

September 8, 2023

Chiquita Brooks-LaSure, MPP Administrator Centers for Medicare & Medicaid Services Attention: CMS-1786-P P.O. Box 8010 Baltimore, MD 21244-1810

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction (CMS-1786-P)

Dear Administrator Brooks-LaSure:

On behalf of the over 88,000 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) 2024 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule published in the *Federal Register* on July 31, 2023.

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 more than 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 2024. Our comments below are presented in the order in which they appear in the rule.

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HOSPITAL OUTPATIENT DEPARTMENT PAYMENT AND POLICY PROPOSALS

Services That Would Be Paid Only as Inpatient Services

Changes to the Inpatient Only (IPO) List

CMS states that it received several requests from interested parties recommending particular services to be removed from the IPO list. The Agency asserts it did not find sufficient evidence that these services meet the criteria to be removed from the IPO list for CY 2024. Therefore, CMS does not propose to remove any services from the IPO list.

We are disappointed that CMS did not acknowledge the ACS' request to remove the following anterior abdominal and parastomal hernia repair Current Procedural Terminology (CPT®) codes from the IPO list for CY 2024:

- **CPT 49596** (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 49616** (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 49617** (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 49618** (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 49621** (Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; reducible)
- **CPT 49622** (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)

In the CY 2023 OPPS, CMS stated that, after clinical review of these services, the Agency determined that these procedures require a hospital inpatient admission or stay and finalized the addition of CPT codes 49596, 49616-49618, and 49621-49622 to the 2023 IPO list.

Following publication of the CY 2023 OPPS final rule, the ACS conducted an extensive review of Medicare utilization data for predecessor anterior abdominal hernia repair CPT codes 49560, 49561, 49565, 49566, 49570, 49572, 49580, 49582, 49585, 49587, 49590, 49652, 49653, 49654, 49655, 49656, and 49657. We notified CMS via a <u>letter</u> sent on February 13, 2023 of our findings, which indicated that none of these predecessor codes were on the IPO list and were all included on the ASC covered procedure list in CY 2022.

In our February 2023 letter to the Agency, we further noted that although a patient undergoing a procedure described by codes 49596, 49616-49618, and 49621-49622 will typically (>50%) be admitted to the hospital under inpatient status, there are instances when it will be appropriate for the patient to undergo these procedures on an outpatient basis that does not include a two-midnight stay, as was the case for some patients undergoing the procedures reported with the predecessor codes. We also believe that these anterior abdominal and parastomal hernia repair codes meet CMS' five criteria for IPO list removal:

- 1. Most outpatient departments are equipped to provide the services to the Medicare population. The Medicare claims data for the deleted predecessor codes indicate that such services were reported at times with outpatient or ASC status, not just inpatient status. Therefore, we conclude that most outpatient departments are equipped to provide the services to the Medicare population.
- 2. The simplest procedure described by the code may be furnished in most outpatient departments. As previously noted, the Medicare claims data for the deleted predecessor codes indicate that such services were reported with all 3 statuses—inpatient, outpatient, and ASC. Therefore, we conclude that all of these services were deemed by CMS as appropriate to be furnished in outpatient departments.
- 3. The procedure is related to codes already removed from the IPO list. All predecessor anterior abdominal hernia repair CPT codes (49560, 49561, 49565, 49566, 49570, 49572, 49580, 49582, 49585, 49587, 49590, 49652, 49653, 49654, 49655, 49656, and 49657) were on the ASC covered procedure list prior to deletion and replacement by codes 49616-49618 and 49621-49622. Not only were these codes excluded from the IPO list, but were also added to the ASC covered procedure list.
- 4. A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis. Medicare claims data indicate that the predecessor codes were furnished across the U.S. on an outpatient basis.
- 5. A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by CMS for addition to the ASC covered procedures list. All predecessor anterior abdominal hernia repair CPT codes (49560, 49561, 49565, 49566, 49568, 49570, 49572, 49580, 49582, 49585, 49587, 49590, 49652, 49653, 49654, 49655, 49656, and 49657) were on the ASC covered procedure list prior to deletion and replacement by codes 49616-49618 and 49621-49622.

Given the above evidence, we do not believe that CPT codes 49596, 49616-49618, and 49621-49622 should have been added to the IPO list in CY 2023. We again request that CMS remove these six codes from the IPO list for CY 2024 and beyond.

Solicitation of Public Comments on the Services Described by CPT Codes 43775, 43644, 43645, and 44204

CMS solicits comments regarding whether the services described by the following CPT codes are appropriate to be removed from the IPO list:

- **CPT 43775** (Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy))
- **CPT 43644** (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Rouxen-Y gastroenterostomy (roux limb 150 cm or less))
- **CPT 43645** (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption)
- CPT 44204 (Laparoscopy, surgical; colectomy, partial, with anastomosis)

The Agency states that it does not have adequate information to determine whether such procedures can be safely performed in the HOPD setting and specifically requests evidence that these services (1) can be performed safely on an outpatient basis, and (2) meet any of the five criteria to be removed from the IPO list.

The ACS strongly opposes removing CPT codes 43775, 43644, 43645, and 44204 from the IPO list and urges CMS to maintain their IPO status. We do not believe that the services described by CPT codes 43775, 43644, 43645, and 44204 meet any of the Agency's criteria for IPO list removal as described below.

- 1. Most outpatient departments are equipped to provide the services to the Medicare population. These services involve the resection of a portion of the stomach or colon. Close monitoring during the first 24 to 48 postoperative hours is crucial for early detection of complications such as internal bleeding, leaks, sepsis, bowel function, and cardiorespiratory function that would require immediate access to surgical, radiological, or other interventions. This level of monitoring requires the vast majority of patients undergoing these procedures to be placed in the intensive care unit for at least the first night following surgery. Most outpatient departments are <u>not equipped</u> to provide this level of care.
- 2. The simplest procedure described by the code may be furnished in most outpatient departments. No level of these procedures is considered "simple." Patients undergoing bariatric procedures described by CPT codes 43775, 43644, and 43645 are, by definition, obese and will have comorbid conditions either due to their obesity or causing their obesity. Patients undergoing the

colectomy procedure described by CPT code 44204 will be debilitated due to cancer or diverticulitis. These patients require significant monitoring that is not available in most outpatient departments.

- 3. The procedure is related to codes already removed from the IPO list. CPT code 43775 corresponds most closely to CPT code 43631 (*Gastrectomy, partial, distal; with gastroduodenostomy*). CPT codes 43644 and 43645 correspond closely to CPT code 43633 (*Gastrectomy, partial, distal; with Roux-en-Y reconstruction*). CPT codes 43631 and 43633 are maintained on the proposed IPO list for CY 2024. The minimally invasive nature of these procedures does not diminish the need for inpatient monitoring in Medicare patients with severe obesity, as the morbidity of the corresponding procedures is the same (i.e., gastrectomy and gastrectomy with reconstruction).
- 4. A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis. We have no information to suggest that these procedures are typically furnished in numerous hospitals on an outpatient basis.
- 5. A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by CMS for addition to the ASC covered procedures list. These procedures are not on the ASC list and should not be on the ASC list. ASCs are not equipped to safely provide these services for the reasons stated above.

NONRECURRING POLICY CHANGES

OPPS Payment for Dental Services

Beginning in CY 2023, certain dental services that are inextricably linked to, and substantially related and integral to the clinical success of, other Medicare-covered medical services—including organ transplantation—became eligible for reimbursement under Medicare Parts A and B. Only 57 Current Dental Terminology (CDT®) codes were assigned to Ambulatory Payment Classifications (APCs) and made payable under the OPPS for CY 2023.

For CY 2024, the Agency proposes to assign 229 additional CDT codes to clinical APCs to enable them to be paid for under the OPPS when applicable payment and coverage requirements are met. Assigning more dental codes to clinical APCs would result in greater consistency in Medicare payment for different sites of service and help ensure patient access to dental services for which payment can be made when performed in the hospital outpatient setting.

The ACS, in coordination with the American Society of Transplant Surgeons (ASTS), thanks CMS for its expansion of Medicare coverage for dental procedures that are substantially related and integral to the clinical success of organ transplantation. We believe that this expansion of dental coverage has the potential to significantly increase access to transplantation for Medicare patients, especially those in medically underserved populations, who historically have had limited access to dental care. In this

regard, we commend the Agency for its proposals to assign APCs to a wide array of dental services and to include dental services on the ASC Covered Procedures List (CPL). Given the limited availability of hospital outpatient operating rooms (ORs) available for dental cases, it is very important that ASC settings become available for the performance of dental procedures for patients whose dental treatment requires the administration of general anesthesia in OR settings.

However, we are concerned that the CMS does not specify the criteria used to determine which dental procedures to assign to APCs or which dental procedures to include on the ASC CPL. In addition, we note that the payment rate for dental rehabilitation (Healthcare Common Procedure Coding System (HCPCS) code G0330), which may be applicable to dental cases requiring extensive work and multiple procedures, would be reduced by over 45 percent under the OPPS if adopted without change. Furthermore, the Agency established an ASC facility rate of less than \$500 for these procedures, an amount that we believe may be insufficient in light of the specialized dental equipment and personnel required for these services. We urge CMS to work with the surgical and dental communities to review the lists of dental procedures for which OPPS and ASC payment are available and to establish payment rates that are sufficient to assure OR availability for those transplant candidates whose dental procedures must be provided under general anesthesia.

REQUIREMENTS FOR THE HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM

Surgical Care in the Outpatient Setting is Increasing

The U.S. healthcare system and care delivery are constantly evolving, including the business model, available technology, and even the settings in which care can now be delivered. In recent years, there has been growth in the services that can be offered in the outpatient setting. This is evident in the national growth of the ASC market, which was \$34.73 billion in 2020 and is projected to grow to \$58.85 billion by 2028. Such growth in the outpatient market can be attributed to payers incentivizing procedures in low-cost settings. With the increase in surgical procedures moving off the IPO list, increasingly complex procedures are occurring in an ambulatory environment. However, quality and safety measurement and incentives have not kept pace in the outpatient setting, especially compared to efforts to track quality in the inpatient setting or at the clinician level. The Ambulatory Surgery Center Quality Reporting (ASCQR) and Hospital Outpatient Quality Reporting programs are in their infancy, providing very little information to stakeholders about care—including patients seeking care and physicians referring care, as well as for internal quality improvement for clinical teams. Given this, there is very little discussion on patient-centered value-based care in the outpatient setting. The system must work toward providing this information in a transparent way to build trust among patients.

¹Fortune Business Insights. U.S. Ambulatory Surgical Centers Market Size, Share & COVID-19 Impact Analysis, By Type of Center (Single-specialty and Multi-specialty), By Ownership (Physician-owned, Hospital-owned, and Corporate-owned), By Application (Diagnostic Services and Surgical Services), and Forecast, 2021-2028. https://www.fortunebusinessinsights.com/u-s-ambulatory-surgical-centers-market-106323. Published February, 2006. Accessed August 31, 2023.

²Newitt P. Payers are Pushing Physicians to ASCs. *Becker's ASC Review*. July 28, 2022. https://www.beckersasc.com/asc-coding-billing-and-collections/payers-are-pushing-physicians-to-ascs.html#page=5. Accessed August 31, 2023.

Some questions to ask include: do patients wish to find more affordable care in outpatient settings without regard to their overall goals of care? Has care become a disjointed set of services, a single care event, without regard for the end objective of a better outcome or quality of life for the condition under treatment, as long as that single service meets a payer's price point? Has moving care to the outpatient setting become a race to the bottom in overall value by overly focusing on cost without realizing the importance to improve quality?

These questions are not an excuse for maintaining the status quo. Most realize that our healthcare system was once the envy of the world because of our advances in medical science. Along the way, our business model resulted in perverse incentives, and we have achieved the most advanced medical science with the least affordability for our patients. As we look across care settings and reframe care by altering business models, we must do so within a framework that focuses on the patient. To be patient-centric means more than altering a site of service or focusing on one metric for one source of care in the complex of a patient's complete care journey. A new framework is needed that looks across the complete care pathway and considers the entire program of care for patients. As part of this program, there should be guardrails to keep patients safe—including verification that there are the necessary resources and structures in place to deliver optimal care. The ACS supports a framework that looks at the quality program needed for the care of a specific condition or episode; episodes should be standardized and verified. This measure framework should be agnostic to the setting of care or the payment program so that there is one standard of care across settings. In other words, the same measure framework should be built out to be used across CMS quality payment programs, as well as by private payers. Our comments below describe how we can use a programmatic measure framework to ensure high quality and safety in the outpatient setting.

The ACS realizes the struggle the Agency faces in trying to define the transformation of our healthcare system from a volume-driven approach that has resulted in the current conundrum to an approach that prioritizes safe, affordable, good, and equitable care for all patients. Our programmatic approach to care, described in more detail below, is consistent with the applied science of medicine. If we are to encourage the change we wish to see, the business model must suit the delivery of a program of care and meet the objectives of affordability. These remarks call for a change in the way that CMS thinks about influencing care. We ask for this change within the Agency's construct for quality and value because we believe it better fits the clinical care model and helps patients find the care they seek. We believe it focuses the care team on the patient and on better overall outcomes—these actions result in more affordability. The lens through which we transform health care must be different from the current landscape. The current state of change is slow-walking, burdensome, and not always headed in the right direction. We all, including CMS, must change to something that rethinks and leverages advances in medical science and does not seek a fix at each single service provided. Care must have value to patients through the sum of all services within a program of care for a patient.

Critical to the Increase in Surgical Care in the Outpatient Setting: Ensuring Quality and Safety

At the root of all quality programs is the ability to form a care team around the patient, a cultural

commitment to quality, an understanding and acknowledgement of the patient's goals for their care, trackable quality and safety metrics, improvement cycles, and informed patients. When you combine elements of quality programs and business models that strive to offer affordable care, the system should be able to reach its goal of providing valuable, patient-centered care to patients. This requires us to refocus care incentives on patient goals and values.

As healthcare becomes increasingly complex and more services are administered in outpatient settings, it is important that we also invest in defining standard episodes that are performed in these settings and align quality programs to the specific care delivered in this environment. For most patients, what matters is meeting their overall goals of care in a trusting environment and how well they can afford that care. From the ACS' perspective, it has been difficult for the Agency and payers in general to appreciate quality and cost from a patient's perspective—this is evident in the measures reported in the ASC/outpatient setting as well as other CMS programs. For example, when suffering from a specific condition, patients cannot turn to the current programs to find information that will give them comfort in making an informed choice based on their values. The information is vague and too general, focusing on siloed measures of avoidable harm. It does not fit the episode of care that a patient will experience. Imagine a patient whose health deteriorates despite the best of primary care and needs a specialist. Patients rely on their primary care provider for a referral and may simultaneously wonder if the referral they receive is the best fit for them. From this perspective, it becomes clear that patients need a framework that reflects a well-defined, standard episode of care. With a standard, the outcomes for an episode become "benchmarkable" and the information can be made available to their primary care and other care decision-makers. It starts to become valuable information in their search for care that best suits them.

There are multiple ways to define the episode or bundle—time period, clinicians, services, facilities, and other elements that constitute the episode. As mentioned, the ACS believes that the most logical way to do this is by examining the healthcare experience from the patient's perspective. Some of the key questions to consider when developing episodes are: who are the role players within the episodes; how do they define outcomes that are meaningful to patients? Also, how do they generate knowledge to drive improvement cycles and continuously iterate on improvement?

Programmatic Approach for Patient-Centered Quality

An episode of care should be as inclusive as possible of the services, resources, and personnel necessary to achieve the patient's desired outcome for the defined condition or diagnosis. The resulting episode in an ASC must consider all the associated services for that episode and the ASC services inclusive of both quality and cost, especially for procedures and other specialty care. To do this, first we must define the service line and the episodes within that service line. Within each service line there are episodes of care or bundled services. Service line examples, also referred to as "programs," from a surgical perspective include ACS Trauma programs, Geriatric Surgery, Bariatric Surgery, ACS Cancer programs, and more. The programmatic approach is a service line view modeled after ACS quality programs, which are commonly linked to verification or accreditation. We think of verification as the foundation necessary to

give the care team what is needed to deliver optimal care. For example, a cancer service line may include a specific cancer and its procedural episodes including surgical oncologic services for biopsy and excision, medical oncology and/or radiation oncology. These services include ancillary services in imaging and pathology. CMS should consider doing this by acknowledging a programmatic approach to measurement that maps to the goals within the episode of care.

Why Verification Programs?

Our delivery systems have become complex. This makes it difficult for hospital administrations to appreciate the multitude of interconnected clinical needs and services with the business operations to transact and resolve all the claims to keep the fiscal house in order. Resources are barely enough to "keep all the trains running" while meeting an array of ever-changing regulations, paying attention to innovative technologies, retooling, and so forth. The ability to step back to see the "forest through the trees" and effect change has become a significant challenge. **Hospitals that have participated in our verification programs for their key service lines find they are more prepared and aligned to adapt than those unverified sites.** For example, evidence in peer-reviewed literature demonstrates that mortality in verified trauma centers is statistically lower than in non-verified centers; bariatric surgical care in verified bariatric centers under the Metabolic and Bariatric Surgical Quality Improvement Program (MBSAQIP) has lower mortality, lower costs, lower complications, and lower failure-to-rescue; and breast cancer care is statistically superior in verified breast cancer centers. ^{3,4,5,6,7,8,9} To reach the Agency's goals for care delivery, care teams must find the capacity to change and find the right rewards in place for change to happen. Our delivery systems need more than alternative payments. Verification is a framework that meets a need.

This framework can be implemented with "programmatic quality measures," which: 1) align multiple structure, process, and outcome measures; 2) target condition or population specific care; 3) apply to multiple quality domains; 4) address the continuum of care; and 5) are informative to and actionable for care teams and patients. The integration of structures, processes, and outcomes for common clinical purposes is fundamental to programmatic measures. More widespread implementation of these measures would benefit patients by increasing transparency and empowering patients to make effective decisions about where to receive care. From the payer perspective, taking a programmatic quality approach aligns and defines the previously mentioned general service lines that brand care in a community setting. Within a population, it is possible to define patient service lines that best suit the

³MacKenzie EJ, Rivara FP, Jurkovich GJ, et al. A National Evaluation of the Effect of Trauma-Center Care on Mortality. N Engl J Med. 2006;354(4):366-378.

⁴ Nguyen NT, Nguyen B, Nguyen VQ, Ziogas A, Hohmann S, Stamos MJ. Outcomes of Bariatric Surgery Performed at Accredited vs Nonaccredited Centers. *J Am Coll Surg*. 2012;215(4):467-474.

⁵ Morton JM, Garg T, Nguyen N. Does Hospital Accreditation Impact Bariatric Surgery Safety? Ann Surg. 2014;260(3):540-548.

⁶ Baidwin NK, Bachiashvili V, Mehta, T. A meta-analysis of bariatric surgery-related outcomes in accredited versus unaccredited hospitals in the United States. Clin Obes. 2020;10e12348.

⁷ Berger ER, Wang CE, Kaufman CS, et al. National Accreditation Program for Breast Centers Demonstrates Improved Compliance with Post-Mastectomy Radiation Therapy Quality Measure. *J Am Coll Surg.* 2017;224(3):236-244.

⁸ Miller ME, Bleicher RJ, Kaufman, CS, et al. Impact of Breast Center Accreditation on Compliance with Breast Quality Performance Measures at Commission on Cancer-Accredited Centers. *Ann Surg Oncol.* 2019;26(5), 1202-1211.

⁹ Winchester DP. The National Accreditation Program for Breast Centers: Quality Improvement Through Standard Setting. Surg Oncol. 2011;20(3):581-586.

market. A musculoskeletal service line may have a total joint replacement program. A women's health service line may include female organ specific oncologic services or a maternity care program. For public transparency and business intelligence, each clinical domain should portray safety (preventable harms), affordability, overall patient goals (Patient Reported Outcomes (PROs)/outcomes), and equitability standards. The programmatic approach can define a standardized definition of an episode where quality (numerator) maps to the denominator (price/cost) and is agnostic across payers and payment programs. These measures can be developed for a multitude of services lines. We envision approximately 12 to 15 major condition-based programmatic measures can be developed to supplement the primary-care focused CMS Universal Foundation. They can eventually evolve to include existing CMS quality measures that measure a process or outcome for the same condition. Verification of a condition should be completed once a year and should not add burden to the facility and care team's already full plate. Individual episode-specific measures are tracked daily, providing episode-based knowledge to the care team and can help the facility and payer look across the delivery system. When reported publicly, this information can help patients find care which can restore trust in healthcare.

Example: Age-Friendly Programmatic Measure for CMS Hospital Inpatient Quality Reporting (IQR) Program

In early 2023, the ACS submitted a programmatic measure, the *Age-Friendly Hospital Measure*, to the CMS Measures Under Consideration (MUC) for inclusion in the Hospital IQR Program. The measure demonstrates how programmatic measures could be designed and implemented in CMS programs. ¹¹ The *Age-Friendly Hospital Measure* considers the full program of care needed to care for geriatric patients and aligns with the core principles of the ACS Geriatric Surgery Verification (GSV) Program. It incentivizes hospitals to take a holistic approach to the care of older adults by implementing multiple data-driven modifications to the entire clinical care pathway, from the emergency department, to the OR, to the inpatient units, and beyond. The measure puts an emphasis on the importance of defining patient (and caregiver) goals not only from the immediate treatment decision but also for long-term health and alignment of care with what the patient values. It includes five domains with attestations that acknowledge certain processes, outcomes, and structures that are necessary for providing high-quality, holistic care for older adults.

Figure 1 below illustrates how the clinical domains of a verification program map for the creation of a programmatic measure. The ACS designed the *Age-Friendly Hospital Programmatic Measure* using a core set of transparency metrics that encompass safety, affordability, acknowledgement of patient goals, and equitable care. These variables include essential elements of the ACS GSV Program. Once a facility completes the steps of verification successfully, the diamond emblem signals to patients that the facility has completed the requirements of verification and is dedicated to delivering high quality care in this (geriatric) population. These standards seek to assure patients of the essential components needed to transition from silos to team-based care and ensure the integrity of a quality program for a condition.

¹⁰ Jacobs DB, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher LA. Aligning Quality Measures across CMS – The Universal Foundation. N Eng J Med. 2023;388:776-779.

¹¹ The measure was reviewed by the Measure Application Partnership (MAP) and was conditionally supported for rulemaking following the group's review.

Figure 1. Programmatic Measure Example: Age-friendly Hospital Measure

Develop a programmatic composite **Geriatric Surgery Transparency Map and** For use in MIPS **Clinical Domains** And transition to MVP & APMs **Verification Program Measure Elements** Generate a core set of transparency metrics which vary AGE FRIENDLY HOSPITAL according to setting (rural, safety PROGRAMATIC MEASURE net, community and academic medical center) and for use by CMS DOMAIN 1: Eliciting Patient Healthcare in its many payment programs Goals Within each of the clinical domains, establish the business intelligence (BI) for public transparency. These DOMAIN 2: Responsible Medication should portray Safety (preventable Management harms), Affordability, overall Patient Goals (PROs/Outcomes) DOMAIN 3: Facility Screening and and Equitability standards. Intervention (i.e. mobility, mentation, and Included in the transparency BI is a **Geriatric Surgery** malnutrition) statement of volumes and a Verification patient risk profile. For example, DOMAIN 4: Social Vulnerability (social does a site attend to high, isolation, economic insecurity, ageism, intermediate or low risk patients limited access to healthcare, caregiver stress, (use Medicare Advantage (MA) risk profilers). Patients know if they elder abuse) personally are high risk and should know where to match care to their DOMAIN 5: Age Friendly Care Leadership

It is important to mention that we are not suggesting CMS build out episodes and programmatic measures specifically for the ambulatory care setting. We are advocating for a standardized program to be built for key conditions regardless of setting. Once the program is built, the Agency can determine how to incorporate programmatic measures across settings and payment programs such as the IQR as described above, the Quality Payment Program, Medicare Shared Savings Program, ASCQR, Hospital OQR, etc. but the program, including the transparency metrics, remain the same.

Though beyond the specific scope of this proposed rule, key to successfully implementing this framework is ensuring that CMS is thinking about developing a numerator (quality, safety, and equitable care metrics) that appropriately maps to the denominator (cost metrics). We see the numerator/denominator as a non-numeric expression that can be used to determine the value of care based on what matters to the patient. It is also critical that access to care is not forgotten when we discuss value, accounting for the risk profiles of patients and the price variation in providing care based on risk will help to promote efforts to increase access and promote health equity.

What Happens When Risk Adjustment is Lacking in Payment Models?

Clinical risk differences should not be ignored. Physicians know that patients with elevated risk require more services and are subjected to more variations in outcomes. Their complications are more frequent and resource use varies when compared to low-risk patients. The unadjusted payment will result in "cherry picking." If the payment model does not appreciate the episode's high-risk cost, specialists will migrate to low-risk patients and high-risk patients will have further reduction in access. In bundled care or episodes of care, a triggering event opens the episode and leads to assignment of pre-trigger and post-

trigger services to complete the episode build. When patients are more complex and the care is more involved and complicated, the pre-trigger and post trigger events require a breakdown of patients into risk categories and into post-triggering sequelae that consume more services. A high-risk patient with 3 to 5 unstable chronic conditions who undergoes a specialty care event will naturally consume more resources than a low-risk patient with no comorbidities.

<u>Proposed Modification of the Appropriate Follow-Up Interval for Normal Colonoscopy in</u> <u>Average Risk Patients Measure Denominator Change to Align with Current Clinical Guidelines</u> Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

In 2021, the United States Preventive Services Task Force issued a revised Final Recommendation Statement on Colorectal Cancer (CRC) Screening that replaced the prior USPSTF 2016 Final Recommendation Statement. The revised statement includes a number of updated policy recommendations based on new evidence and understandings of CRC and CRC screening, such as recent changes in clinical guidelines to begin CRC screening at age 45 instead of age 50. To account for these updates in the guidelines, CMS proposes to modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the Colonoscopy Follow-Up Interval) measure denominator to "all patients aged 45 to 75 years" for the Hospital OQR Program, beginning with the CY 2024 reporting period/CY 2026 payment determination. **The ACS supports the proposed changes to this measure.**

Proposed Re-Adoption with Modification of the HOPD Volume Data on Selected Outpatient
Surgical Procedures Measure Beginning with the Voluntary CY 2025 Reporting Period Followed
by Mandatory Reporting Beginning with the CY 2026 Reporting Period/CY 2028 Payment
Determination

CMS proposes to re-adopt the HOPD Procedure Volume measure with modification, with voluntary reporting beginning with the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. Prior to removing this measure, CMS finalized that HOPDs would report all-patient volume data with respect to selected outpatient procedures in eight categories:

- 1. Cardiovascular
- 2. Eye
- 3. Gastrointestinal
- 4. Genitourinary
- 5. Musculoskeletal
- 6. Nervous System
- 7. Respiratory
- 8. Skin.

The sole modification to this measure is that instead of collecting and publicly displaying data

surrounding these eight broad categories, CMS would more granularly collect and publicly display data reported for the top five most frequently performed procedures among HOPDs within each category. The top five procedures in each category would be assessed and updated annually as needed to ensure data collection of the most accurate and frequently performed procedures.

As we have stated in past responses similar measures, the ACS does not support the use of volume measures in the OQR program without additional information on the quality of care. 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.

We reiterate the following points that we shared with CMS in our response to the *Request for Comment* on *Reimplementation of Hospital Outpatient Volume on Selected Outpatient Surgical Procedures*Measure or Adoption of Another Volume Indicator in the CY 2023 OPPS proposed rule:

- 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. 12
- 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." 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. If the goal is to move to value-based healthcare, the delivery of

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¹² Statement on Credentialing and Privileging and Volume Performance Issues. American College of Surgeons. April 1, 2018. https://www.facs.org/about-acs/statements/credentialing-and-privileging-and-volume-performance-issues. Accessed September 7, 2023.

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.

Given these factors, 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. 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.

PROPOSED UPDATES TO REQUIREMENTS FOR HOSPITALS TO MAKE PUBLIC A LIST OF THEIR STANDARD CHARGES

Hospital Price Transparency Consumer-Friendly Displays and Alignment with Transparency in Coverage and No Surprises Act Requirements

Introduction

The ACS recognizes the importance of making accurate, actionable information available about the price a patient can expect to pay for care. We also welcome CMS' acknowledgement that the lack of consistency and standards in pricing information provided (both among hospitals and across transparency programs) has the potential to create unnecessary confusion for patients. The Agency notes that standardizing hospital pricing information alone in this context could be difficult because hospitals may set standard charges in unique ways, "resulting in charge/item and charge/service combinations that are often unique to that hospital."

Having accurate prices is important, as is standardization, both of which are reflected in this proposed rule. Allowing patients to look up reliable information on how much a given service or appointment will cost through a list of shoppable services is an important step and ensuring that such prices are comparable across hospitals is vital. However, when a diagnosis is more severe or care is more complex, the value of information on the prices of individual services quickly diminishes. This is because more complex care involves large numbers of items, services, clinicians, and even multiple sites of service, some of which are not independently "shoppable" once the physician or delivery system have been selected. Furthermore, many of the services that a patient with a complex condition receives may not be provided at or by a hospital and therefore would not be included in the list of standard charges. If CMS intends to make available information more consumer-friendly, with the patient being the ultimate consumer, then a different approach will be needed for the majority of care provided and billed. For these reasons, it is logical to move away from a transactional, single service approach to price

transparency—which adds significant burden with minimal benefit—and instead adopt an episodic approach. A large portion of healthcare spending could be accounted for using episode definitions currently available, and with minimum investment, the vast majority of all charges could be accounted for.

However, as an organization founded to improve the quality of care for surgical patients, the ACS would be remiss if we did not note the indispensable nature of quality metrics that align with price transparency information. In the absence of specific, reliable, and actionable data on quality, patients cannot make decisions based upon value. This must be quality information specific to the type of care being provided and include the same services and providers measured for price. Episodes of care lend themselves to this type of value assessment. Without trusted quality information, patients may choose what appears to be the least expensive site of service even though that site may or may not have the structures, processes, and personnel in place to provide the highest quality care. Alternately, some patients, especially those undergoing treatment to the extent that they will likely reach their out-of-pocket maximum, may choose the most expensive site of care using price as a proxy for quality. The ACS has written extensively in letters to CMS and other entities about the importance of having a trusted source of information on the quality and safety of surgical care.

Ideally, to avoid unnecessary confusion, prices used for physician scoring or public reporting should also be comparable to prices provided to patients as part of price transparency programs. Good faith estimates (GFEs) and advanced explanation of benefits (EOBs) for the summary of all services a patient would expect to receive are currently administered as separate programs. These efforts are also completely unrelated to the cost metrics accounting for 30 percent of the final Merit-Based Incentive Payment System (MIPS) score for physicians in fee-for-service Medicare representing the cost (or price) of care. The assessment of cost under MIPS currently relies heavily on broad measures with few exclusions (Medicare Spending Per Beneficiary and Total Per Capita Cost of Care) or a small number of overly narrow episode-based cost measures applicable to only a small (but growing) percent of physicians.

Like with quality, these measures are frequently reported at the large group level, and the episodes and measures in question may not even capture the price of care provided by the physician being measured. It is therefore conceivable that the pricing information received by patients to inform their assessment of value and care decisions will differ substantially from the pricing information used for payment purposes, resulting in confusion and mixed incentives. For example, under current requirements, a patient could receive an estimate for a scheduled service at an unrealistically low price due to a lack of completeness in defining the inclusive list of services which are key to their care. That patient could also find MIPS cost score information that shows the same provider as being more expensive than average because his or her score was based on population measures for the employer. Meanwhile, the truth could be somewhere in the middle. Having standardized episode definitions and grouping logic and using these standards across programs could reduce complexity, burden, and the likelihood of confusion to the patient.

CMS seeks comment on the consumer-friendly components of the Hospital Price Transparency (HPT), Transparency in Coverage (TiC), and No Surprises Act (NSA) policies. We provide feedback to the Agency's specific questions below.

1. How, if at all, and consistent with its underlying legal authority, could the HPT consumer-friendly requirements be revised to align with other price transparency initiatives?

Given the requirements and authorities under the TiC and NSA, there is no longer a benefit to hospitals reporting standard charges. Hospitals are required to publish shoppable services provided by their facility, but such price information is not specific to an individual patient. The TiC requirements, on the other hand, are more beneficial to a patient compared to the hospital transparency requirements because health plans are required to provide real time cost-sharing liability under the plan's deductible, coinsurance, and copay structure that is based on actual rates, allowed amounts, and individual-specific cost-sharing requirements. The NSA GFE requirements cover, in part, uninsured and self-pay patients. As such, the TiC and NSA requirements are broader than the hospital transparency requirements, making the details shared by hospitals less useful to consumers. Patients should have access to standardized, trusted, and validated price information, and making this information available to patients will be more straightforward with health plans as the primary generator of this information.

In addition, we believe that hospitals and health systems should instead focus on delivery of care rather than providing price information. While some regulatory obligations are necessary, requiring institutions to perform regulatory activities, such as those related to transparency, that are not focused on care delivery should be limited. Such activities, possibly requiring a subcontractor, draw resources away from clinical services, clinical staff recruitment, quality improvement, and more. In the case of transparency, heath plans are also better situated to provide patient-specific information in a consumer-friendly format given that the plan is responsible for determining the patient's cost-sharing liability.

We also do not believe that hospitals and physicians should be burdened with defining and providing episode pricing. Once patients enter into a care pathway, especially when that pathway extends over time and multiple sites of service, it is an additional burden to administer business logic that would best define the total cost of care. This burden should not be an excuse for dismissing the need for price transparency. Instead, it is important that the payer community step forward and underwrite the business logic needed to advance price transparency toward its ultimate utility for patients and other decision-makers.

2. How aware are consumers about healthcare pricing information available from hospitals? How can CMS raise consumer awareness?

There is most likely a lack of awareness among patients that healthcare pricing is available from hospitals. More broadly, there is also a lack of awareness among patients of the transactional nature of medicine. In the case of surgery, many services are provided in the pre-, intra-, and postoperative stages

in both the facility and office settings. Surgeons themselves might only be responsible for less than 10 percent of the total cost of care for the entire surgery and related services. We urge CMS to continue to study and test how to best present healthcare pricing information to patients and to learn more about how patients consume and use this information. As noted above, we believe that hospital pricing information is less useful than health plan information, so our comments apply to the Agency's approach to the requirements for health plans rather than to requirements for hospitals.

3. What elements of health pricing information do consumers find most valuable in advance of receiving care?

One important element of valuable pricing information is the out-of-pocket cost to a patient. However, patients must be able to assess out-of-pocket cost estimates for a given episode in its entirety, not simply for the individual service items. Pricing information should be presented as episodes rather than single services so that patients receive a more comprehensive picture of the care they will receive. The episodes should also be sufficiently nuanced to encompass atypical patients. Patients have comorbidities, and more complex patients with multiple comorbidities tend to require more clinical services in support of treating the primary condition under consideration. In sophisticated pricing models, it is possible to define expected prices based on patient comorbidities.

The ACS believes that the episode logic supporting these processes can be most readily accomplished and maintained by an impartial, nongovernmental, not-for-profit organization with the support and input of the medical community to verify clinical content. We have been involved in the formulation of such an entity, the not-for-profit Patient-Centered Episode System (PACES) Center for Value in Healthcare, which was officially incorporated in 2019 to create a single industry standard for defining clinical episodes of care using the current medical record and payment systems, and based on consensus across multiple stakeholders including providers, payers, purchasers, and consumers.

The basic foundation of any episode grouper is the business logic which ultimately must align with the clinical care pathway. Most groupers rely on a business logic which runs inside claims data to define an episode of care by the propensity or association of multiple co-occurring services. This method for episode identification will fall short of clinical care pathways for several reasons. Patients may have more than one condition at the same time (such as acute care needs overlapping with chronic care needs) and therefore may have overlapping episodes. Episode grouper logic should have rules to discern which services to assign to a primary episode and which to split proportionally between contemporaneous episodes. Additionally, in a grouper with weak business logic, rare complications or sequelae to services used in treating a condition can seem of such a low propensity or association that they are not assigned to the episode. However, some of these rare events, such as deep vein thrombosis and pulmonary embolism, can prove exceedingly costly. This is important for the patient to be aware of, but also is an important opportunity for improvement. Furthermore, care pathways are subject to constant changes due to emerging technologies, therapies, and scientific research, which alter standards of care.

Some groupers are "black boxes" with episode definitions that are reviewed internally and not shared openly for proprietary reasons. Others are subjected to clinical review and then strategically built by payers without regard to clinical reliability, validity, and completeness for use in public reporting of price. We favor the episode grouper maintained by the PACES Center because it is built on an open standard with episode definition updates on a recurring basis to achieve trusted information for patients and clinical care teams. With the logic and specifications for episodes available in the public domain, there will be full transparency and a standard framework that interested parties can use to measure cost, set benchmarks, align quality metrics, and optimize value within and across systems nationwide.

Price information should be based on a specific patient's insurance coverage, such as their benefits package, deductible, and coinsurance responsibilities. This information is included in the TiC requirements, but is not information that hospitals can provide, which is why we recommend that payers be the focus of price transparency requirements. Ultimately, we urge CMS to develop requirements that allow relevant information to be distilled down so that it can be actionable by the end user and does not inundate the patient with information that obscures the pricing information they seek.

4. How do consumers currently access this pricing information?

In many cases, hospitals and physicians provide details about a patient's cost liability before the patient receives care. Typically, this occurs for a single service such as a lab test, office visit, or imaging service. From a business standpoint, this makes sense. The transaction is not delayed and the need to follow up for delinquent payment is mitigated. This timely step often involves calculating the patient's copay and requiring the patient to pay any out-of-pocket costs before receiving the service—however, it does not provide the patient with complete information about the pricing of their care journey nor information about all the associated care included in the episode. While it is useful for the patient to know the amount of their copay prior to receiving the service, the information provided as part of the TiC requirements is still necessary, along with information on the entire episode of care.

5. What are consumers' preferences for accessing this price information?

Patients prefer to access information that is clearly presented, easy to navigate, and actionable. Ideally, patients would have access to price information that is comprehensive but not obscured by too much noise. Most patients would likely prefer to access this information online, while others may prefer a paper copy.

6. Given the new requirements and authorities through TiC final rules and the NSA, respectively, is there still benefit to requiring hospitals to display their standard charges in a "consumer-friendly" manner under the HPT regulations?

We believe there is no longer a need for the hospital transparency requirements given the TiC and NSA rules. See our response to question 1, above, for more detail.

7. Within the contours of current statutory authority, should information in the hospital consumer-friendly display (including the information displayed in online price estimator tools) be revised to enhance alignment with price information provided under the TIC final rules and NSA regulations? If so, which data should be revised and how?

No additional comments.

8. How effective are hospital price estimator tools in providing consumers with actionable and personalized information?

No additional comments.

9. What is the minimum amount of personalized information that a consumer must provide for a price estimator tool to produce a personalized out-of-pocket estimate?

We encourage CMS to do further research to better understand this area. Payers can use their own business intelligence and analytics to establish a personalized profile for a patient and provide price information to the patient based on their plan's deductible, coinsurance, and copay structure that reflect actual rates, allowed amounts, and individual specific cost-sharing requirements. Other patient characteristics, such as social determinants of health, could affect care as well. There is more to learn about these other aspects to know the minimum amount of personalized information that is necessary for a price estimator tool to produce a custom out-of-pocket estimate for a given patient.

10. How are 3rd parties using machine readable file data to develop consumer-friendly pricing tools?

We are concerned that 3rd parties can use machine readable files to inappropriately develop pricing tools that are not ultimately consumer-friendly (e.g., a tool that only reported single services instead of episodes of care). As described above, price information should be presented as episodes rather than single services so that patients receive a more comprehensive picture of the care they will receive.

3rd party use of machine readable files inappropriately to determine price presents another flaw in this system. For example, some 3rd parties determine the percentage of all services associated with a triggering event, then draw a line at a certain percentage (for example, 20 percent) as a cut off for services that are and are not considered part of the triggering event and included in the price. This is also known as an association index. While this could be an appropriate first step, stopping here is problematic. The 3rd party should go on to consider additional context that could add nuance to the price such as patient risk adjustment; social determinants of health; and additional input from patients, clinicians, and payers. Some patients, such as those who are high risk, could have services that are in the 20 percent range and that would otherwise be excluded from the price. If patient subtypes are not

sufficiently nuanced, and the 3rd party simply uses an associated index corresponding to the triggering event, the pricing tool will not be capable of providing decision-makers with the information they need.

11. Should CMS consider additional consumer-friendly requirements for future rulemaking (e.g., what types of pricing information might give consumers the ability to compare the cost of healthcare services across healthcare providers)?

As described above, there are several refinements that we recommend for the consumer-friendly requirements. Some of these would require changes in future rulemaking. We again stress that CMS should focus on the perspective of the patient in considering changes to the consumer-friendly requirements. The focus should be on obtaining the right amount of information, presented in the right way for the patient to best navigate, understand, and make informed decisions about their healthcare.

12. Is there an industry standard set of healthcare services or service packages that healthcare providers could use as a benchmark when establishing prices for consumers?

Currently, there is no single industry standard set of healthcare service packages or episodes. This is not because delivery systems and payers fail to see the value of episodes, but rather because they have recognized this value, but with no obvious choice, many competing and incompatible systems have been created. Some groupers may include pre-hospital services or post-facility services, while others may contain both or neither. Other methodologies for price comparisons have been designed to work within a performance measurement system or a specific payment model to limit confusion in comparisons among physicians without serving the ultimate consumer, the patient. Of the episode definitions and grouping logics currently available, the one provided and maintained by the PACES Center is the closest to meeting the requirements for becoming a broadly adopted standard.

We believe that to be widely adopted as a national standard, any episode grouper and definitions must be built on open-source architecture with clinical input from physician experts across the medical community. Such episodes must also be regularly updated in order to ensure that they remain actionable as the practice of medicine evolves and changes. It is important also that they be defined in a way that is comprehensive of charges likely to occur and exclusive of charges unrelated to the care in question. An episode grouper is essentially a piece of software that combs through charges and assigns them to episodes of care based on a collection of clinical data files and a set of specified rules or logic. Of the groupers currently used, only that provided by the PACES Center is fully open-sourced, with most using a black box approach to clinical logic and service assignment. Clinical oversight of the episode definitions in an open-source manner with trusted engagement of payers and patients allows for an episode definition to reach broad adoption as a standard for price transparency.

The catalog of episodes maintained by the PACES Center contains defined and independently vetted episodes covering a majority of the care provided in terms of cost. Adopting episode definitions such as these as a standard could help improve clarity in contracting and facilitate models that are applicable

across payers. This approach would readily translate not only into an improved framework for hospital price transparency across payers, but could also meet or exceed the accuracy of information provided to meet other current transparency requirements such as for transparency in coverage or compliance with the NSA.

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,

Patricia L. Turner, MD, MBA, FACS

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Executive Director & CEO