CMS to adopt the ACS' recommendations for payment weight assignments presented in Table 6 below.** It would be disingenuous to assign a payment weight consistent with an open procedure not requiring mesh for all of the new anterior abdominal hernia repair codes.

Table 6: ACS Payment Weight Recommendations for CY 2023

CPT Code	Descriptor	Recommended Payment Indicator	Recommended Payment Weight	Recommended Payment Rate
49X01	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), initial including placement of mesh or other prosthesis, when performed total length of defect(s); less than 3 cm, reducible	G2	28.7365	\$1,474.61
49X02	less than 3 cm, incarcerated or strangulated	G2	28.7365	\$1,474.61
49X03	3 cm to 10 cm, reducible	G2	48.4566	\$2,486.55
49X04	3 cm to 10 cm, incarcerated or strangulated	G2	48.4566	\$2,486.55
49X05	greater than 10 cm, reducible	G2	48.4566	\$2,486.55
49X07	Repair of anterior abdominal hernia(s) (ie, epigastric, incisional, ventral, umbilical, spigelian), any approach (ie, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis, when performed total length of defect(s); less than 3 cm, reducible	G2	48.4566	\$2,486.55
49X08	less than 3 cm, incarcerated or strangulated	G2	48.4566	\$2,486.55
49X09	3 cm to 10 cm, reducible	G2	48.4566	\$2,486.55

ASC Payment System Policy for Non-Opioid Pain Management Drugs and Biologicals that Function as Surgical Supplies

CMS is required by section 1833(t)(22)(A)(i) of the Social Security Act to review payments under the OPSS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. In the CY 2019 OPSS/ASC rule, CMS

reported findings from its analysis of utilization patterns for drugs that function as a surgical supply—specifically, Exparel[®]—in HOPDs and ASCs to determine whether the Agency’s packaged payment policy affected the use of this drug. CMS asserted that, if this policy discouraged the use of or impeded access to Exparel[®], it would expect to see a significant decline in the utilization of the drug over time. The Agency stated that it had observed such a decrease in Exparel[®] use in the ASC setting after the drug’s pass-through payment status expired in 2014 but did not observe a similar decrease in the HOPD setting. CMS therefore finalized a provision to unpack and pay separately for the cost of Exparel[®] in ASCs for CY 2019. The Agency did not make any changes to its payments for non-opioid drugs in the HOPD setting. In the CY 2020 OPPS/ASC rule, CMS reported findings from a second review of utilization patterns for drugs that function as a surgical supply in HOPDs and ASCs, and indicated that such review did not produce compelling evidence to suggest that revisions to OPPS payment policies for non-opioid alternatives are necessary.¹

In CY 2022, CMS stated that it has not found conclusive evidence to support the notion that the OPPS packaging policy, under which non-opioid drugs and biologicals are packaged when they function as a supply in a surgical procedure, has created financial incentives to use opioids instead of evidence-based non-opioid alternatives for pain management. Therefore, CMS continued its policy to pay separately for non-opioid pain management drugs that function as surgical supplies in the ASC setting, but continue packaging in the HOPD setting.

For CY 2023, CMS proposes to continue paying separately for non-opioid pain management drugs that function as surgical supplies in the ASC setting, but continue packaging in the HOPD setting. In addition, the Agency proposes to codify two additional technical criteria for separate payment for non-opioid pain management drugs and biologicals that function as surgical supplies. First, CMS proposes to provide that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if the drug or biological does not have transitional pass-through payment status. Second, CMS proposes that the drug or biological must not already otherwise be separately payable under the OPPS or ASC payment systems.

CMS states the products described by Healthcare Common Procedure Code System (HCPCS) codes C9290 (*Injection, bupivacaine liposome, 1 mg*) (i.e., Exparel[®]), J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*) (i.e., Omidria), and C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*) continue to meet the required criteria and should receive separate payment in the ASC setting. However, CMS states that, under the newly proposed criterion, the product described by HCPCS code C9088 (*Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg*) (i.e., Zyenrelief) would not receive separate payment in the ASC setting under this policy, as it will be separately payable during CY 2023 under OPPS transitional pass-through status. Finally, the Agency proposes that HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*) (i.e., Dextenza) be eligible under this policy to receive separate payment for CY 2023.

¹ 84 F.R. 61176-61180

The misuse and abuse of prescription opioids has increased dramatically over the last decade, and the ACS appreciates CMS' efforts to identify and eliminate regulatory obstacles that inhibit utilization of non-opioid alternatives for pain management, including those obstacles related to coverage and reimbursement. **We remain supportive of the Agency's proposal to continue to unpackage and pay separately for non-opioid postoperative pain management medications that function as surgical supplies when furnished in ASCs; however, we continue to urge CMS to expand this policy and allow for unpackaging of non-opioid postoperative pain management medications in all care settings where surgery is performed.** These therapies are often cost-prohibitive for facilities under current Medicare policy because the fees associated with the provision of non-opioid medications—which may be significantly more expensive than opioid therapy—are bundled into the overall payment for “supplies” related to surgical procedures, such that a non-opioid medication is paid at the same fixed Medicare rate as an opioid for postoperative pain management, regardless of the difference in the cost of the two drugs.

Additionally, we continue to believe the Agency's current method to evaluate utilization of non-opioid alternatives—under which CMS reviews Medicare claims data for certain drugs before and after their pass-through status expired—is too narrow and excludes other factors that may be stronger indicators of the accessibility and use of opioid-sparing therapies by physicians and facilities. We thereby encourage the Agency to investigate other barriers to access to non-opioid postsurgical pain management alternatives beyond pass-through payment status. The ACS suggests that CMS create a new CPT code or modify existing codes to account for the work associated with opioid-sparing therapies furnished by surgeons, which we believe would provide the Agency with reliable claims-based data for a more extensive group of surgeon-administered non-opioid alternatives—including neural blockades and intravenous acetaminophen, among others—and enable CMS to better track utilization and identify access barriers via Medicare billing trends.

REQUIREMENTS FOR THE HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM (OQR)

Request for Comment on Reimplementation of Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) Measure or Adoption of Another Volume Indicator

For the 2012 OQR reporting year, CMS adopted the *Hospital Outpatient Volume on Selected Outpatient Surgical Procedures* measure (OP-26). The structural measure collected surgical procedure volume data on eight categories of procedures frequently performed in the hospital outpatient setting: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin. However, CMS removed the measure in the CY 2018 OP/ASC final rule, citing a lack of evidence to support the measure's link to improved clinical quality. Since the removal of this measure, no volume measures have been included in the OQR program. In this request for comment, CMS describes the gradual shift from inpatient to outpatient settings—based on a 2021 Medicare Payment Advisory Commission (MEDPAC) report to Congress, outpatient services have increased by 0.7 percent while inpatient services

decreased by 0.9 percent.² Due to the migration of procedures from the inpatient setting to the outpatient setting, CMS seeks comment on the potential inclusion of a volume measure in the Hospital OQR Program, either by re-adopting the *Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26)* measure or adopting another volume indicator. CMS also seeks comment on what volume data hospitals currently collect and if it is feasible to submit these data to the Hospital OQR Program, to minimize the collection and reporting burden of an alternative, new volume measure.

The ACS does not support the use of volume measures in the OQR program as described. Measuring procedure volume does not reliably predict high quality care and is, therefore, an outdated proxy—essentially, this is a step backwards in the identification of high-quality care. Merely reporting volume without context could create an unintentional misdirection for patients and other end users. Contextualizing information in a value expression requires more than a factual report of volume. It requires understanding the clinical appropriateness of the procedure for each specific patient, the risk profile for the volume of patients, their observed to expected safety report for preventable harms, and the overall outcomes that meet patient expectations. Without a proper framework, the use of volume may lead to information that could impact patient trust, especially to the most vulnerable in high-risk public hospitals or rural care where access and choice are the first order of quality to be addressed. This may also create perverse incentives to increase volume. Measuring volume in the absence of quality (or as a proxy) is a mixed signal as the nation transitions to appreciating value-driven care and moves away from volume-driven care.

This is supported by the following points:

- **Quality measurement systems at the surgeon-specific level remain underdeveloped, especially for uncommon complex procedures. It is difficult to determine a volume threshold that indicates high quality with meaningful statistical power at the individual clinician level, and the volume threshold will typically differ from procedure to procedure.** In fact, achieving reliability at the hospital level is often not accomplished for some procedures. A minimal case number threshold for the required experience of rarely performed operations or those performed for rare diseases is likely impossible to define or be meaningful.³
- **The ACS Statement on Credentialing and Privileging and Volume Performance Issues notes for some complex procedures, high case volume could be associated with improvement in surgical outcomes, however, “these outcomes may reflect not only the knowledge, experience, and skill of the individual surgeon, but also the aggregate ability of the institution and hospital staff to provide high-quality care for specific groups of patients.”**⁴ It is also well documented that some surgeons performing a relatively low volume of these

² Medicare Payment Advisory Commission. (2021). *Report to the Congress: Medicare payment policy*. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf

³ The American College of Surgeons. (2018, April 1). *Statement on credentialing and privileging and volume performance issues*. <https://www.facs.org/about-ac/s/statements/credentialing-and-privileging-and-volume-performance-issues/>

⁴ The American College of Surgeons. (2018, April 1). *Statement on credentialing and privileging and volume performance issues*. <https://www.facs.org/about-ac/s/statements/credentialing-and-privileging-and-volume-performance-issues/>

procedures also achieve excellent outcomes.

- From our work running verification and accreditation programs, we know that using standards of care established as part of a quality program will align facility and providers for continuous, reliable, and standardized care. In other words, it takes much more than just a single surgeon's volume of cases to determine optimal outcomes. If the goal is to move to value-based healthcare, the delivery of care must be reframed from focusing on volume as its key, fiscal, sustainable objective. This means reorienting and restructuring the design and organization of care. In addition to good outcomes, adhering to clinical protocols, having the correct personnel and equipment, and adequate organization are good indicators of quality. It is for these reasons the ACS advocates for implementing full quality programs organized around the patient for the delivery of optimal care.

To this end, publicly reporting volume data will be misleading and confusing to patients who are using the CMS Care Compare website to determine where they will receive the best care. It is not appropriate to assume that performing a high case volume of certain procedures always equates to better outcomes, especially when considering data integrity issues outlined above. It is important to understand volume, patient risk profiles, price, and quality collectively to make an informed decision. An example from ACS Thrive, Figure 1 titled *Contextualizing Volume to Support Understanding Value* (page 35), displays the connections between quality, price, and volume that are necessary to provide context and understanding of the true value of care. ACS Thrive is a pilot project that defines an episode of surgical care, in this instance colectomy for cancer, and portrays the quality and price—based on Medicare FFS patients.⁵ The figure provides (1) the payer mix; (2) a volume and price graphic for the region (hospital referral regions [HRR]); and (3) the mean price for Medicare patients and the Medicare Hierarchical Condition Categories (HCC) risk stratification for the types of patients undergoing care at this facility.

In conclusion, the ACS does not support volume as a proxy for value without being more informed by these other parameters. The reframing of healthcare must realize a patient-centered, market mindset branded by value.

Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs

CMS points readers to the Request for Information (RFI) included in the Fiscal Year (FY) 2023 Hospital Inpatient Prospective Payment System/Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) proposed rule titled “*Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs*,” which describes key considerations that CMS might take into account across all CMS quality programs, including the Hospital OQR Program, when advancing for the use of measure stratification to address healthcare disparities and advance health equity. CMS asks for comment and feedback on how these principles would apply to the Hospital OQR Program.

⁵ American College of Surgeons. (n.d.). *Transforming healthcare resources to increase value and efficiency: ACS Thrive*. <https://www.facs.org/quality-programs/standards-and-staging/acs-thrive/>

It is well established that social determinants of health (SDOH) impact quality of care. Patients with certain social risk factors may experience lack of access to healthcare services, limits on resources, lack of preventative care, poor early detection, and limited chronic care maintenance, which can contribute to care inequities, and ultimately result in worse overall outcomes in surgical care. In recent years, CMS has highlighted its commitment to achieving equity in healthcare outcomes for beneficiaries and outlines various efforts, such as implementing the CMS Disparity Methods for confidential reporting of stratified data. The Agency plans to do this by supporting healthcare providers' quality improvement (QI) activities to reduce health disparities, enabling beneficiaries to make informed decisions, and promoting healthcare provider accountability for healthcare disparities.⁶ To achieve this, CMS believes it is important to consistently measure differences in care received across diverse groups of beneficiaries. This includes examining the possibility of reporting disparities in care based on additional social risk factors and demographic variables associated with historic disadvantage in the healthcare system, and examining these data using stratified healthcare quality measures across a variety of care settings.

CMS expresses interest in continuing to evaluate opportunities to expand its measure stratification reporting initiatives using existing sources of data with the goal of providing comprehensive and actionable information on health disparities to support QI efforts. As the Agency works to advance the use of measurement and stratification tools to address disparities and advance equity in healthcare, it asks for stakeholder input on five specific areas to inform their approach:

- Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Programs
- Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting Across CMS Quality Reporting Programs
- Principles for Social Risk Factor and Demographic Data Selection and Use
- Identification of Meaningful Performance Differences
- Guiding Principles for Reporting Disparity Results

The ACS commends CMS for its continued commitment to closing the health equity gap and agrees that creating goals and principles to guide these efforts is essential. As the ACS, we witness the many dimensions of inequities in surgical care and seek to use all our resources to help the nation overcome the barriers created by inequities. Our comments below reiterate our FY 2023 IPPS/LTCH proposed rule comments submitted in response to this RFI. The principles and suggestions we outline in the following comments are applicable across all care settings.

Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Programs

CMS discusses how it has focused on illuminating healthcare disparities by reporting stratified results of existing quality measures by dual eligible status in two complimentary

⁶ Centers for Medicare & Medicaid Services. (2022). *CMS National Quality Strategy*. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>

ways—the “within-provider” disparity method and the “across-provider” disparity method.

- **“Within-Provider” Disparity Method:** This method identifies disparities, or gaps in care or outcomes between patient, payer-class groups (such as dual eligible or non-dual eligible groups) at a hospital. After stratification by dual eligible status, measure results for subgroups of patients served by an individual healthcare provider can be directly compared. This method can be used for most measures that include patient-level data for most care settings and, according to CMS, is a helpful means by which to quantitatively express disparities in care at the provider level.
- **“Across-Provider” Disparity Method:** A healthcare provider’s performance on a measure for only dual eligible patients (or any particular social risk factor) is compared to other healthcare providers’ performance for that same subgroup of patients. This approach allows for comparisons for specific performance to be better understood and compared to peers, or against state and national benchmarks.

CMS notes that alone, each approach may provide an incomplete picture of disparities in care for a particular measure, but when reported together with overall quality performance, they may provide detailed information about where differences in care exist or where additional scrutiny may be appropriate. The Agency also acknowledges the need to ensure that measurement bias is avoided in all disparity reporting methods.

In our comments to the “*Closing the Health Equity Gap in CMS Hospital Quality Programs – RFI*” in the FY 2022 IPPS/LTCH proposed rule, we asked CMS to first state the goals it wishes to accomplish before taking steps to identify quality measures and stratify performance. **We thank CMS for responding to our call for the identification of goals and highlighting the importance of balancing the pursuit of meaningful impact with burden reduction in implementation. Once specific goals can be defined, then all efforts can be aligned around what is necessary to continue moving us closer to achieving the goals. As CMS continues to develop its strategy for measuring healthcare disparities, we ask the Agency to take a comprehensive look at how its policies can enrich hospitals and ASCs that care for the most complex patients.** ASCs and hospitals are faced with many challenges when striving to achieve good outcomes of care for complex and at-risk patient populations, which can be exacerbated by perverse incentives that reduce their already strained resources. **There is a critical need to better measure inherent disparities to bring attention and investment to under-resourced areas and populations, and then change the payment system so that it is accountable for the results of every individual.**

As the ACS has stated in previous comments, we think when setting goals for advancing equity and addressing disparities, it will be important to take a phased approach. We recommend the following steps:

- **Shine a light on the problem.** CMS should continue to focus on ways to reliably define and identify the multifactorial challenges that impact Medicare beneficiaries. CMS should not incentivize facilities based on performance until

the challenges can be reliably and validly identified, and the metrics used in the quality reporting programs are tested to ensure they are providing actionable information that drives improvement.

- **Reward innovation.** CMS should take steps to reward those who have proven their ability to define and identify factors that present greater challenges for at-risk patient groups and are using their resources in innovative ways to address the problems. Their methods should be shared to help inform efforts, including research.
- **Research and development.** Research and development will drive the advancement of these efforts. This is the stage where the problems and solutions can be tested to ensure that desired outcomes to advance equity can be achieved.
- **Socializing solutions.** To continue to drive change, it is critical that the healthcare community socializes their experiences. Sharing solutions that have worked, along with methods that have not worked, will help the broader healthcare community as it continues to discover how to best address healthcare disparities.

We also suggest, in addition to the hospital-to-hospital and provider-to-provider comparisons, CMS should explore stratifying and comparing metrics based on conditions and/or procedures. A condition-specific comparison would help identify if complex care is the same or different across patient groups. From our perspective, having the ability to drill down to more conditions and procedures would be most informative and impactful, and present opportunities to motivate improvements in care within service lines that deliver complex care to patients with social risk factors. We suggest exploring conditions beyond acute myocardial infarction (AMI), chronic obstructive pulmonary disease (COPD), heart failure (HF), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). As CMS considers different stratification methods, it is also important that the Agency continues to test the measures to ensure they have enough statistical power to truly show differences in care, recognizing that different statistical thresholds might be more appropriate depending on the measure or scenario. This is especially important when measuring disparities at the level of the individual clinician. Once measures are stratified, measures should be tested on a measure-by-measure basis.

However, most importantly, we must not rush this process when hospital payment is affected. It will take time to achieve impactful solutions because the solution is highly dependent on defining the right problem to be solved and its confounding challenges. We are still in the discovery phase of these efforts and more work needs to be done to advance health equity.

Finally, it is important that at the root of these efforts, CMS continues to consider how it will help patients seek out trusted care that will meet their needs. Reporting on patient experience will reflect whether patients felt they were treated respectfully, whether they felt their voice was heard and personal goals understood, and if they experienced a trusting relationship with the care team. Inclusion is a much-needed area of development in healthcare and could encompass a patient's feeling of receiving care that is sensitive to their culture, beliefs, language, race, ethnicity, sexual orientation and gender identification, personal circumstances, and so on. Inclusion can also comprise whether patients feel they are in an environment where they can be connected to community-

based organizations or other resources that may be necessary to optimize their goals of care. Transparent public reporting of these measures can help patients seek out care based on their personal circumstances and values.

Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting Across CMS Quality Reporting Programs

CMS plans to expand its efforts to provide stratified reporting for additional quality measures. The Agency expresses the aim to standardize approaches, when possible, but acknowledges that decisions about how to identify and prioritize measures for possible stratification should be made at the program level to ensure results, provide the most actionable data, and limit potential bias. To help inform prioritization of the next generation of candidate measures for stratified reporting, CMS is soliciting feedback on several systematic principles under consideration that it believes will help prioritize measures for disparity reporting across quality programs.

- Prioritize Existing Clinical Quality Measures
- Prioritize Measures with Identified Disparity in Treatment or Outcomes for the Selected Social or Demographic Factor
- Prioritize Measures with Sufficient Sample Size to Allow for Reliable and Representative Comparisons
- Prioritize Outcome Measures and Measures of Access and Appropriateness of Care

In general, the ACS supports CMS in its efforts to create a strategy to prioritize measures for disparity reporting. It is extremely important that CMS identify the measurement methodologies and measures that will have the most impact and then take time to properly implement the measurement methodologies, instead of moving forward with many changes quickly that may be confusing and ultimately unsuccessful. As CMS works to create its strategy for prioritization, we suggest that the Agency explore how to incorporate equity in a way that is integrated in the care cycle, instead of selecting siloed measures that are used to determine payment.

The identification of social needs and SDOH should be foundational pieces of the quality program and implementing structures and processes that enable regular assessments of a patient’s social needs are critical. Patient experiences and patient reporting outcomes (PROs) can also be used to identify patient goals, inform care, and highlight gaps. To achieve this, CMS should explore the necessary resources and tools that put hospitals in the best position to screen and assess patients. Once hospitals can identify patient social needs, the needs can then be evaluated to determine what processes are in place to take the actions needed for a high quality outcome.

Lastly, CMS should explore the potential stratification of measures that have “topped out” performance or have recently been removed because of topped out performance. By stratifying these measures, the Agency can evaluate if there are differences in performance across certain populations that could demonstrate an ongoing gap in care. If CMS can identify gaps in care through stratification efforts, this should be considered as a criterion for maintaining these measures in the programs.

Principles for Social Risk Factor and Demographic Data Selection and Use

In the FY 2023 IPPS/LTCH proposed rule, CMS refers to the World Health Organization (WHO), which defines social risk factors as “...non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life.” While it is widely known that these factors play a role in health outcomes, the availability of standardized and self-reported data on social risk factors and demographics is limited. The Agency refers to multiple efforts to develop data standards for collecting self-reported patient social risk and demographic data (the gold standard) and discusses the advantages and disadvantages of the available data sources. As CMS evaluates patient-reported sources of these data, it shares the following sources of social risk and demographic data for consideration as variables to report within stratified measure results:

- Billing and Administrative Data
- Area-based Indicators of Social Risk Information and Patient Demographics
- Imputed Sources of Social Risk Information and Patient Demographics

The ACS commends CMS for the resources it has invested in identifying ways to promote health equity and agrees that identifying means to improve the healthcare of populations who are underserved should be a top priority of the Agency and the entire U.S. healthcare system.

Data sources that are currently in use, such as billing and administrative data, can serve as proxies, but will not be able to provide the proper level of detail and context that gets to the heart of the issues patients face. These broad approaches will be helpful in giving us a general sense of the needs within a population. **As the ACS has stated in the past, the lack of standardization in demographic and SDOH data presents a major challenge in addressing patient needs. We agree that to achieve more widespread collection, aggregation, and tracking of SDOH data, improvements in collection methodologies and standardization are necessary across the entire healthcare system. In the same way that emphasis has been put on standardization of clinical information data in the medical record, SDOH information should also be consistently collected and maintained as part of the patient’s medical record. Key to collecting these data is also the clinical team’s ability to establish a trusting relationship with the patient so that the patient is comfortable sharing personal information.** The ability to collect accurate and real-time SDOH data and put these variables in the hands of the clinician at the bedside could drastically change care delivery across the phases of care. Having these data would allow clinicians to tailor care based on SDOH from how they conduct screening, prevention, and early intervention to preoperative planning, postoperative recovery, and post-discharge management.

Finally, we seek clarification from CMS on how the Agency plans to put in safeguards to prevent discrimination when more comprehensive SDOH data is available. It is important to ensure that access to safe and affordable care is not decreased as we gain more information and data about patients.

Identification of Meaningful Performance Differences

In CMS' work to examine ways to report healthcare disparity data (or the results of quality measure stratification), it also will consider different approaches to identify meaningful differences in performance. CMS asks for feedback on the benefits and limitations of the following possible disparity reporting approaches.

- **Statistical Differences:** The Agency believes that statistical testing can be helpful when trying to reliably group results, using confidence intervals, creating cut points based on standard deviations, or using a clustering algorithm. However, it recognizes that these groupings may be statistically different, but not meaningfully different.
- **Ranking Ordering and Percentiles:** CMS envisions that healthcare providers could be ranked based on their performance on disparity measures to allow comparison between their performance and other similar healthcare providers.
- **Threshold Approach:** In this system, CMS could group healthcare providers based on their performance using defined metrics, such as fixed intervals of results of disparity measures, indicating varying levels of performance.
- **Benchmarking:** This approach would compare individual results to other state or national averages or other group averages. CMS states that this approach, especially if combined with a ranked or threshold approach, could give providers more information on how they compare to the average care for a patient group.

As mentioned earlier, evaluating a facility's ability to identify the problem should be the first step in measuring performance. Since further research is required to decipher the best methodologies and variables for identifying and addressing social needs, hospitals should not be measured or compared based on their ability to reverse negative trends. **Instead, we think it is critically important to find ways to highlight and recognize the facilities that can accurately identify social needs and have taken steps to provide services and resources to reverse trends. From the ACS' perspective, we are too premature in these efforts to reward or penalize facilities based on their performance on measures that are stratified for SDOH variables.**

In the current state, CMS should use its resources to share information with healthcare providers and determine what metrics provide information that spurs action and improvements in care. As we have stated previously, in general, an important standard to apply in evaluating payment quality incentives is their effectiveness in providing patients with knowledge of where to find high quality care in their community. When considering meaningful performance differences, this should be key—what information do patients value and how will that information reliably help them seek equitable care? Finally, when the Agency determines that performance-based comparisons are appropriate across their programs, it must not adopt a one-size-fits all approach to applying statistical standards or other methodologies for identifying meaningful differences in performance. Statistical standards and approaches are specific to the use case.

Guiding Principles for Reporting Disparity Results

The Agency describes the advantages of confidential reporting, which is a process that is typically used for newly adopted measures in CMS quality programs to give healthcare providers time to familiarize themselves with their performance, the calculation methods, and to begin improvement activities before the results are publicly reported or used for determining payment. The Agency asks for comment on the benefits of confidentially reporting all stratified measure results that are adopted into a quality reporting program before the results are publicly reported.

The ACS supports CMS' strategy to initially share stratified measure results through confidential reports. However, CMS should not publicly report outcomes until the measure science for reporting outcomes in at-risk patient populations is further developed. Instead, when publicly reporting SDOH information, CMS should report a facility's ability to identify and address the social needs of the patients.

The ACS is supportive of reporting structural measures that show facilities have processes in place to support patients, such as programs for underinsured patients to receive prevention, screening, and early detection. In addition to giving patients information about where to seek the best in applied medical science for their care, patients may also seek out clinicians who culturally, socially, and economically suit their needs. Patients will look for an environment they can trust for their care and feel comfortable enough to share their goals with a clinical team that stands the best chance to understand them and deliver on their personal goals. Therefore, we reiterate our belief that public reporting must include information that will be most valuable and informative for patients as they try to select facilities and clinicians that will be able to meet their needs and provide them the best care.

REQUIREMENTS FOR THE AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM

Request for Comment on a Potential Future Specialty Centered Approach for the ASCQR Program

In recognition of the specialized clinician and/or clinician group-centered nature of care delivered in ASCs, and because ASC services for Medicare beneficiaries are concentrated on a limited number of procedures, CMS seeks comment on the future direction of quality reporting for this care setting. The Agency specifically solicits feedback on the potential future direction of quality reporting under the ASCQR Program that would allow quality-related data for ASCs to be reported on a customizable measure set. The customizable set would more accurately reflect the care delivered in this setting and account for the services provided by individual facilities (e.g., ophthalmology, from which ASCs could choose a specified number, but individualized combination of measures). Another option could include the creation of specific specialized tracks which would standardize quality measures within a specialty area.

CMS discusses the Merit-Based Incentive Payment System (MIPS) as an example of a specialty-centered approach to quality reporting that is relevant to ASCs as clinically

specialized facilities. CMS notes that quality reporting for ASCs would benefit from measures that:

- Consist of limited, connected, and complementary sets of measures and related activities that are meaningful to clinicians;
- Include measures and activities resulting in comparative performance data that are valuable to patients and caregivers in evaluating clinician performance and making choices about their care;
- Promote subgroup reporting that comprehensively reflects the services provided by multispecialty groups; and
- Include measures selected using the Meaningful Measures approach and, wherever possible, include the patient voice.

To achieve value-based care, the ACS asserts that the concept of “value” in healthcare must be defined in terms of results that matter to the patient for the condition they have, with the goal for all stakeholders to deliver care based on what the patient values. Patients on a care journey need patient-centric measures across their clinical pathway that appreciate the achievement of their care goals. These measures should inform patients about where to get safe (preventable harms), affordable, good (outcomes), equitable care. Delivering on patient goals and gaining the trust of the patient requires the orchestration of the clinical team working together. Measuring quality efforts at the patient-level and rewards for quality attainment or improvement should celebrate all members of the care team jointly—including the facility—coming together to co-manage the patient for their condition. To do this, the ACS advocates for a “comprehensive quality program,” which we define as an overarching quality framework focusing on the care of the patient, including the goals and outcomes important to the patient, while also valuing the infrastructure, resources, and processes needed to deliver optimal care and improvement. If CMS considers implementing a condition focused pathway in the ASCQR program, we offer several objectives that could guide the Agency towards patient-centric value-based care. We encourage CMS to evaluate the success of their programs based on these objectives.

Programs should inform patients about where to get care for their condition.

Twenty years of the National Quality Forum (NQF) and CMS actions in quality have not produced reliable public knowledge for patients. If a patient is diagnosed with a condition such as a cancer, no reliable information is available on the Care Compare website showing where to seek care for the type of cancer they have; even referring clinicians often do not have transparent and reliable information to use for directing referrals. Currently, CMS Care Compare for hospitals only shows performance on broad outcome measures and hospital use of Certified Electronic Health Record Technology (CEHRT). **Where possible, for highly prevalent conditions, quality programs should build teams, leverage condition-specified measures to drive improvement, and use these attributes to inform patients about where to find the care they expect, and for payers to incentivize and reward quality.** In instances where conditions are not as prevalent, quality programs should assure the proper structure, processes, and outcomes are framed by the care team to fit the domains of care (such as excellence in trauma, cancer, and geriatric surgical care). This type of information is what should be prioritized

for public reporting.

Quality programs should incentivize shared accountability with co-managed elements of care across the team and the facility.

In complicated care models, it takes a well-orchestrated team to deliver the outcomes safely, affordably, adequately, and equitably. That is to say that care models are complicated, and patients are complex when factoring in their goals and expectations of care. Appreciating the distinction of applied medical science alongside meeting a patient's needs by a care team co-managing the care plan is key to achieving true quality in healthcare. Comprehensive quality programs take the complicated care model and translate it into a customized care plan.

Yet, the current CMS quality programs (including MIPS Value Pathways [MVPs]) continue to individually measure clinicians in silos, separately from facilities. This framework ends up disaggregating the care team's efforts, is contrary to the ongoing transition to patient-centered value-based care that relies on the co-management of patients, and moves us farther away from our goals of truly raising the bar on patient care. Specialty-focused efforts, such as MVPs and the subgroup reporting, have potential to align care teams around a patient for a condition, but currently are largely measuring the wrong things—they continue to focus on siloed actions, individual processes, or avoidable harms.

For shared accountability, the clinical team, including the facility, should be measured on the joint effort of a comprehensive quality program where they must come together to achieve outcomes that matter to the patient. Integrating structure, process, and outcome elements—originally introduced by Donabedian—are critical to the comprehensive quality program, as well as how these elements come together as an interconnected and interrelated set of measures for a condition.⁷ By using standards, facilities and providers are aligned for continuous, reliable, and standardized care. In addition to adequate outcomes, adhering to clinical protocols, having the correct personnel and equipment, and having an aligned organization are essential attributes for achieving high quality.

CMS and other payers must use the appropriate levers for payment incentives to achieve value-based care outlined in objectives.

To date, there have been many hurdles to incentivizing comprehensive quality programs that deliver on what matters to the patient and transparently informs the public on how to find care for their condition. The ACS has put forth efforts across CMS programs that aim to appreciate what is needed to transition toward patient-centered value-based care. However, these efforts have largely failed because of the lack of incentives for hospitals and clinicians to change the way they participate in programs. This, coupled with the unknown impact of these changes on their revenue, is simply not worth the risk.

Change is hard. If a hospital-owned physician practice has employed its quality staff for CMS quality programs and built resources to aggregate the traditional measures for the surgical team, the primary care and medical specialists similarly have a cadre of staff combing through records to meet hospital or ASC measures. These efforts meet a payment incentive objective but are not likely to drive transitions to a more patient-

⁷ Donabedian, A. (1980). *Explorations in quality assessment and monitoring* (Vol 1), Health Administration Press.

focused QI program. Our experience informs us that without a health plan or CMS incentive, most prefer to remain in their current set of measures when given a choice between continuing current measures or moving to an improved quality program. The return on investment by plans and federal efforts through quality programs must exceed the initial incentives to create the change movement needed for value-based care. Without implementing quality as a program, the cost to patients and the overall cost of care are negatively impacted.

If CMS truly wants to transform healthcare, the incentives must make it worth the effort. From the ACS' perspective, the mindset needs to be changed from one of penalty avoidance to one that: (1) rewards care teams for implementing and maintaining the elements of quality programs that are built around care for specific conditions; (2) aligns with the team-based nature of care delivery; (3) applies continuous improvement cycles; and (4) can provide useful information that supports patients when they must determine where to seek medical care.

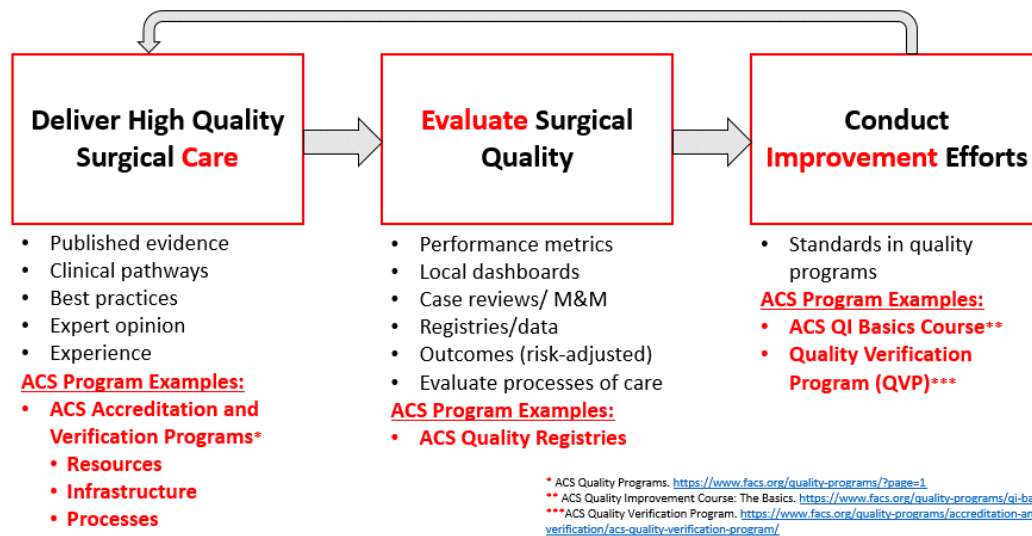
The quality framework used must appreciate that healthcare is complicated (measurable of team functionality relative to the science of medicine that comes from guidelines down to care plans) and complex (less easily measured and deals with the variation in care—when customizing care to the patient, their goals/expectations, the resources available, and so forth). This is an important distinction because it determines what and where you measure and how you drive improvement. In surgical care, simple “lumps and bumps” are not overly complicated or complex. However, with multi-morbid patients, multiple organ injury in trauma, cancer, or vascular reconstruction, and so on, care can get very complicated. Care plans with multiple inputs with joint or shared accountability can result in care coordination and better-informed patients, leading to optimal outcomes.

To operationalize a program that can meet these objectives, improving quality improvement, or “improving improvement” is central to the goal and part of all ACS verification and accreditation programs (Trauma Verification, Commission on Cancer, Children’s Surgery Verification, Geriatric Surgery Verification, National Accreditation Program for Breast Centers, and others). To support “improving improvement” efforts, the ACS recently developed the ACS Basics Quality Improvement Course designed to ensure the surgical workforce and other quality improvement staff are well-educated on the basic principles of surgical quality and safety.⁸ To drive improvement, we must first have a cultural commitment across the care team, as well as with leadership, to ensure the appropriate resources are made available and quality is a priority. Then we must ask ourselves, how have we re-engineered care teams to emerge and measure care to deliver high quality surgical care? This is inclusive of the appropriate evidence, experience, and alignment with a clinical pathway, which is all included in the ACS verification programs. Does the care team have the data to evaluate care and find problems with the care plan as delivered? To do this, clinical teams rely on dashboards, clinical data registries, key metrics, case review, and revelation of processes. Finally, do clinical teams have the resources to implement a quality improvement framework, such as a Plan, Do, Study, Act (PDSA) cycle? Did they fix the problem, and how is success evaluated? And the cycle repeats. The figure below illustrates how the ACS implements “improving

⁸ The American College of Surgeons. (n.d.). *The ACS quality improvement course: The basics*. <https://www.facs.org/quality-programs/qi-basics-course/>

improvement” across the ACS quality programs, including the various components of the ACS quality programs. The necessary resources, structures, and educational needs are embedded into the ACS Quality Programs to fully support a continuous quality improvement cycle, as illustrated in Figure 2.

Figure 2. Improving Quality Improvement



Another example of a quality program with a similar framework is the Collaborative Quality Initiatives (CQIs) in Michigan in partnership with Blue Cross Blue Shield of Michigan (BCBSM), described in a recent publication by Howard et al.⁹ There are currently 23 CQIs which are organized around a condition. The CQI framework is “data driven, clinician led, and collaborative.” CQIs also rely on a continuous QI framework that includes five key components: collection of clinical data, analysis of data, feedback on performance, development of QI initiatives, and implementation of QI initiatives, with a secondary component of the dissemination of knowledge with publications and national presentations. Centers have dedicated clinician leadership and direct their own QI initiatives. Dedicated Coordinating Centers are responsible for ensuring the validity of the CQI program data and for managing QI activities focused on improving outcomes, increasing efficiencies, and ultimately reducing patient care costs. They implement QI frameworks similar to those across the ACS quality programs, such as PDSA. CQIs have regular collaborative-wide meetings, and with clinical dashboards, the performance of individual hospitals is shared internally, and results are not used or shared beyond QI efforts to enable a learning health system across participating hospitals where both high performing and low performing hospitals are engaged for shared learning.¹⁰

Once we have applied quality frameworks, as described above, the focus can turn to measuring the complicated care and the complexity of a patient (their goals and expectations). This re-engineering must be recognized structurally and process-wise as an

⁹ Howard, R., Grant, J., Leyden, T., & Englesbe, M. (2022). Improving the quality of health care through 25 years of statewide collaboration in Michigan. *NEJM Catalyst Innovations in Care Delivery*. 3(9), 1-29. <https://doi.org/10.1056/CAT.22.0153>

¹⁰ Howard, R., Grant, J., Leyden, T., & Englesbe, M. (2022). Improving the quality of health care through 25 years of statewide collaboration in Michigan. *NEJM Catalyst Innovations in Care Delivery*. 3(9), 1-29. <https://doi.org/10.1056/CAT.22.0153>

essential step if we are to achieve patient-centered accountability. Our experience through the ACS verification and accreditation programs has informed our thinking. For the payer community to assume that care teams are already properly organized into continuous improvement in clinical operations is a bridge too far. If we are to someday arrive at tracking PROs for specific conditions, we must first reconsider how to optimally frame a team in a patient-centered, condition-specific manner. Rethinking how we get there means pulling back from the silos of measures in the NQF-style and think about what a measure framework looks like. A way to validate this framework that might serve as a bridge from how NQF reviews measures is considering whether a set of measures can come together to inform a broader construct, such as the “quality of community-based maternity care,” described as “content validity” by Schang et al. Content validity looks at the “valid set” of indicators instead of “valid indicators” in a silo.¹¹ **The authors explain that because of the multidimensional nature of care, conclusions about measure constructs depend on the indicator set as a whole, and not just single indicators. For example, patients might be interested in the construct of “quality of community-based maternity care” instead of simply focusing on timely support during labor.**¹²

Request for Comment: Potential Future Reimplementation of ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC-7) Measure or Other Volume Indicator

CMS previously adopted the ASC Facility Volume Data on Selected Procedures measure (ASC-7) beginning with the CY 2013 reporting period/CY 2015 payment determination. This structural measure of facility capacity collected surgical procedure volume data on six categories of procedures frequently performed in the ASC setting: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary (76 FR 74507). CMS adopted ASC-7 based on evidence that the volume of surgical procedures, and particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased medical errors and mortality. However, in the CY 2018 OPPTS/ASC final rule with comment period (82 FR 59449 and 59450), CMS removed ASC-7 due to a belief that measures on specific procedure types would provide patients with more valuable ASC quality of care information as these types of measures are more strongly associated with desired patient outcomes. As a result, the ASCQR Program currently does not capture outpatient surgical procedure volume in ASCs.

Similar to the Hospital OQR Program proposal, CMS is considering to reimplement the ASC-7 measure or another volume measure because, in addition to being an important component of quality, the shift from the inpatient to outpatient setting has placed greater importance on tracking the volume of outpatient procedures. The Agency is also considering the reintroduction of a facility-level volume measure to support potential future development of a pain management measure, as described in a request for comment in the CY 2022 OPPTS/ASC final rule with comment period (86 FR 63902 through 63904). A CMS analysis found that pain management procedures were the third most common procedure in CYs 2019 and 2020 and concluded that a pain management

¹¹ Schang, L., Blotenberg, I., & Boywitt, D. (2021). What makes a good quality indicator set? A systematic review of criteria. *International Journal for Quality in Health Care*, 33(3), 1-10. <https://doi.org/10.1093/intqhc/mzab107>

¹² Schang, L., Blotenberg, I., & Boywitt, D. (2021). What makes a good quality indicator set? A systematic review of criteria. *International Journal for Quality in Health Care*, 33(3), 1-10. <https://doi.org/10.1093/intqhc/mzab107>

measure would provide consumers with important quality of care information. Thus, The Agency believes a volume measure would provide Medicare beneficiaries and other interested parties information on numbers and proportions of procedures by category performed by individual facilities, including for ASC procedures related to pain management.

The Agency seeks comment on the potential inclusion of a volume measure in the ASCQR Program, either by adopting the ASC Facility Volume Data on Selected ASC Surgical procedures (ASC-7) measure or adopting another volume indicator, what volume data ASCs currently collect and if it is feasible to submit this data to the ASCQR Program, and an appropriate timeline for implementing and publicly reporting the measure data. The ACS reiterates our comments made in the *Request for Comment on Reimplementation of Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) Measure or Adoption of Another Volume Indicator* section of this letter.

The ACS does not support the use of volume measures in the ASCQR program as described. Measuring procedure volume does not reliably predict high quality care and is, therefore, an outdated proxy—essentially, this is a step backwards in the identification of high-quality care. Merely reporting volume without context could create an unintentional misdirection for patients and other end users. Contextualizing information in a value expression requires more than a factual report of volume. It requires understanding the clinical appropriateness of the procedure for each specific patient, the risk profile for the volume of patients, their observed to expected safety report for preventable harms, and the overall outcomes that meet patient expectations. Without a proper framework, the use of volume may lead to information that could impact patient trust, especially to the most vulnerable in high-risk public hospitals or rural care where access and choice are the first order of quality to be addressed. This may also create perverse incentives to increase volume. Measuring volume in the absence of quality (or as a proxy) is a mixed signal as the nation transitions to appreciating value-driven care and moves away from volume-driven care.

This is supported by the following points:

- **Quality measurement systems at the surgeon-specific level remain underdeveloped, especially for uncommon complex procedures. It is difficult to determine a volume threshold that indicates high quality with meaningful statistical power at the individual clinician level, and the volume threshold will typically differ from procedure to procedure.** In fact, achieving reliability at the hospital level is often not accomplished for some procedures. A minimal case number threshold for the required experience of rarely performed operations or those performed for rare diseases is likely impossible to define or be meaningful.¹³
- **The ACS Statement on Credentialing and Privileging and Volume Performance Issues notes for some complex procedures, high case volume could be**

¹³ The American College of Surgeons. (2018, April 1). *Statement on credentialing and privileging and volume performance issues*. <https://www.facs.org/about-acsc/statements/credentialing-and-privileging-and-volume-performance-issues/>

associated with improvement in surgical outcomes, however, “these outcomes may reflect not only the knowledge, experience, and skill of the individual surgeon, but also the aggregate ability of the institution and hospital staff to provide high-quality care for specific groups of patients.”¹⁴ It is also well documented that some surgeons performing a relatively low volume of these procedures also achieve excellent outcomes.

- From our work running verification and accreditation programs, we know that using standards of care established as part of a quality program will align facility and providers for continuous, reliable, and standardized care. In other words, it takes much more than just a single surgeon’s volume of cases to determine optimal outcomes. If the goal is to move to value-based healthcare, the delivery of care must be reframed from focusing on volume as its key, fiscal, sustainable objective. This means reorienting and restructuring the design and organization of care. In addition to good outcomes, adhering to clinical protocols, having the correct personnel and equipment, and adequate organization are good indicators of quality. It is for these reasons the ACS advocates for implementing full quality programs organized around the patient for the delivery of optimal care.

To this end, publicly reporting volume data will be misleading and confusing to patients who are using the CMS Care Compare website to determine where they will receive the best care. It is not appropriate to assume that performing a high case volume of certain procedures always equates to better outcomes, especially when considering data integrity issues outlined above. It is important to understand volume, patient risk profiles, price, and quality collectively to make an informed decision. An example from ACS Thrive, Figure 1 titled *Contextualizing Volume to Support Understanding Value* (page 35), displays the connections between quality, price, and volume that are necessary to provide context and understanding of the true value of care. ACS Thrive is a pilot project that defines an episode of surgical care, in this instance colectomy for cancer, and portrays the quality and price—based on Medicare FFS patients.¹⁵ The figure provides (1) the payer mix; (2) a volume and price graphic for the region (hospital referral regions [HRR]); and (3) the mean price for Medicare patients and the Medicare Hierarchical Condition Categories (HCC) risk stratification for the types of patients undergoing care at this facility.

In conclusion, the ACS does not support volume as a proxy for value without being more informed by these other parameters. The reframing of healthcare must realize a patient-centered, market mindset branded by value.

Request for Comment: Interoperability Initiatives in ASCs

In 2009, under the Health Information Technology for Economic and Clinical Health Act (HITECH Act), financial incentives were authorized for hospitals and clinicians to adopt and meaningfully use certified electronic health record (EHR) technology. ASCs were

¹⁴ The American College of Surgeons. (2018, April 1). *Statement on credentialing and privileging and volume performance issues*. <https://www.facs.org/about-acs/statements/credentialing-and-privileging-and-volume-performance-issues/>

¹⁵ American College of Surgeons. (n.d.). *Transforming healthcare resources to increase value and efficiency: ACS Thrive*. <https://www.facs.org/quality-programs/standards-and-staging/acs-thrive/>

not included in the HITECH Act and were ineligible for the financial incentives under the Promoting Interoperability (PI) Program. CMS states that potentially as a result, only 54.6% of ASCs use an EHR in their facility, indicating that ASCs have a lower adoption rate compared to the 85.9% of office-based physicians reported by the Office of the National Coordinator (ONC). The Agency seeks comment to explore how ASCs are implementing tools in their facilities toward the goal of interoperability as it considers a future shift from Quality Net to electronic clinical quality measures (eCQMs). They also invite comment on what ASC's perceive would be the benefits, risks, possible improvements associated with implementing interoperability initiatives.

The ACS has advocated for CMS to expand the focus of the PI Program beyond the function and utilization of EHRs. Instead of focusing on EHR use, the Agency should be acknowledging facilities that have implemented the necessary infrastructure to meaningfully use health information technology (HIT), send/receive data and incorporate it into clinician workflows, manage referrals, etc. By using digital tools to capture the full scope of patient data, ASCs will be able to facilitate better care coordination, patient monitoring before, during, and after receiving care at the ASC, determine adherence to care plan, inform quality improvement efforts, etc.

The ACS asserts that patient-centered care should incorporate digitally shared knowledge that tracks the patient throughout their entire care journey, regardless of the site of service. Now that many major surgical services are being performed in ASCs, it is essential that we link ASCs with other sources of shared knowledge to prevent harms and track to the best outcomes in the most efficient way. **All major sites of service, such as an office, urgent care clinic, emergency department, ASCs, inpatient facilities, skilled nursing facilities and home health, represent sites where a patient could receive healthcare services. Therefore, measuring and improving care should track to the patient, not the site.** Because of this, everyone should have the ability to exchange and share data.

Digital services can be leveraged by building knowledge around a patient's care pathway through aggregating clinical care on open standards-based platforms that can ingest data from numerous sources. These digital services are nascent and hold great promise to enhance knowledge sharing around care and can enable the following services:

1. Support the use of clinical decision support (CDS) to make clinical guidelines and pathways available as a digital service through platforms that are not constrained by proprietary efforts from EHRs.
2. Support the ability to gather condition or procedural cohort data for outcomes reporting and to assess conformance with guidelines-based care.
3. Support data aggregation and analytics for near real-time research and clinical trials for expanding sample sizes in randomized clinical trials (RCTs) and observational studies.
4. Support quality metrics payers seek for their payment incentive programs in a patient centered manner.

These open architecture platforms are essential to expand medical knowledge management and optimize care. By using open standards-based platforms, data can be

assembled for the individual patient (not the single EHR level) to build a patient perspective inside health information exchanges (HIEs) and allow for more shared and coordinated care. This architecture can meet and exceed the payer needs for quality metrics as well as enrich clinical knowledge.

Finally, if CMS takes steps to require ASCs to implement EHRs and other digital services, we ask they consider all aspects of implementation, including cost to the system. EHR systems are extremely costly, and in some ways, their proprietary, closed systems still have not fulfilled the intent of the Congressional efforts to overcome the bidirectional impacts of EHR vendor data blocking. To fully reduce the burdens of implementation, the digital environment needs an open marketplace that can absorb these costs. It is not enough to reduce clinical burden of data aggregation if the fiscal burden of constrained, proprietary vendor actions consume more and more precious healthcare resources. In addition to affordable digital services, as data flows from the EHRs into clinical analytics, the EHRs should also provide a reasonable and affordable environment for data to become available to the EHR from other sources, such as the platforms and data lakes mentioned above. Without this ability, the EHRs will continue to data block elements of care.

ORGAN ACQUISITION PAYMENT POLICY

The ACS appreciates CMS' proposals in this rule that would authorize additional surgeons to determine whether an organ is usable and allow costs incurred prior to the death of a donor to be reimbursable. However, we wish to highlight serious concerns about the Agency's proposed modifications to the cost reporting rules related to research organs. **If finalized, we believe such proposals could significantly raise the costs of critical transplant research and inappropriately incentivize organ procurement organizations (OPOs) to discard organs that are not suitable for transplantation rather than making these organs available to researchers.**

We are also concerned that the proposed exclusion of the purchase price of organs in the statistics used to allocate a hospital's general and administrative (G&A) costs would treat organ acquisition costs differently from other purchased items and services, which would adversely impact patient care and could result in significant Medicare payment reductions. **The ACS urges the Agency to clarify that the purchase price of an organ that a recipient transplant hospital pays to an OPO or another transplant hospital may be included in the accumulated cost statistic by which G&A costs are allocated.**

ADDITION OF A NEW SERVICE CATEGORY FOR HOSPITAL OUTPATIENT DEPARTMENT (OPD) PRIOR AUTHORIZATION PROCESS

Controlling Unnecessary Increases in the Volume of Covered OPD Services

In the CY 2020 OPDS/ASC final rule, CMS established a prior authorization process for certain HOPD services using its authority under 42 U.S.C. § 1395l(t)(2)(F), which allows the Agency to develop a method for controlling unnecessary increases in the volume of covered HOPD services.¹⁶ After additional policies were added in CY 2021, as a

¹⁶ 84 F.R. 61142

condition of payment under the Medicare program, prior authorization must be obtained for the following services when provided in the HOPD setting: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, vein ablation, cervical fusion with disc removal, and implanted spinal neurostimulators.

For CY 2023, CMS proposes to add a new service category to the list of services requiring prior authorization: facet joint interventions. CMS has identified the following CPT codes in that category:

- **CPT 64490** (*Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level*)
- **CPT 64491** (*Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level*)
- **CPT 64492** (*Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s)*)
- **CPT 64493** (*Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level*)
- **CPT 64494** (*Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level*)
- **CPT 64495** (*Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)*)
- **CPT 64633** (*Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint*)
- **CPT 64634** (*Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint*)
- **CPT 64635** (*Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint*)
- **CPT 64636** (*Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint*)

We are concerned that the Agency is misinterpreting an increase in the volume of utilization for certain procedures in the HOPD setting as “unnecessary,” when such increases may instead simply reflect an appropriate shift from inpatient to outpatient care over time and is setting a constantly changing standard for what level of increase substantiates addition to the list. In CY 2020 rulemaking, CMS identified “higher than expected growth” as utilization growth rates of 19.3%, 9.2%, and 11.1%; cost and payment increases of 27.8%, 13.9%, and 11.5%; and unique patient growth of 17.9%, 9.2%, and 9.5%.¹⁷ Then, as part of CY 2021 rulemaking, CMS cited

¹⁷ 84 Fed. Reg. 61,456 (Nov. 12, 2019).

increases of both over 100% and 10% as the basis for adding procedures to the prior authorization list.¹⁸ For CY 2023 rulemaking, CMS proposes to add facet joint interventions because of a 4% increase from 2012-2021.¹⁹

The ACS strongly objects to the introduction of any new prior authorization requirements into the Medicare program. We request that CMS investigate a possible misplaced assumption that all increases in the volume of certain HOPD services are “unnecessary,” and urge the Agency to rescind its policy to require prior authorization in the HOPD setting. We believe this is particularly important given that CMS has made concerted efforts to address site-of-service payment differentials to encourage selection of the most clinically appropriate setting for a given service, and thus, one would expect shifts in sites of service that could cause a justifiable increase to the volume of cases presenting in HOPDs. **The ACS has numerous concerns with CMS’ prior authorization processes and the Agency’s interpretation of its statutory authority to make these proposals, which are described in detail below.**

- **Administrative burden.** By CMS’ own admission in the CY 2020 OPPTS/ASC final rule, its prior authorization policies significantly change how physicians must bill for services, resulting in a \$19.8 million increase in administrative costs for private sector providers by CY 2025. In its discussion of this added financial burden on physicians, the Agency stated, “we do not view decreased revenues from OPD services subject to unnecessary utilization by providers to be a condition that we must mitigate,” and has failed to offer any offsetting increases in payments for other services.²⁰ **As insurers continue to subject a growing number of services to prior authorization, many physicians can no longer afford the increased practice costs related to compliance with prior authorization requirements and are left with no option but to leave insurance networks.** When a physician becomes out-of-network, beneficiaries must either seek care elsewhere or pay out-of-pocket, both of which inappropriately delay care and shift costs onto patients. CMS’ prior authorization policies could substantially limit patient access and lead to a decline in the number of physicians participating in the Medicare program.
- **Barriers to payment.** Surgeons across the country are facing setbacks in furnishing services to patients—and being reimbursed for such services—even when they comply with insurers’ prior authorization requirements. CMS indicates that, as a condition of payment, a physician must submit a prior authorization request to the Agency that includes all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules. Claims submitted for services that require prior authorization but have not received a provisional affirmation of coverage (i.e., a preliminary finding that a future claim will meet Medicare coverage, coding, and payment rules) from CMS or its contractors would be denied. Moreover, the Agency states that, even when a provisional affirmation has been granted, a claim may still be denied based on either technical requirements that

¹⁸ 85 Fed. Reg. 86,237 (Dec. 29, 2020).

¹⁹ 87 Fed. Reg. 44,803 (July 26, 2022).

²⁰ Centers for Medicare & Medicaid Services. (2019). *CY 2020 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Proposed Rule*. Retrieved from <https://www.govinfo.gov/content/pkg/FR-2019-08-09/pdf/2019-16107.pdf>

can only be evaluated after the claim has been submitted for formal processing or information not available at the time the prior authorization request is sent to CMS.

We wish to highlight the following example of a prior authorization denial experienced by ACS members: in the case of a patient requiring segmental phlebectomy for treatment of extremity pain and swelling following failed pain management using compression therapy stockings, prior authorization was obtained for CPT code 37766 (*Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions*), with the prediction that, based on a preoperative examination of the patient, the surgeon would need to remove more than 20 symptomatic veins. Once the procedure was performed, only 15 symptomatic veins were removed. This procedure is more appropriately described by CPT code 37765 (*Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions*). When the surgeon reported CPT code 37765—the correct code for the service ultimately furnished—the patient’s insurer denied the claim simply because the code reported (CPT code 37765) was not the code for which prior authorization was granted (CPT code 37766), despite the fact that (1) CPT code 37765 was the correct code to report for the procedure performed, and (2) the procedure was less complex with lower relative value units (RVUs), meaning that it was less expensive than the one the insurer had originally approved. **We believe that payment for services for which prior authorization was granted should not be later denied based on billing technicalities. Reimbursement should not be withheld when the service performed is clinically comparable to an approved service but is more properly reported using a different CPT code, when a procedure’s necessity could not be anticipated before it was furnished, or when a procedure is performed incident to, or during the course of, an approved operation.**

- **Violation of statutory authority.** Medicare statute authorizes CMS to “develop a method for controlling unnecessary increases in the volume of covered OPD services.”²¹ We wish to highlight that this provision does not actually authorize CMS to make any adjustments or changes to *payment rates* at all; instead, it merely authorizes the Agency to develop a *methodology* for controlling unnecessary increases in the volume of services. If CMS determines that the volume of a given service in the HOPD setting has grown beyond the expected amount established through its methodology, it may address this unnecessary increase in volume only through across-the-board adjustments to all items and services paid for under the OPDS. Specifically, the Agency can adjust the update to the conversion factor (CF) applicable in a subsequent year.²² The CF is a uniform amount that is used in the formula to calculate payment rates for *all* items and services paid for under the OPDS, and a CF adjustment can increase or decrease the entire OPDS by a percentage-factor. However, the adjustment cannot reduce the relative payment rate for a *particular set of items or services*. If the Agency instead wants to adjust payment rates for specific services, it must do so in a budget-neutral manner.²³

²¹ 42 U.S.C. § 1395l(t)(2)(F)

²² 42 U.S.C. § 1395l(t)(9)(C)

²³ 42 U.S.C. § 1395l(t)(9)(B)

While Medicare statute allows for reductions to the total amount of Medicare payments in limited circumstances through changes to the CF, there is no statutory mechanism through which CMS is permitted to reduce the total amount of Medicare spending by cutting reimbursement rates for a specific service or group of services. By requiring budget neutrality for service-level payment reductions, the statute is intended to limit any incentive for CMS to engage in unjust cost-control measures.

Therefore, we believe that contrary to CMS' assertion, 42 U.S.C. § 1395l(t)(2)(F) does *not* confer authority to implement prior authorization processes in response to unnecessary increases in the volume of HOPD services. Rather, as noted above, if the methodology developed by CMS shows that there are unnecessary increases in the volume of HOPD services, the Agency's recourse is to modify the CF and effectuate an across-the-board reduction in payment rates under the OPPS.

The ACS does not support the application of prior authorization to any services under the Medicare program. We believe that there are existing tools in place that CMS can rely upon (e.g., clarification of Medicare coverage criteria within National Coverage Determinations, auditing of claims submitted by providers whose ordering patterns stray significantly from clinical guidelines) to identify and control for the potential overutilization of services that may not be medically necessary.

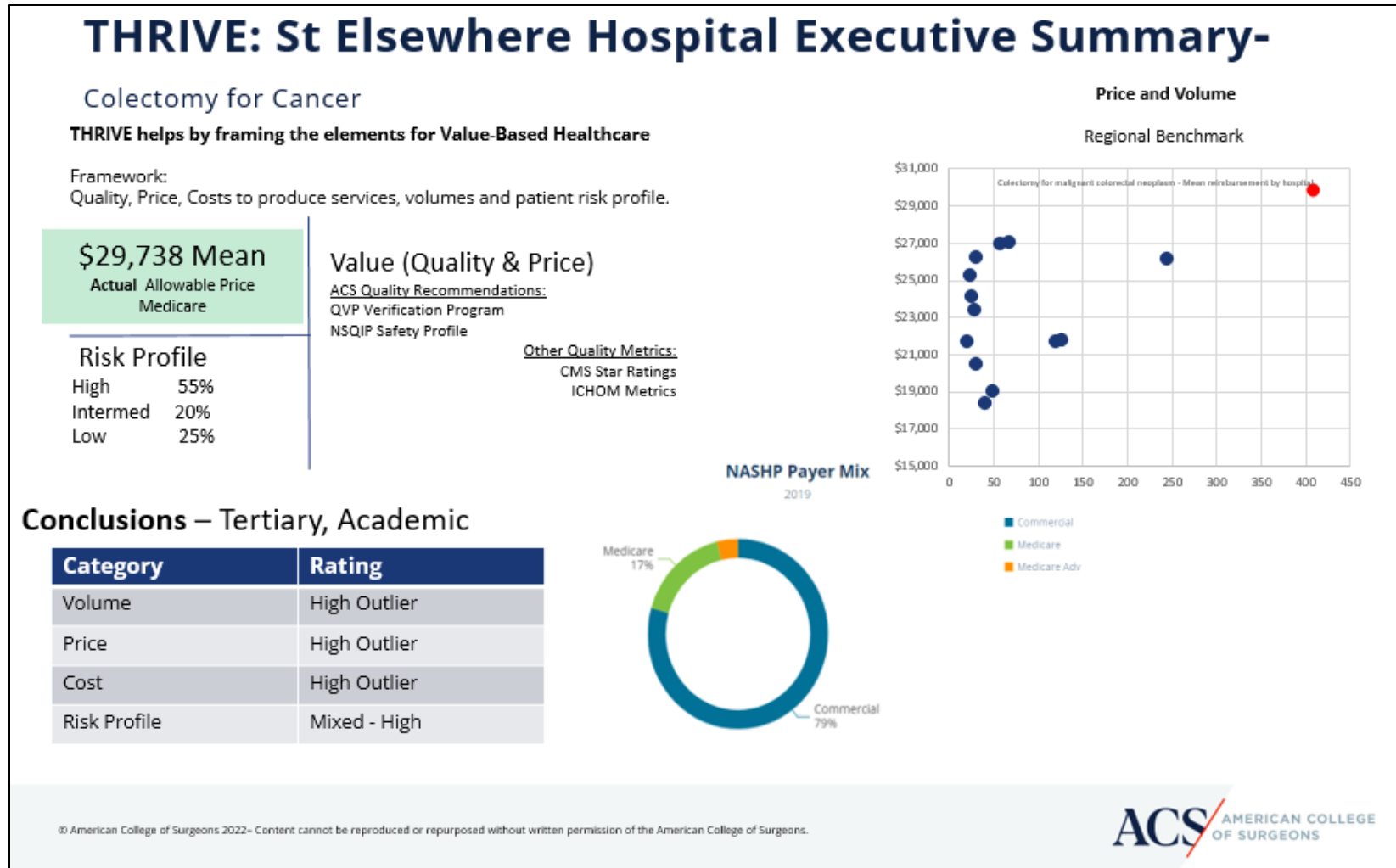
The ACS appreciates the opportunity to provide feedback on this proposed rule and looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Vinita Mujumdar, Chief of Regulatory Affairs, at vmujumdar@facs.org, or Jill Sage, Chief of Quality Affairs, at jsage@facs.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'P. Turner', with a long horizontal flourish extending to the right.

Patricia L. Turner, MD, MBA, FACS
Executive Director

Figure 1. Contextualizing Volume to Support Understanding Value ²⁴



²⁴ In this figure, St. Elsewhere is a fictitious hospital and the various reports are data taken from different sites in the pilot. The results depicted reflect a blend of 4-5 different facilities. Note: this example is for illustrative purposes only.