

June 9, 2023

Chiquita Brooks-LaSure, MPP Administrator Centers for Medicare & Medicaid Services Attention: CMS-1785-P P.O. Box 8013 Baltimore, MD 21244-8013

RE: Medicare Program; Proposed Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership (CMS-1785-P)

Dear Administrator Brooks-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 or the Agency) fiscal year (FY) 2024 Hospital Inpatient Prospective Payment Systems (IPPS) proposed rule published in the *Federal Register* on May 1, 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 the inpatient hospital setting, the College has a vested interest in the IPPS and related hospital quality improvement efforts. 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 changes to the IPPS. Our comments below are presented in the order in which they appear in the rule.

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PROPOSED CHANGES TO MEDICARE SEVERITY DIAGNOSIS-RELATED GROUP (MS-DRG) CLASSIFICATIONS AND RELATIVE WEIGHTS

Proposed Changes to Specific MS-DRG Classifications

Physicians use the International Classification of Diseases, 10th Revision (ICD-10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS-DRG system. The ICD-10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding. CMS annually reviews stakeholder requests to update MS-DRG classifications to better align with ICD-10 coding and reporting guidelines and major diagnosis categories (MDCs).

MDC 06 (Diseases and Disorders of the Digestive System): Appendicitis

Over the last several years, CMS has received stakeholder feedback indicating that the difference in MS-DRG assignment for appendectomy procedure codes inappropriately suggests that localized peritonitis is more severe or requires an additional level of care above that for generalized peritonitis. In the FY 2023 IPPS rule, the Agency stated that any future proposed changes to the MS-DRGs for appendectomy procedures would be dependent on the outcome of diagnosis code revisions proposed by the Centers for Disease Control and Prevention (CDC)/National Center for Health Statistics (NCHS). Specifically, the CDC/NCHS sought to expand diagnosis codes K35.20 (Acute appendicitis with generalized peritonitis, without abscess) and K35.21 (Acute appendicitis with generalized peritonitis, with abscess), making them sub-categories and creating new diagnosis codes to identify and describe acute appendicitis with generalized peritonitis, and unspecified as to perforation.

Since last year's rulemaking, six new diagnosis codes (shown in the table below) for acute appendicitis with generalized peritonitis, with and without perforation or abscess, have been finalized by the CDC/NCHS and are effective for discharges on and after October 1, 2023. As such, CMS believes it is now appropriate to address MS-DRG assignments for appendectomy procedures.

ICD-10-CM Code	Description	Proposed MS-DRGs
K35.200	Acute appendicitis with generalized peritonitis, without perforation or abscess	371, 372, 373
K35.201	Acute appendicitis with generalized peritonitis, with perforation, without abscess	371, 372, 373
K35.209	Acute appendicitis with generalized peritonitis, without abscess, unspecified as to perforation	371, 372, 373
K35.210	Acute appendicitis with generalized peritonitis, without perforation, with abscess	371, 372, 373
K35.211	Acute appendicitis with generalized peritonitis, with perforation and abscess	371, 372, 373
K35.219	Acute appendicitis with generalized peritonitis, with abscess, unspecified as to perforation	371, 372, 373

The Agency analyzed claims data reporting diagnosis codes describing acute appendicitis and states that its findings support eliminating the logic for "complicated" (i.e., with complication or comorbidity [CC]/major complication or comorbidity [MCC]) and "uncomplicated" (i.e., without CC/MCC) diagnoses and restructuring the six related MS-DRGs. Based on this analysis, CMS no longer believes that the distinction between "complicated" and "uncomplicated" is relevant for purposes of describing resource consumption, and that both localized and generalized peritonitis in association with an appendectomy require the same level of patient care, including extensive intraoperative irrigation at the surgical site, direct inspection or imaging of the abdomen to identify possible abscess, use of intravenous antibiotics, and prolonged monitoring. The Agency also notes that, in its review of the logic for the appendectomy procedures, it identified procedures listed in the current logic that do not reflect an actual appendectomy as suggested in the title of the current MS-DRGs, but instead describe various procedures performed on the appendix.

CMS therefore proposes to delete existing MS-DRGs 338-343 and create new MS-DRGs 397-399, as shown in the table below. These proposed new MS-DRGs would no longer require a diagnosis in the definition of the logic for case assignment. CMS also proposes to include the current list of appendectomy procedures in the logic for case assignment of appendix procedures for the proposed new MS-DRGs.

Proposed Change	MS-DRG	Description
Delete	338	Appendectomy with Complicated Principal Diagnosis with MCC
Delete	339	Appendectomy with Complicated Principal Diagnosis with CC
Delete	340	Appendectomy with Complicated Principal Diagnosis without CC/MCC
Delete	341	Appendectomy without Complicated Principal Diagnosis with MCC
Delete	342	Appendectomy without Complicated Principal Diagnosis with CC
Delete	343	Appendectomy without Complicated Principal Diagnosis without CC/MCC
Add	397	Appendix Procedures with MCC
Add	398	Appendix Procedures with CC
Add	399	Appendix Procedures without CC/MCC

The ACS opposes CMS' proposal to delete existing MS-DRGs 338-343 and create new MS-DRGs 397-399. We are strongly concerned that the three new proposed MS-DRGs do not properly reflect the differences in both complication and cost across the range of appendectomy procedures (e.g., appendicitis with gangrene or perforation, interval appendectomies). We are also concerned that CMS has failed to recognize changes in clinical best practices for appendectomy procedures—for example, in cases of localized peritonitis without perforation, it is no longer recommended to irrigate the region due to an increased risk of spreading contamination. However, in the setting of generalized peritonitis with or without perforation, irrigation is recommended. The Agency's proposed changes to the MS-DRGs do not acknowledge the clear differences between these two conditions. **Given our concerns with CMS' proposals and its demonstrated lack of understanding about the complexities of appendectomy procedures, we urge CMS to maintain the existing appendectomy MS-DRGs and reassign code K35.20 to MS-DRGs 338, 339, and 340. As stated in our comments to the FY 2021 and FY 2023 IPPS rules, we believe that all ruptured/perforated appendicitis diagnosis codes should group to MS-DRGs 338-340 and that the condition described by code K35.20 can be associated with risk of postoperative abscess formation and extended length of hospital stay, thereby warranting classification as a complicated diagnosis.**

MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): Complications of Arteriovenous Fistulas and Shunts

CMS received a request to add eight ICD-10-CM diagnosis codes to the list of principal diagnoses assigned to MS-DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) when reported with procedure codes describing the insertion of totally implantable vascular access devices (TIVADs) and tunneled vascular access devices. The applicable codes are shown in the table below.

ICD-10-CM Code	Description	MDC
T82.510A	Breakdown (mechanical) of surgically created arteriovenous fistula, initial encounter	05
T82.511A	Breakdown (mechanical) of surgically created arteriovenous shunt, initial encounter	05
T82.520A	Displacement of surgically created arteriovenous fistula, initial encounter	05
T82.521A	Displacement of surgically created arteriovenous shunt, initial encounter	05
T82.530A	Leakage of surgically created arteriovenous fistula, initial encounter	05
T82.531A	Leakage of surgically created arteriovenous shunt, initial encounter	05
T82.590A	Other mechanical complication of surgically created arteriovenous fistula, initial encounter	05
T82.591A	Other mechanical complication of surgically created arteriovenous shunt, initial encounter	05

CMS disagrees with this request and proposes to maintain the current assignments of these cases to MDC 05 (Diseases and Disorders of the Circulatory System), stating that it would not be appropriate to move these diagnoses into MDC 11 because it would inadvertently cause cases reporting the eight diagnosis codes that describe mechanical complications of arteriovenous fistulas and shunts with operating room procedures assigned to MDC 05 to be assigned to an unrelated MS-DRG. The Agency notes that patients can sometimes require the insertion of tunneled or totally implantable vascular access devices for hemodialysis while surgically created AV fistulas or AV shunts are unable to be accessed due to mechanical complications, but effective treatment of these mechanical complications related to AV fistulas or AV shunts more often requires inpatient admission and surgery. CMS believes that the eight diagnosis codes describing mechanical complications of arteriovenous fistulas and shunts are most clinically aligned with the diagnosis codes assigned to MDC 05.

The ACS supports CMS' proposal to maintain the current assignment of these cases to MDC 05. While we recognize that insertion of TIVADs and tunneled vascular access devices may be performed to treat renal failure, the resources used for such treatment—including surgical equipment, interventional radiology services, clinical staff, among others—are more consistent with vascular disease than the primary diagnosis that led to the procedure (i.e., kidney disease).

Operating Room (O.R.) and Non-O.R. Issues

In this proposed rule, CMS addresses requests submitted by stakeholders regarding changing the designation of specific ICD-10-PCS codes from non-O.R. to O.R. procedures or changing the designation from O.R. procedures to non-O.R. procedures. For each requested procedure code change, the Agency considers whether the procedure would typically require the resources of an operating room, whether it is an extensive or a non-extensive procedure, and to which (if any) MS-DRGs the procedure should be assigned.

Non-O.R. Procedures to O.R. Procedures

• <u>Diagnostic and Therapeutic Endoscopic Procedures Performed on Thoracic and</u> <u>Abdominal Organs</u>. CMS received a request to change the designation of *all* ICD-10-PCS procedure codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs from non-O.R. to O.R. The requestor stated diagnostic and therapeutic thoracoscopic and laparoscopic procedures on thoracic and abdominal organs are always performed in the operating room under general anesthesia.

The Agency indicated that it received this same request during FY 2023 rulemaking but has not received a specific list of the applicable procedure codes that are currently

designated as non-O.R. for review. Given that there are over 19,000 ICD-10-PCS codes in the classification that describe procedures performed using a percutaneous endoscopic approach, CMS believes that analysis of the designation of such procedure codes should instead be performed across MS-DRGs as part of a broader systemic ICD-10-PCS code review. The Agency does not propose any changes to the designation of these codes from non-O.R. to O.R. for FY 2024.

While we do not dispute that there may be over 19,000 ICD-10-PCS codes that describe procedures performed using a percutaneous endoscopic approach, this list can be narrowed down substantially by considering ICD-10-PCS codes for thoracic and abdominal organs. Even with a smaller list utilizing the code criteria above, we are unable to envision a thoracoscopic or laparoscopic procedure that would not require general anesthesia and be performed in an O.R. As such, we strongly urge CMS to assign O.R. status to any ICD-10-PCS code that represents a thoracic or abdominal procedure using a percutaneous endoscopic approach.

• <u>Open Drainage of Subcutaneous Tissue and Fascia.</u> In the FY 2022 IPPS final rule, CMS redesignated 22 codes that describe the open drainage of subcutaneous tissue and fascia from O.R procedures to non-O.R. procedures. The applicable 22 codes are listed in the table below.

ICD-10-PCS Code	Code Description
0J900ZZ	Drainage of scalp subcutaneous tissue and fascia,
0370022	open approach
0J910ZZ	Drainage of face subcutaneous tissue and fascia, open
	approach
0J940ZZ	Drainage of right neck subcutaneous tissue and fascia,
	open approach
0J950ZZ	Drainage of left neck subcutaneous tissue and fascia,
0375022	open approach
0J960ZZ	Drainage of chest subcutaneous tissue and fascia,
0390022	open approach
0J970ZZ	Drainage of back subcutaneous tissue and fascia, open
0397022	approach
0J980ZZ	Drainage of abdomen subcutaneous tissue and fascia,
0398022	open approach
0J990ZZ	Drainage of buttock subcutaneous tissue and fascia,
0399022	open approach
0J9B0ZZ	Drainage of perineum subcutaneous tissue and fascia,
039B02Z	open approach
0J9C0ZZ	Drainage of pelvic region subcutaneous tissue and
UJ9CUZZ	fascia, open approach
010D077	Drainage of right upper arm subcutaneous tissue and
0J9D0ZZ	fascia, open approach

0J9F0ZZ	Drainage of left upper arm subcutaneous tissue and
0371 022	fascia, open approach
0J9G0ZZ	Drainage of right lower arm subcutaneous tissue and
0390022	fascia, open approach
0J9H0ZZ	Drainage of left lower arm subcutaneous tissue and
03911022	fascia, open approach
0J9J0ZZ	Drainage of right-hand subcutaneous tissue and
0393022	fascia, open approach
0J9K0ZZ	Drainage of left-hand subcutaneous tissue and fascia,
039K0ZZ	open approach
0J9L0ZZ	Drainage of right upper leg subcutaneous tissue and
0392022	fascia, open approach
0J9M0ZZ	Drainage of left upper leg subcutaneous tissue and
039101022	fascia, open approach
0J9N0ZZ	Drainage of right lower leg subcutaneous tissue and
03910022	fascia, open approach
0J9P0ZZ	Drainage of left lower leg subcutaneous tissue and
039F0ZZ	fascia, open approach
0100077	Drainage of right foot subcutaneous tissue and fascia,
0J9Q0ZZ	open approach
0100077	Drainage of left foot subcutaneous tissue and fascia,
0J9R0ZZ	open approach

For both FYs 2023 and 2024, CMS has received requests to reexamine this change in designation. Requestors asked that the Agency return the designation of these procedure codes to O.R. procedures to reflect the operating room resources utilized in the performance of these services, stating that open procedures for the drainage of subcutaneous tissue and fascia are indeed typically performed in the O.R. and involve making incisions through the subcutaneous tissue into fascia for therapeutic drainage, breaking up of loculations, and irrigation. CMS reiterated in the FY 2023 IPPS—and again in this FY 2024 proposed rule—that it believes procedures involving the open drainage of subcutaneous tissue and fascia can be safely performed in the outpatient office setting. As such, CMS proposes to maintain the non-O.R. designation for these 22 procedure codes.

The ACS disagrees that these 22 ICD-10-PCS procedures do not typically require the resources of an O.R. when occurring in the inpatient setting, and we do not believe they can be safely performed in the non-O.R. setting. We wish to highlight that, in the FY 2018 IPPS proposed rule, the same 22 ICD-10-PCS codes for open drainage were identified by a commenter as not requiring the resources of an O.R.¹ However, other stakeholders opposed changing the designation of these codes from O.R. to non-O.R. procedures. The stakeholders indicated that such procedures

¹ Centers for Medicare & Medicaid Services. Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates [Proposed Rule]. *86 F.R. 25070*. 2017.

were invasive, performed on deep subcutaneous tissue and fascia, and most often furnished in the O.R. setting under general anesthesia. Stakeholders also noted that the primary objective of these procedures was to incise through the skin into the subcutaneous tissue and fascia in order to drain and clean out an abscess or hematoma. Furthermore, stakeholders highlighted that CMS disagreed with a separate recommendation in the FY 2018 IPPS proposed rule to reclassify open extraction of subcutaneous tissue and fascia as non-O.R. procedures, and for the same reasons, open drainage of subcutaneous tissue and fascia should not be changed from an O.R. procedure to a non-O.R. procedure. In response to the issues raised by these stakeholders, CMS determined in the FY 2018 IPPS final rule that it was appropriate to maintain the designation of the 22 procedure codes as O.R. procedures.²

We find the Agency's rulemaking on this issue between FY 2018 and FY 2024 to be contradictory and believe that the rationale to designate such codes describing the open drainage of subcutaneous tissue and fascia as O.R. procedures (as presented to CMS by stakeholders for the FY 2018 IPPS) remains the same: the intent of these procedures—which are more complex and resource intensive than ICD-10-PCS codes describing open drainage with a drainage device (e.g., procedure code 0J9N00Z)—is not to place a drainage device but instead to incise and drain not only subcutaneous tissue but also the fascia in order to reach the infection in the subfascial space. There is no safe way to effectively drain an infection involving the subfascial plane without the resources of an O.R. Therefore, the ACS opposes CMS' proposal to maintain the non-O.R. designation for the above 22 ICD-10-PCS codes and requests that these codes be redesignated as O.R. procedures for FY 2024.

HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM: PROPOSED POLICY CHANGES

<u>Revising the Hospital VBP Program Scoring Methodology to Add a New</u> <u>Adjustment That Rewards Hospitals Based on Their Performance and the</u> <u>Proportion of Their Patients Who Are Dually Eligible for Medicare and Medicaid</u>

CMS is proposing to add Health Equity Adjustment (HEA) bonus points to a hospital's Total Performance Score (TPS) that would be calculated using a methodology that incorporates a hospital's performance across all four domains for the program year and its proportion of patients with dual eligibility status (DES). CMS proposes to implement a "measure performance scaler" and "underserved multiplier" as defined below:

• <u>Measure performance scaler</u>—the sum of the points awarded to a hospital for each domain based on the hospital's performance on the measure in that domain.

² Centers for Medicare & Medicaid Services. Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates [Final Rule]. *82 F.R. 37990*. 2017.

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• <u>Underserved multiplier</u>—the number of inpatient stays for patients with DES out of the total number of inpatient Medicare stays during the calendar year two years before the start of the respective program year.

CMS proposes to calculate HEA bonus points as the product of the measure performance scaler and the underserved multiplier. The bonus points are designed to award higher points for hospitals that (1) serve greater percentages of underserved populations, which are defined for the purpose of this proposal as hospital patients with DES who receive inpatient services, and (2) have higher quality performance.

We commend CMS for continuing to emphasize issues related to social determinants of health (SDOH) in their quality programs. Physicians that care for complex patients with various social risk factors are faced with many challenges to achieving good patient outcomes. Some evidence demonstrates that hospitals treating a high number of dualeligible patients score lower on performance measures and may be more likely to be penalized by CMS incentive programs. This can create perverse incentives, reducing already strained resources, which can result in lack of access to proper care and recovery services.³ Through decreased access and a reduction of resources to hospitals who care for the most vulnerable patients there is potential that these patients' health conditions and risks of multiple comorbidities will be exacerbated, ultimately causing an increase in healthcare costs. Therefore, 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 physician. Therefore, the ACS supports efforts to reward hospitals who care for dual-eligible populations and are taking steps to provide quality care to these patients. This proposal represents an important first step in this process by applying a more favorable scoring methodology to hospitals that provide good care to underserved populations.

Looking beyond scoring adjustments, the ACS envisions the adoption of health equity standards that could be used across medicine as a programmatic measure,⁴ aligning with the Inpatient Quality Reporting (IQR) Health Equity measure across CMS programs or other quality incentive programs. This type of measure could evaluate and help to improve a practice's and facility's commitment to closing the health equity gap across the various domains of a quality program, including: culture, resources, and staffing to support this effort; protocols to identify patient goals and expectations to support shared decision making; data collection and surveillance with data-driven quality improvement; and community outreach and education programs. By evaluating hospitals within domains that align with the needs of vulnerable populations, CMS can identify the

³ Wasfy JH, Bhambhani V, Healy EW, et al. Relative Effects of the Hospital Readmissions Reduction Program on Hospitals that Serve Poorer Patients. *Med Care*. 2019;57(12):968-976.

⁴ Programmatic measures represent a specific clinical program and combine structure, process, and outcomes measures along with improvement activities in hopes of informing patients about the care they seek and driving care teams to improve.

facilities that are extraordinary in their efforts and then provide resources to help them to elevate care for these patients. A programmatic measure can also help CMS publicly report how hospitals are meeting these standards in a way that is easy for patients to understand. This information is meaningful and important for patients as they make choices about where to seek care based on their needs. Shining a light on these facilities and supporting their efforts is critical to improving care for vulnerable patients. We are eager to work in collaboration with CMS on the development of equity standards for incentive programs.

CMS also seeks comment on the use of indicators for underserved populations beyond DES, such as the Area Deprivation Index (ADI) or Low-Income Status, and the incorporation of patients with partial-dual eligibility in scoring hospitals in the Hospital VBP program. The ACS strongly supports efforts to evaluate various socioeconomic status (SES) indices to identify socially at-risk populations and their degree of risk. We also support the incorporation of partial-dual eligible patients in the evaluation of underserved populations because they have many similar social risk factors as dual-eligible patients, including lack of access to care.

The ACS has analyzed SES indices for sensitivity in ACS National Surgical Quality Improvement Program (NSQIP) and other ACS registries. The findings indicated that for surgery, ADI is the most sensitive SES index currently available. **However**, it is important to note that ADI and many other SES indices are developed by combining American Community Survey data points (housing, education, job, income, transportation, etc.), which do not consider the outcome to be predicted. In that regard, these indices are generic for assessing risk. A better approach would be to construct an index (e.g., using regression) that is tuned for predictive strength with respect to the outcome of interest.

HOSPITAL ACQUIRED CONDITION (HAC) REDUCTION PROGRAM

Advancing Patient Safety in the HAC Reduction Program – Request for Comment

CMS seeks feedback on the adoption of patient safety focused electronic clinical quality measures (eCQMs) to strengthen the growing portfolio of eCQMs and promote further alignment across quality reporting and VBP programs. They discuss how they aim to have the HAC Reduction Program advance the CMS National Quality Strategy goals of improving health equity by addressing underlying disparities in our health system and promoting safety by preventing harm or death from health care errors. CMS also shares that they seek to align with the U.S. Department of Health and Human Services (HHS)-led National Healthcare System Action Alliance to Advance Patient Safety and its priority of establishing and sustaining a strong culture of safety in a way that is equitable and engaging to patients, families, care partners, and the health care workforce. As part of

ongoing efforts to evaluate and strengthen the HAC Reduction Program, CMS is conducting a review of the patient safety and healthcare-associated infection measures and the scoring and weighting methodology. They solicit feedback on potentially adopting patient safety related eCQMs, which are currently used in the Hospital IQR Program, including:

- Hospital Harm Opioid-Related Adverse Events eCQM
- Hospital Harm Severe Hypoglycemia eCQM
- Hospital Harm Severe Hyperglycemia eCQM
- Hospital Harm Acute Kidney Injury eCQM
- Hospital Harm Pressure Injury eCQM
- Excessive Radiation Dose or Inadequate Image Computer Tomography in Adults eCQM

The set of measures that are included in the HAC program reflects the safety profile of an institution. However, these individual metrics can be broad and general and may not reflect a true proxy for safety. ACS believes it is imperative that this information is easy to interpret and meaningful to patients and care partners. When we think of avoidable harms, there are multiple goals:

- 1. Ensure that the events are truly avoidable. When the measures are overstated or understated the importance and intent can be overlooked.
- 2. Assure patients that the institution delivering their care has the structures, resources, and processes in place to: detect avoidable harms, seek a culture of improvement, and engage patients and care providers to adhere to safety plans for care. Patients do not want to track individual harms that may or may not apply to the care they seek.

We recommend CMS conduct an analysis that can weigh the various indicators for patient-centered value—in other words, which measures are important and meaningful to patients?

CMS also asks for suggestions about measures that should be introduced in the HAC Reduction Program to address equity gaps on the rate and severity of patient harm events and healthcare-associated infections. The ACS urges CMS to consider measures that address maternal mortality in the U.S. It is well established that the U.S. has the highest rates of maternal mortality among high-income countries, with the highest levels of maternal mortality occurring among ethnic minorities.⁵ One of the leading causes of postpartum mortality is infection, which disproportionally impacts ethnic minorities.⁴

⁵ Petersen EE, Davis NL, Goodman D, et al. Racial/Ethnic Disparities in Pregnancy-Related Deaths - United States, 2007-2016. MMWR Morb Mortal Wkly Rep. 2019 Sep 06;68(35):762-765.

Therefore, we believe a measure that can detect or predict postpartum sepsis prior to discharge is an important metric to track as part of the HAC Reduction Program. An institution should have the ability to use the patient's current conditions, medical history, etc. to identify patients at high risk for sepsis. Risk adjustment and sub-analysis of population analytics can also be used to predict sepsis risk. This information should be reported in a way that is easy for patients to understand.

As discussed in the Hospital VBP Program section, the ACS recommends that CMS consider the adoption of health equity standards that could be used across medicine as a programmatic measure (a measure that incentivizes a comprehensive quality program such as an accreditation or verification program). These standards should align with the Hospital IQR Program Health Equity measures and other CMS quality incentive programs as part of the CMS Universal Foundation.⁶ This type of measure could evaluate and help to improve a practice's and facility's commitment to closing the health equity gap across the various domains of a quality program, including: culture, resources, and staffing to support this effort; protocols to identify patient goals and expectations to support shared decision making; data collection and surveillance with data-driven quality improvement; and community outreach and education programs.

CHANGES TO THE HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM

Potential Future Inclusion of Two Geriatric Care Measures

The Agency asks for public feedback on two attestation-based structural measures which were submitted by the ACS for consideration in the IQR—the *Geriatric Hospital Measure* and the *Geriatric Surgical Measure*. CMS highlights the need for a comprehensive measure that addresses the aging population during hospital stays. They note that hospitals are increasingly faced with older patients who have complex medical, physiological, and psychosocial needs that are often inadequately addressed by the current healthcare infrastructure. The *Geriatrics Hospital Measure* and the *Geriatrics Surgical Measure* and this gap.

Background

The ACS submitted the *Geriatric Hospital and Geriatric Surgical Measures* for the CMS Measures Under Consideration list in 2022. The two geriatric measures are a new type of measure, a "programmatic composite"⁷ measure, that considers the full program of care

⁶ 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.

⁷ Programmatic measures represent a specific clinical program and combine structure, process, and outcomes measures along with improvement activities in hopes of informing patients about the care they seek and driving care teams to improve.

needed for geriatric patients. Developed in partnership with the ACS, the Institute for Healthcare Improvement (IHI), and the American College of Emergency Physicians (ACEP), they are meant to assure Medicare that the conditions surrounding frailty in the geriatric population are brought into focus, and that geriatric patients and their families know where to seek good care.

Both measures were reviewed by the National Quality Forum (NQF) Measures Application Partnership (MAP) for consideration in the Hospital IQR. There was support across the MAP workgroups for the importance and critical need for a measure that focuses on older adults in the hospital. Ultimately, the MAP Coordinating Committee conditionally supported the *Geriatric Hospital Measure* and the *Geriatric Surgical Measure*, with potential for mitigation. The MAP suggested two mitigating factors: combining the two geriatric measures into a single measure that is less burdensome or focusing on only one measure.

ACS Response to MAP Feedback

The ACS understands that CMS faces many challenges in maintaining the large library of measures implemented in their quality incentive programs and appreciates steps CMS is taking to reduce burden associated with reporting quality measures. Given both CMS' and the MAP's feedback to reduce burden, the ACS recently reconvened the IHI and ACEP to review CMS and MAP feedback, then submit a new measure, titled the Age-Friendly Hospital Measure. This measure is similar to the Geriatrics Hospital Measure but streamlined to include fewer domains. It incentivizes hospitals to take a holistic approach to care delivery for older adults by implementing multiple data-driven modifications to the entire clinical care pathway from the emergency department (ED), to the operating room, 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 aligning care with what the patient values. It includes five domains with attestations that acknowledge certain processes, outcomes, and structures necessary for providing high-quality, holistic care for older adults. The difference from a burden perspective is that programmatic measures bring teams together, thereby removing the reporting silos that create burden. The domains of the Age-Friendly Hospital Measure are:

- 1. Eliciting Patient Healthcare Goals
- 2. Responsible Medication Management
- 3. Frailty Screening and Intervention (i.e., mobility, mentation, and malnutrition)
- 4. Social Vulnerability (social isolation, economic insecurity, ageism, limited access to healthcare, caregiver stress, elder abuse)
- 5. Age-Friendly Care Leadership

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The *Age-Friendly Hospital Measure* was designed using attestation-based reporting, which aligns with the framework of CMS' recently implemented *Hospital Commitment to Health Equity* and *Maternal Morbidity* structural measures. Attestation-based measures are new to the measure landscape and have received critique since their introduction; however, the ACS suggests that CMS consider the attestation structure as the first phase in the lifecycle of this measure. Phase one is intended to promote adoption of the standards at a basic level of effort using attestation for the initial implementation. After hospitals understand the first phase of the measure, the next phase would incorporate external review to verify that the hospitals are fulfilling the intent of the standards, such as gathering data, and implementing improvement cycles that align with the measure. In this advanced phase, verification ensures hospitals demonstrate that they can first find and then fix the problems as part of the external review.

Part of what is needed in rethinking care for the older adult population is programmatic, facility-level geriatric measurement. This solution is different from the current types of CMS measures. A programmatic approach incentivizes team-based care organized around the geriatric patient to meet the challenges unique to geriatric patients. Although existing quality metrics have improved both the rate and reporting of clinical outcomes (falls, appropriate use of anticoagulants, etc.) that are important to older individuals, these measures can be narrow in scope and may have limited long-term effectiveness due to ceiling effects. The traditional reductionist approach to measurement is overly simplistic and lacks patient-centric, holistic impact. It carries the burden of measurement with inadequate returns on patient outcomes and limits bi-directional communication of care teams. Rather than simply addressing individual clinical issues in isolation, optimizing care for older patients with multifaceted vulnerability profiles requires an integrated approach with the goal of reframing the entire care pathway to better serve the needs of this unique population—this is the intent of the Age-Friendly Hospital Measure. Of important note, programmatic measures can also evolve to include existing CMS measures which measure a process or outcome for the same condition, similar to the Universal Foundation framework.⁵ Beyond an Age-Friendly Hospital measure, we envision approximately 12-15 major condition-based programs to supplement the primary-care focused Universal Foundation.

The *Age-Friendly Hospital Measure* was developed with the Modified Delphi method, receiving input from more than 50 organizations, including the ACS. The multistakeholder group identified clinical frameworks based on evidence and best practices that provide goal-centered, clinically effective care for older patients. As a result, this programmatic measure consists of structural and process measures that address all six Institute of Medicine domains (safe, effective, patient-centered, timely, efficient, equitable), and is comprehensive across the full spectrum of geriatric care. Surgery, the ED, and hospitalization (in general) were targeted because this is where older adults are especially vulnerable. The measure incentivizes hospitals to take an

integrated approach to the care of older adults by implementing multiple data-driven modifications to the entire clinical care pathway from the ED, to the operating room, to the inpatient units, and beyond. It puts an emphasis on the importance of defining patient (and caregiver) goals not only from the immediate treatment decision, but also for longterm health and aligning care with what the patient values.

Programmatic measures are based on several decades of history implementing programs that demonstrably improve patient care provided by the team of clinicians along with the facility. This approach encourages hospitals and the clinical team to see older patients not as isolated data points to be narrowly focused on but rather as whole, complex individuals who require a multidisciplinary, all-encompassing approach to their care. It incorporates elements of IHI's Age-Friendly Health Systems program, known as the 4Ms (What Matters, Medications, Mentation, Mobility), and standards from the Geriatric Emergency Department Accreditation (GEDA) framework developed by ACEP. ACEP's GEDA standards improve the care of the geriatric population in the ED and allocate health care resources, optimize admission and readmission rates, decrease iatrogenic complications, and decrease extended length-of-stay due to complications. The surgical components of the measure use the four-part ACS Quality Model, which includes 1. standards, 2. infrastructure, 3. data, and 4. verification. Amongst the most recognized of the ACS programs are the Trauma Center Verification Program, the Commission on Cancer (CoC), and the Metabolic and Bariatric Surgery Verification program. Evidence in peer-reviewed literature demonstrate that mortality in verified trauma centers is statistically lower than the mortality rate in non-verified centers; that bariatric surgical care in verified bariatric centers (MBSAQIP – Metabolic and Bariatric Surgical Quality Improvement Program) have lower mortality, lower costs, lower complications, and lower failure-to-rescue (FTR); and that breast cancer care is statistically superior in verified breast cancer centers.^{8,9,10,11,12,13,14}

Components of the *Age-Friendly Hospital Measure* have been implemented nationally, demonstrating feasibility and usability of the measure(s). As of March 2022, over 2700 sites of care participate in IHI's Age-Friendly Health Systems recognition, and over 420 EDs have been accredited as geriatric EDs, of which 22% self-identify as rural facilities. It is also noteworthy that approximately 90% of GEDA accredited EDs have not hired additional staff to deliver age-friendly care in the ED, showing that the standards can be

⁸ MacKenzie 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.

⁹ 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.

¹⁰ Morton JM, Garg T, Nguyen N. Does Hospital Accreditation Impact Bariatric Surgery Safety? Ann Surg. 2014;260(3):540-548.

¹¹ 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.

¹² 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.

¹³ 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.

¹⁴ Winchester DP. The National Accreditation Program for Breast Centers: Quality Improvement Through Standard Setting. *Surg Oncol.* 2011;20(3):581-586.

feasibly implemented. Over 50 hospitals participate in the ACS Geriatric Surgery Verification (GSV) program, and components of the GSV programs are in more than 500 ACS-verified Trauma centers, and 1500 CoC sites. The measure also has broad support across organizations who care for older adults and was recently highlighted in Health Affairs.¹⁵

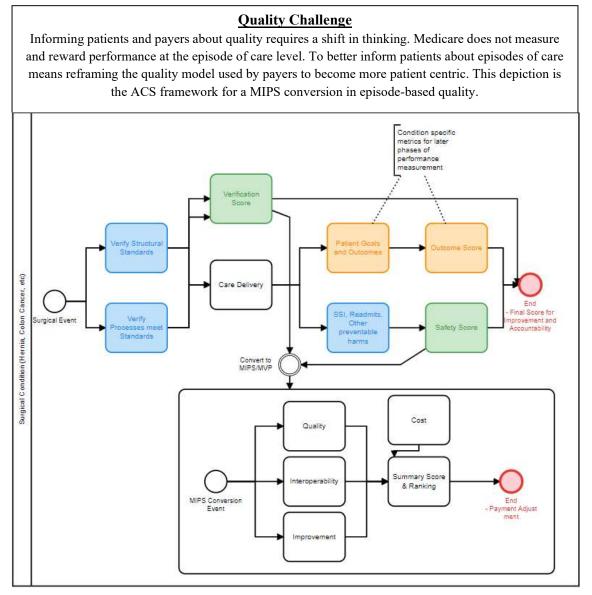
When CMS and NQF consider what we know as traditional structural and process measures, we agree that singular elements that are part of a series of transactions in health are "check-the-box" measures. These have limited impact on quality or improvement. However, within clinical domains of care such as geriatric surgical care, there are crucial structures and processes of care that reach across multiple transactions and link the care team's efforts together. While the Age-Friendly Hospital Measure may appear long in its specification, it is a yearly attestation measure, and therefore reporting is less burdensome on the care team and facility when compared to most CMS measures that require regular reporting of individual events included in the numerator. The Age-Friendly Hospital Measure incorporates key standards within the ACS GSV program, which follows the ACS Quality Model—the framework used across all ACS Quality programs, including the Trauma Center Verification Program, the CoC, the Metabolic and Bariatric Surgery Verification program, and so on. Since programmatic measures are developed with the same framework, they can be designed for various conditions, such as cardiac care, cancer, bariatrics, etc., and are effective across multiple care settings, including rural hospitals. Orchestrating all these elements results in better outcomes and improving their implementation would be an essential first step in outcomes for geriatric patients.

Currently, CMS quality programs consist of a large, extremely costly universe of measures in multiple different payment programs. They often lack the consideration for focusing a care team in a patient-centered way. Measuring a surgeon with sporadic metrics and disjointedly measuring anesthesia services, pathology, radiology, and facility care with disparate measure sets does not create the alignment needed nor allow us to see the bigger picture. While current fee-for-service payment models reinforce the use of specific and often disconnected measures, these individual measures provide an incomplete picture of quality and appropriateness of care received by the patient. As we shift towards more value-driven payment and delivery models, we will need to consider alternative approaches to measurement and performance-based payment that focus more holistically on the condition and/or patient-type. This proposed approach supports a hospital's efforts to implement an evidence-based program that focuses on team-based, patient-centered care within a clinical domain. This approach to measurement can be applied across most clinical domains. Its implementation will guide care teams in their efforts to optimize the patient's chance at achieving their desired outcome.

¹⁵ Snyder RE, Fulmer T. The Need For Geriatrics Measures. *Health Affairs*. April 14, 2023. Available at: https://www.healthaffairs.org/content/forefront/need-geriatrics-measures. Accessed May 15, 2023.

Figure 1 below depicts the way the ACS thinks about developing quality measures and programs. The top process map (ACS-Think) demonstrates how quality activities can be built to acknowledge the structures, processes, outcomes, verification activities, and outcomes/safety scoring that support the entire medical team who is caring for a patient with a specific condition. The second process map (CMS-Think) displays the siloed nature of the quality measurement mechanisms in CMS quality programs.

Figure 1.



In the proposed rule, CMS also asks for comment on the potential establishment of a publicly reported hospital designation to capture the quality and safety of patient-centered geriatric care. From our perspective, it is time to question whether the approach used by payers and the NQF that uses (singleton measures) represent the best means for informing patients about the care they seek, driving care teams to improve, and meet the intent of the incentive payment programs for safe, affordable, good and equitable care.

Twenty years of NQF and payer actions in quality have not produced reliable public knowledge or a public-facing website that informs patients about where to get the care they need for the *condition* they have. Information on the comprehensiveness of a quality program, along with comparable information on the price of that care, are the prerequisites for a valid depiction of the value of care. In assessing the effectiveness of our measures, we believe that if the patient has information on how a hospital implements and meets the standards and processes depicted in this measure, they would be enabled to easily find information on a website for the types of care they seek, for a safety and equitability profile and for personal goal attainment. Therefore, the ACS supports the development of a hospital designation for hospitals that show a commitment to providing high quality geriatric care by reporting the *Age-Friendly Hospital Measure*. This programmatic approach also offers useful information that patients will find beneficial when deciding where to seek care.

This programmatic measure is the first step needed to build the foundation to care for the rapidly aging Medicare population. At this point, this effort does not meet all the goals toward value-based care, but it is designed to be added to appropriate condition or procedure specific cost measures, which would help patients determine the affordability of the care they desire. Combining quality and price for care is a key step in establishing value.

The ACS' effort is intended to be a first step in partnering with the Agency on a new construct for making more effective measurement to inform patients, drive clinical improvement, reduce excessive burden, help rid the nation's healthcare of wasteful spending, and find pathways for more equitable care. We realize there is more to discover in these complex dimensions of healthcare, beyond the clinical pathways themselves. The nation's first step into quality measurement was never intended to be the last. We must improve our ability to improve. We have to question if the metrics we are using are burdensome because of their sheer volume or burdensome because they lack the implementation science care teams hope to find in driving them to optimal care.

It is our hope that CMS will view programmatic measures as more than fitting into a typical structural measure. We are compelled to continue our efforts to use measurement science, implementation science, improvement, and payment incentives collectively as the key tools in the transformation to value-based care.

CHANGES TO THE PPS-EXEMPT CANCER HOSPITAL QUALITY REPORTING (PCHQR) PROGRAM

<u>Public Display of the Surgical Treatment Complications for Localized Prostate</u> <u>Cancer Measure Beginning with the FY 2025 Program Year</u>

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The *Surgical Treatment Complications for Localized Prostate Cancer Measure* (PCH-37) was adopted in the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program in the FY 2020 IPPS/LTCH PPS final rule and included in the PCHQR measure set beginning with the FY 2022 program year. CMS also finalized that it would confidentially report PPS-Exempt Cancer Hospitals (PCH) performance on this measure to individual PCHs and that it would propose to publicly display PCH performance on this measure in the future. In this rule, CMS proposes to publicly display the PCH-specific results for the PCH-37 measure beginning with the FY 2025 program year data in the summer of 2024, which would reflect PCH performance for the July 1, 2021, through June 30, 2022 reporting period. CMS would make these data publicly available following a 30-day period in which PCHs would have an opportunity to review the data.

The ACS agrees that this measure addresses important outcomes following prostate cancer treatment and the information gathered from this measure should be made available to the public. However, we have major concerns about the way the data is displayed for patients. We have made efforts to locate and evaluate the publicly reported information for this program and it was difficult to find any data that would help a patient identify a provider or facility that would meet their specific needs. It should be of highest priority to educate and inform patients by providing them with valuable information that helps them make decisions about where they can expect the best care for their condition in their community. In addition to providing them with data about the care, making that information easy to find and understandable by patients with all levels of health literacy is critical. Patients may value different things when they make decisions about their care, such as proximity to their home, cultural competency of the healthcare facility, quality of services, communication protocols, etc. Given the diverse values of patients, the information that is publicly reported for them should incorporate these elements.

As discussed above in the IQR section, we also recommend that CMS consider the use of programmatic measures in the PCHQR program. Programmatic measures, similar to the *Geriatric Hospital* and *Geriatric Surgical Measures*, are designed to incorporate key structures, processes, and outcomes for a condition that focuses on the needs of patients and what the clinical team requires to deliver on what matters to the patient, including bidirectional communication. These measures highlight communication with the patient, development of evidence-based protocols and processes that support delivery of high-quality patient-centered care and incorporate outcomes to identify where improvements can be made. We also believe that when publicly reported, programmatic measures will push our systems closer to providing patients with valuable information that better informs decisions about their care.

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,

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