

June 10, 2024

Chiquita Brooks-LaSure, MPP Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1808-P P.O. Box 8013 Baltimore, MD 21244-8013

RE: Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes (CMS-1808-P)

Dear Administrator Brooks-LaSure:

On behalf of the over 90,000 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) 2025 Hospital Inpatient Prospective Payment Systems (IPPS) proposed rule published in the *Federal Register* on May 2, 2024.

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.

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

Proposed Changes to Specific MS-DRG Classifications

Physicians and hospitals 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,

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WASHINGTON OFFICE 20 F Street NW, Suite 1000 Washington, DC 20001 T 202-337-2701 F 202-337-4271 E-mail: ahp@facs.org Procedure Coding System (ICD-10-PCS) for hospital inpatient 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): Excision of Intestinal Body Parts

CMS identified a replication issue from the International Classification of Diseases, 9th Revision (ICD-9)-based MS-DRGs to the ICD-10-based MS-DRGs regarding the assignment of eight ICD-10-PCS codes that describe the excision of intestinal body parts by open, percutaneous, or percutaneous endoscopic approach designated as an operating room (O.R.) procedure and assigned to MDC 06 (Diseases and Disorders of the Digestive System) in MS-DRGs 347, 348, and 349 (Anal and Stomal Procedures with Major Complication or Comorbidity [MCC], with Complication or Comorbidity [CC], and without CC/MCC, respectively). These eight procedure codes are shown in the table below.

ICD-10-PCS Code	Description
0DB83ZZ	Excision of small intestine, percutaneous approach
0DBA3ZZ	Excision of jejunum, percutaneous approach
0DBA4ZZ	Excision of jejunum, percutaneous endoscopic approach
0DBB3ZZ	Excision of ileum, percutaneous approach
0DBB4ZZ	Excision of ileum, percutaneous endoscopic approach
0DBC0ZZ	Excision of ileocecal valve, open approach
0DBC3ZZ	Excision of ileocecal valve, percutaneous approach
0DBC4ZZ	Excision of ileocecal valve, percutaneous endoscopic approach

During its review, CMS also noted that there are four additional ICD-10-PCS code translations that provide more detailed and specific information for ICD-9-CM code 45.33; however, these four codes currently group to MS-DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC), with CC, and without CC/MCC, respectively), not MS-DRGs 347, 348, and 349. These four procedure codes are shown in the table below.

ICD-10-PCS Code	Description
0DB80ZZ	Excision of small intestine, open approach
0DB84ZZ	Excision of small intestine, percutaneous endoscopic approach
0DBA0ZZ	Excision of jejunum, open approach
0DBB0ZZ	Excision of ileum, open approach

After examination of claims data from the September 2023 update of the FY 2023 Medicare Provider Analysis and Review (MedPAR) file for MS-DRGs 347, 348, and 349 and for MS-DRGs 329, 330, and 331, the Agency determined that the eight procedure codes that describe excision of intestinal body parts

by an open, percutaneous, or percutaneous endoscopic approach are not clinically consistent with procedures on the anus or stoma, and it is clinically appropriate to reassign these procedures to be consistent with the four other procedure codes that describe excision of intestinal body parts by an open, or percutaneous endoscopic approach in MS-DRGs 329, 330, and 331.

Accordingly, CMS proposes the reassignment of procedure codes 0DB83ZZ, 0DBA3ZZ, 0DBA4ZZ, 0DBB3ZZ, 0DBB4ZZ, 0DBC0ZZ, 0DBC3ZZ, and 0DBC4ZZ from MS-DRGs 347, 348, and 349 (Anal and Stomal Procedures with MCC, with CC, and without CC/MCC, respectively) to MS-DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 06 effective FY 2025. We thank CMS for this review and agree that the proposed reassignment will correct an error that was made during the transition from ICD-9 to ICD-10 coding.

MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders): Resection of Right Large Intestine

CMS identified an inconsistency in the MDC and MS-DRG assignment of procedure codes describing resection of the <u>right</u> large intestine and resection of the <u>left</u> large intestine with an open or percutaneous endoscopic approach. The Agency noted that ICD-10-PCS procedure codes 0DTG0ZZ and 0DTG4ZZ are currently assigned to MDC 10 (Endocrine, Nutritional, and Metabolic Diseases and Disorders) in MS-DRGs 628, 629, and 630. However, codes 0DTF0ZZ and 0DTF4ZZ that describe resection of the right large intestine with an open or percutaneous endoscopic approach are not assigned to MDC 10 in MS-DRGs 628, 629, and 630. CMS thereby proposes to add procedure codes 0DTF0ZZ and 0DTF4ZZ to MDC 10 in MS-DRGs 628, 629, and 630 effective FY 2025 to ensure clinical alignment and consistency, as well as appropriate MS-DRG assignment. The current DRG mapping and proposed changes are summarized in the table below.

ICD-10-PCS Code	Current DRG Mapping Rules for MS-DRG	Proposed DRG Change to Mapping Rules
 ODTG0ZZ (Resection of left large intestine, open approach) ODTG4ZZ (Resection of left large intestine, percutaneous endoscopic approach) 	 MDC 05: Diseases and Disorders of the Circulatory System MDC 06: Diseases and Disorders of the Digestive System MDC 10: Endocrine, Nutritional and Metabolic Diseases and Disorders MDC 17: Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms MDC 21: Injuries, Poisonings and Toxic Effects of Drugs MDC 24: Multiple Significant Trauma 	No change
 ODTF0ZZ (Resection of right large intestine, open approach) ODTF4ZZ (Resection of right large intestine, percutaneous endoscopic approach) 	 MDC 05: Diseases and Disorders of the Circulatory System MDC 06: Diseases and Disorders of the Digestive System MDC 17: Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms MDC 21: Injuries, Poisonings and Toxic Effects of Drugs MDC 24: Multiple Significant Trauma 	Add codes to MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders) to be consistent with MDC assignments for codes 0DTG0ZZ and 0DTG4ZZ

The ACS agrees with these mapping changes for ICD-10-PCS codes 0DTF0ZZ and 0DTF4ZZ as proposed. We also wish to highlight our concern that, as evidenced by the inconsistencies discussed above, there may be other inaccurate MDC/MS-DRG assignments for ICD-10-PCS codes. While CMS provides an index of ICD-10-PCS codes assigned to each MDC in its ICD-10-CM/PCS MS-DRG Definitions Manual, there is no "reverse" index that would be useful to find errors such as the one discovered by the Agency above—for example, if CMS had a list showing all MDCs for each ICD-10-PCS code, the wrongful omission of MDC 10 for 0DTF0ZZ and 0DTF4ZZ would have been much more visible. We urge the Agency to publish these data on its website in user-friendly "reverse" format so that specialty societies have the ability to easily review MDC/MS-DRG assignments for ICD-10-PCS codes.

O.R. and Non-O.R. Procedures

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>Laparoscopic Biopsy of Intestinal Body Parts:</u> CMS identified inconsistencies in how procedures involving laparoscopic excisions of intestinal body parts are designated. Specifically, ICD-10-PCS codes describing the laparoscopic excision of intestinal body parts for diagnostic purposes have been assigned different attributes in terms of designation as an O.R. or a non-O.R. procedure when compared to similar procedures describing the laparoscopic excisions of intestinal body parts for nondiagnostic purposes.

The five ICD-10-PCS codes shown in the table below are currently recognized as non-O.R. procedures for purposes of MS-DRG assignment, while similar excision of intestinal body part procedure codes with the same approach but different qualifiers are recognized as O.R. procedures. To address this inconsistency, CMS proposes to redesignate such codes for laparoscopic biopsy of intestinal body parts reported with the diagnostic modifier "X" as O.R. procedures and to group such codes to the same MS-DRGs as the nondiagnostic codes for laparoscopic excision procedures performed on the same intestinal body parts effective FY 2025.

ICD-10-PCS Code	Proposed O.R./Non-O.R. Designation	Proposed MDC	Proposed MS-DRG
0DBF4ZX (Excision of right large intestine, percutaneous endoscopic approach, diagnostic)	O.R. (currently non-O.R.)	MDC 05: Diseases and Disorders of the Circulatory System	264 (Other Circulatory System O.R. Procedures)
0DBG4ZX (Excision of left large intestine, percutaneous endoscopic approach, diagnostic)	O.R. (currently non-O.R.)	MDC 06: Diseases and Disorders of the Digestive System	329, 330, and 331 (Major Small and Large Bowel Procedures, with MCC, with CC, and without CC/MCC, respectively)

ICD-10-PCS Code	Proposed O.R./Non-O.R. Designation	Proposed MDC	Proposed MS-DRG
ODBL4ZX (Excision of transverse colon, percutaneous endoscopic approach, diagnostic)	O.R. (currently non-O.R.)	MDC 17: Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms	820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedures with MCC, CC, without CC/MCC, respectively)
ODBM4ZX (Excision of descending colon, percutaneous endoscopic approach, diagnostic)	O.R. (currently non-O.R.)	MDC 21: Injuries, Poisonings and Toxic Effects Of Drugs	826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively)
0DBN4ZX (Excision of sigmoid colon, percutaneous endoscopic approach, diagnostic)	O.R. (currently non-O.R.)	MDC 24: Multiple Significant Trauma	907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively)

The ACS agrees with CMS' changes to ICD-10-PCS codes 0DBF4ZX, 0DBG4ZX, 0DBL4ZX, 0DBM4ZX, and 0DBN4ZX as proposed. We wish to remind the Agency that laparoscopic procedures—whether diagnostic or nondiagnostic—will always be performed in an O.R., and urge the Agency to publish O.R./non-O.R. designation data on its website for *all* ICD-10-PCS codes—not just new codes—so that specialty societies can more easily review and identify possible errors.

• <u>Laparoscopic Biopsy of Gallbladder and Pancreas:</u> CMS identified inconsistencies in how procedures involving laparoscopic excisions of the gallbladder or pancreas are designated. Specifically, ICD-10-PCS codes describing the laparoscopic excision of the gallbladder or the pancreas for diagnostic purposes listed previously have been assigned different attributes in terms of designation as an O.R. or a non-O.R. procedure when compared to similar procedures describing the laparoscopic excisions of the gallbladder or the pancreas for nondiagnostic purposes.

ICD-10-PCS codes 0FB44ZX and 0FBG4ZX are currently recognized as non-O.R. procedures for purposes of MS-DRG assignment, while similar excision of the gallbladder or the pancreas procedure codes with the same approach but different qualifiers are recognized as O.R. procedures. To address this inconsistency, CMS proposes to redesignate such codes for laparoscopic excision of the gallbladder or pancreas reported with the diagnostic modifier "X" as O.R. procedures and to group such codes to the same MS-DRGs as the nondiagnostic codes for laparoscopic excision procedures performed on the gallbladder or pancreas effective FY 2025. The ACS agrees with CMS' changes to ICD-10-PCS codes 0FB44ZX and 0FBG4ZX as proposed in the following table.

Proposed O.R./Non- O.R. Designation	Proposed MDC	Proposed MS-DRG			
ICD-10-PCS Code: 0FE	ICD-10-PCS Code: 0FB44ZX (Excision of gallbladder, percutaneous endoscopic approach, diagnostic)				
	MDC 07: Diseases and Disorders of the Hepatobiliary System and Pancreas	411, 412, 413 (Cholecystectomy with common duct exploration (C.D.E.), with MCC, with CC, and without CC/MCC, respectively)			
		417, 418, and 419 (Laparoscopic Cholecystectomy without C.D.E., with MCC, with CC, and without CC/MCC, respectively)			
	MDC 17: Myeloproliferative	820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively)			
O.R. (currently non-O.R.)	Diseases and Disorders, Poorly Differentiated Neoplasms	826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively)			
	MDC 21: Injuries, Poisonings and Toxic Effects of Drugs	907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively)			
	MDC 24: Multiple Significant Trauma	957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively)			
ICD-10-PCS Code: 0F	BG4ZX (Excision of pancreas	s, percutaneous endoscopic approach, diagnostic)			
	MDC 06: Diseases and Disorders of the Digestive System	405, 406, and 407 (Pancreas, Liver and Shunt Procedures, with MCC, with CC, and without CC/MCC, respectively)			
O.R.	MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders)	628, 629 and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively)			
(currently non-O.R.)	MDC 21: Injuries, Poisonings and Toxic Effects of Drugs	907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively)			
	MDC 24: Multiple Significant Trauma	957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively)			

REQUIREMENTS FOR AND CHANGES TO THE HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM

Proposed Adoption of the Patient Safety Structural Measure Beginning with the Calendar Year (CY) 2025 Reporting Period/FY 2027 Payment Determination for the Hospital IQR Program and the CY 2025 Reporting Period/FY 2027 Program Year

CMS proposes the adoption of the Patient Safety Structural measure within the Hospital IQR and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) program beginning with the CY 2025 reporting period/FY 2027 payment determination. CMS explains that although there are several outcome and process measures currently in use under CMS' hospital quality measurement programs, they capture specific conditions or procedures. While important, they are not sufficient by themselves to incentivize a more holistic, proactive, systems-based approach to patient safety. This new attestation-based measure assesses whether hospitals demonstrate a structure, culture, and leadership commitment that prioritize safety. The Patient Safety Structural measure includes five complementary domains, each containing a related set of statements that aim to capture the most salient, evidenced-based, structural, and cultural elements of safety. This measure is intended to be a foundational measure and designed to assess hospital implementation of a systems-based approach to safety best practices, as demonstrated by the following domains:

- Leadership commitment to eliminating preventable harm;
- Strategic planning and organizational policies;
- Culture of safety and learning health systems;
- Accountability and transparency; and
- Patient and family engagement.

Hospitals participating in the Hospital IQR Program and the PCHQR Program would satisfy their reporting requirement for the measure if they attest "yes" or "no" to each attestation statement in all five domains once annually.

The ACS supports the Patient Safety Structural measure, which takes a systems-based comprehensive approach to addressing patient safety. This measure aligns with many of the key domains of the ACS Quality Model, which is used across all ACS quality programs, including Trauma, Bariatrics, and Cancer. The ACS Quality Model domains include: 1) Institutional Administrative Commitment; 2) Program Scope and Governance; 3) Facilities and Equipment Resources; 4) Personnel and Services Resources; 5) Patient Care: Expectations and Protocols; 6) Data Surveillance and Systems; 7) Quality Improvement; 8) Professional; and 9) Community Outreach Research.

The Patient Safety Structural measure is complementary to patient safety indicators (PSIs)—such as PSI-90, which solely focus on avoiding adverse events—but goes beyond solely tracking PSIs by building a culture of safety with focus on the patient. We believe too much is assumed by reliance on measurement as the end point. Measures are a reflection of the activity and one's ability to attain specific objectives. A facility's ability to build teams to achieve clinical objectives has been assumed for too long. In the ACS' decades of experience assessing structure and process in hospitals through our verification programs for services such as trauma care, we have learned about the importance of having the right structure and assuring processes are well-executed in optimally achieving an outcome. This measure will support

hospitals as they address the complexities of ensuring safety in the inpatient setting and provide assurance to patients seeking safe care.

Proposal to Adopt the Age Friendly Hospital Measure Beginning with the CY 2025 Reporting Period/FY 2027 Payment Determination

CMS is proposing the Age Friendly Hospital measure for inclusion in the Hospital IQR Program, beginning with the CY 2025 reporting period/FY 2027 payment determination. The Agency states that with being the largest provider of healthcare coverage for the nation's older population, it is timely to propose a quality measure aimed at optimizing care for older patients, using a holistic approach to better serve the needs of this unique population. The ACS thanks CMS for its consideration of the measure and writes to express our strong support for the inclusion of the Age Friendly Hospital measure in the CMS Hospital IQR Program. We also thank CMS for recognizing that structural measures have value in developing evidence-based programs and processes that drive improvements in care delivery.

Background

The Age Friendly Hospital measure is a new type of measure, a "programmatic composite" measure, that considers the full program of care needed for geriatric patients in the hospital. As discussed in the rule, the measure was developed in partnership with the ACS, the Institute for Healthcare Improvement (IHI), and the American College of Emergency Physicians (ACEP), to help build a better, safer environment for older adults and to support patients and caregivers when seeking where to find good care. This measure is designed to support hospitals as they address the complexities of caring for the medical, physiological, and psychosocial needs of older patients that are often inadequately addressed by the current healthcare infrastructure. In response to this gap in care, the Age Friendly Hospital measure was developed and built on evidence-based best practices to provide patient-centered, clinically-effective care for older patients.

The Age Friendly Hospital measure combines two measures previously reviewed by the National Quality Forum's (NQF) Measures Application Partnership (MAP) in 2022: the Geriatrics Hospital Measure (MUC 2022-112) and the Geriatrics Surgical Measure (MUC 2022-032). Both measures received broad support; however, the MAP Hospital Workgroup recommended that the two measures be combined into a single measure to reduce burden. Based on this feedback, the ACS submitted the updated Age Friendly Hospital measure for review under the 2023-2024 Pre-Rulemaking Measure Review (PRMR) process. The updated measure includes domains that are more streamlined and target high-yield points of intervention for older adults—Eliciting Patient Healthcare Goals, Responsible Medication Management, Frailty Screening and Intervention (i.e., Mobility, Mentation, and Malnutrition), Social Vulnerability (social isolation, economic insecurity, ageism, limited access to healthcare, caregiver stress, elder abuse), and Age Friendly Care Leadership.

The measure was developed with 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 6 Institute of Medicine domains (safe,

¹ Peters X, Sage J, Collins C, Opelka F, Ko C. Programmatic quality measures: a new model to promote surgical quality. *Health Aff Sch.* 2024; 2(1):qxad094.

effective, patient-centered, timely, efficient, equitable), and is comprehensive across the full spectrum of geriatric care. Surgery, the emergency department (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 O.R. 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 long-term health and aligning care with what the patient values.

We designed the measure 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 while calling attention to the critical need to improve care of older adults in the hospital using attestation of key standards for the initial implementation. After hospitals understand the first phase of the measure, the next phase could 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.

Rethinking Quality Measurement with Programmatic Measures

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 typical measures used in CMS quality programs. 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 necessary alignment. Development of individual measures and the combination of these measures into payment incentive programs may be useful for fee-for-service payment, but value-based payments need a more condition-specific, patient-type approach. The programmatic approach used in the Age Friendly Hospital measure focuses on care within a clinical domain. We believe by implementing this measure we will be moving closer to creating a team-based approach that optimizes the patient's chances to achieve their desired outcome.

The concept behind the programmatic measure is based on several decades of history implementing programs that demonstrably improve patient care provided by the clinical team along with the facility. The Age Friendly Hospital measure incorporates elements of IHI's Age-Friendly Health Systems program known as the 4Ms (What Matters, Medications, Mentation, Mobility), standards from the Geriatric Emergency Department Accreditation (GEDA) framework developed by ACEP, and ACS Geriatric Surgical Verification (GSV) standards. The programmatic approach is modeled after ACS quality programs, which lead to demonstrable improvements in patient outcomes across a broad range of

populations.^{2,3,4,5,6,7,8} 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 is our hope that CMS continues to appreciate the clinical programmatic linkages across its various incentive payment initiatives. For too long we have locked ourselves into measures that have been tied to an individual service and not always tied to the patient's outcome as the key objective. We applaud efforts that measure the completeness and functional competencies of a team in a well-orchestrated program of care across the patient's complete care journey.

Public Support for the Age Friendly Hospital Measure

The Age Friendly Hospital measure has received broad support since the concept of geriatrics-focused programmatic measures was first introduced in 2022. Support for the measure has continued to grow as the measure was refined and streamlined into its current version. Most stakeholders, including CMS, understand that hospitals are struggling to optimize care for elderly patients and have been supportive of the measure's intent to shine a light on the needs of this patient population. This is highlighted in an article published in *Health Affairs* that describes support for the measure across organizations who care for older adults.⁹

Over the last two years, the ACS submitted sign on letters to the 2022 NQF MAP review of the Geriatrics measures, a request for information (RFI) in the 2024 IPPS proposed rule where CMS highlighted the need for a comprehensive measure that addresses the aging population during hospital stays, and the 2023 PRMR public comment. The measure has received diverse support with signatories representing hospital systems, patient advocacy groups, clinical quality collaboratives, geriatric nursing groups, professional medical societies, and more. Details of each letter are described below.

- The sign on letter to 2022 NQF MAP in support of the Geriatrics Surgical and Geriatrics Hospital measures included signatures from 9 organizations.
- A sign on letter to the 2024 IPPS proposed rule RFI discussing the need for a comprehensive measure focused on geriatric care included signatures from 12 supporting organizations.
- A sign on letter to the 2023 PRMR public comment included signatures from 16 organizations that supported the implementation of the measure in the Hospital IQR.

During the 2023 PRMR public comment period, CMS received a total of 25 public comments on the Age Friendly Hospital measure, with 20 comments in support of the measure and four in opposition. In

² 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.

³ 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.

⁴ Morton JM, Garg T, Nguyen N. Does hospital accreditation impact bariatric surgery safety? Ann Surg. 2014;260(3):504-508.

⁵ Baidwan 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;10(1):e12348.

⁶ 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.

⁷ Miller ME, Bleicher RJ, Kaufman CS, et al. Impact on Breast Center Accreditation on Compliance with Breast Quality Performance Measures at Commission on Cancer-Accredited Centers. Ann Surg Oncol. 2019;26(5):1202-1211.

⁸ Winchester DP. The National Accreditation Program for Breast Centers: quality improvement through standard setting. *Surg Oncol Clin N Am.* 2011; 20(3):581-586.

⁹ Snyder RE, Fulmer T. The Need for Geriatrics Measures. *Health Affairs*. April 14, 2023. Accessed December 1, 2023. https://www.healthaffairs.org/content/forefront/need-geriatrics-measures.

addition to support for the measure's intent, comments also supported elements of the measure that screen for malnutrition and social vulnerabilities in older adults and its holistic nature. One commenter stated that the measure will "prepare hospitals for the changing demographics and needs of an increasingly aging population. Reframing geriatric care will benefit not only the patients but also families, caregivers and health systems with improved outcomes and patient-centered care."

<u>Proposal to Adopt the Thirty-day Risk-Standardized Death Rate Among Surgical Inpatients with</u> Complications (Failure-to-Rescue) Measure Beginning With the FY 2027 Payment Determination

CMS proposes to adopt the Failure-to-Rescue measure beginning with the performance period of July 1, 2023-June 30, 2025. The measure is a risk-standardized measure of death after hospital-acquired complication. The denominator includes patients 18 years old and older admitted for certain procedures in the General Surgery, Orthopedic, or Cardiovascular MS-DRGs who were enrolled in the Medicare program and had a documented complication that was not present on admission. The measure numerator includes patients who died within 30 days from the date of their first "operating room" procedure, regardless of site of death.

Over the years, the ACS has continuously monitored the measures within the PSI composite and raised issues with various measures in the PSI composite. In general, patient safety measures are useful in assuring hospitals focus additional attention on high-risk patients undergoing surgical services (safety) and that the necessary precautions are taken to prevent deaths. However, they fail to provide useful information to inform patients or referring physicians and are not well-suited for incentive programs due to their limitations.

We recommend CMS take great care when applying these measures to hospitals in public reporting and/or incentive payment programs to not misinform patients and/or rewards related to payments. We have concerns about unintended consequences that may arise based on well-known limitations in measurement science, such as the statistical challenges with small sample sizes, unanticipated variables, such as social determinants or patient preferences, and more. These limitations, as well as imprecision, limited confidence, and excessive margins of error, may lead to misclassification of care delivery. Measures that are tied to payment or public reporting will influence care and should be tracked for their potential to mislabel care and render a suboptimal interpretation of a provider. Assessment of measures for their effectiveness, impact, and overall performance are an important part of measurement science and should be carried out regularly. These assessments should be carried out by various unbiased parties with expertise in the community to ensure that when issues arise they are tracked and reported in a timely manner.

The following points outline our ongoing concerns with these measures:

- Risk Adjustment: Inadequate risk adjustment may not fully account for the varying complexity of patient populations across different hospitals. Hospitals treating sicker or more complex patients might appear to have worse outcomes, even if their quality of care is high.
- Coding and Documentation Variability: Differences in how hospitals document and code complications can lead to discrepancies in rates of these events, which can result in low validity and reliability.

- Present on Admission (POA) Indicator Challenges: Misuse or inconsistent use of the POA indicator can lead to incorrect inclusion of cases. This can inflate a hospital's rates if complications present on admission are not correctly identified.
- Surveillance Bias: Hospitals with more diligent surveillance and reporting practices may detect and document more complications, potentially making their performance appear worse compared to hospitals with less rigorous practices, thereby misclassifying care.

We also present suggestions on how CMS can begin to mitigate the challenges associated with these measures.

- Improving Coding Accuracy: Providing training and resources to ensure accurate and consistent use of ICD-10-CM codes and POA indicators can help improve the reliability of failure to rescue data.
- Enhanced Risk Adjustment: Incorporating more detailed clinical data into risk adjustment models can provide a fairer comparison of hospital performance.
- Continuous Monitoring and Feedback: Regularly reviewing measure data and providing feedback to clinical teams can help identify and address potential issues in documentation and patient safety practices.
- Collaboration and Best Practices: Sharing best practices and collaborating with other hospitals can help improve overall data quality and patient safety outcomes.

OTHER PROVISIONS INCLUDED IN THIS PROPOSED RULE

Proposed Transforming Episode Accountability Model (TEAM)

CMS proposes the implementation and testing of the TEAM, a mandatory alternative payment model, beginning on January 1, 2026, and ending on December 31, 2030. The Agency states that the proposed TEAM intends to test whether an episode-based pricing methodology linked with quality measure performance for select acute care hospitals reduces Medicare program expenditures while preserving or improving the quality of care for Medicare beneficiaries who initiate certain episode categories. The proposed TEAM would test the following five surgical episode categories:

- Coronary artery bypass graft (CABG);
- Lower extremity joint replacement (LEJR);
- Major bowel procedure;
- Surgical hip/femur fracture treatment (SHFFT); and
- Spinal fusion.

CMS proposes that the acute care hospital TEAM participant will be the only entity eligible to initiate an episode—this was done to reduce administrative complexity experienced in previous models. CMS also describes how they designed the TEAM to build upon previous CMS Innovation Center episode-based payment models, including the Bundled Payments for Care Improvements (BPCI) Advanced and Comprehensive Care for Joint Replacement (CJR) models. TEAM is intended to center accountability on beneficiary health care needs during narrow, focused periods of acute and post-acute care while health care needs outside of this scope would be addressed with other elements of the CMS Innovation Center (CMMI) specialty care strategy. We highlight our positions and feedback on multiple TEAM proposals in the summary below.

Summary of ACS TEAM Positions

- Mandatory Participation Requirement: If finalized, participation in TEAM will be mandatory for hospitals in selected geographic areas. The ACS has been a strong advocate for using episodes as a glide path to incentivize high-value care; however the ACS strongly opposes requiring mandatory participation in the TEAM, particularly due to misaligned quality indicators and potential unintended consequences. The ACS emphasizes the need for alignment between quality and cost models to ensure that TEAM incentivizes high-value, coordinated care.
- Definition of Major Bowel Procedure Episode: Major Bowel Procedure Episodes is included as one of the five surgical episodes proposed for testing within the TEAM. However, in order for the major bowel episode to be successful, the ACS recommends that CMS split the episode into small and large bowel episodes and only include elective procedures, due to the broad nature of the procedures and complex diagnoses included. Creating more specific episode groupings better aligns with clinical care and is better suited for: determining the value of an episode, assigning quality metrics, informing patients, providing information to referring primary care providers (PCP), and aiding health plans seeking to contract for episodic-specific services.
- Risk Adjustment Methodologies for TEAM: Multiple risk adjustment methods are proposed for the TEAM. Risk adjustment is critical to accurately compare costs and outcomes of surgical procedures across diverse patient populations. The ACS asserts that the current methodology is limited and will likely not be adequate for supporting clinical decisions for care teams and patients. We recommend CMS consider a number of additional variables, including demographic factors, clinical factors, and procedure-specific factors.
- Quality Measurement Mechanisms: Quality measures proposed for TEAM include all-cause readmission, patient safety composites, and patient-reported outcomes for specific episodes. The ACS opposes the use of these metrics and argues that the TEAM is not ready for mandatory participation until CMS can define quality metrics that align with the proposed episodes and focus on patient-centric care and transparency. The ACS recommends CMS explore expanding on measures that are 1) programmatic measures, similar to the proposed Age Friendly Hospital measure, as a means to assess episode-specific quality, and 2) measures that include the patient's voice, such as the Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure as proposed for the LEJR Episode. Developing a quality framework that maps to each episode is paramount. The TEAM will not move the needle in the way CMS intends if a better solution for quality is not defined. We strongly urge CMS to focus on developing the right measures and processes to drive improvement and engage subject matter experts in this effort before making this model mandatory.
- Considerations for Safety Net Hospitals: Participation in the TEAM will require facilities to realign care to focus on episodes, meet patient goals and outcomes, and be efficient in cost to value-based care. A complete redesign of clinical care and culture changes are required for success and will take major investment and resources. Given this, the ACS is concerned about mandating TEAM in rural and safety net hospitals when there are insufficient resources to support the changes to switch their business model. We raise questions around how CMS plans to support these facilities as they implement these new elements of care to prevent putting them in a more

difficult position. We also are concerned that the single episode target price would be very difficult for small rural and safety net hospitals to achieve.

Proposed Mandatary Participation

The Agency proposes to require hospitals located in selected geographic areas that meet the TEAM participant definition to participate in the model. The Agency states that they considered making participation in TEAM voluntary but felt that a fully voluntary model would not lead to meaningful evaluation findings based on past experience with voluntary episode-based payment models.

The ACS has been a strong advocate for using episodes as a glide path to incentivize high-value care, and thanks CMS for its efforts in building episodes for surgical services. While we appreciate this effort, we do not support the mandatory participation requirement. In the proposed TEAM, we question the model's readiness for mandatory participation due to the lack of alignment of the quality indicators to the proposed episodes. We believe that this is a gap that must be resolved prior to requiring participation in the model to ensure quality of care does not get worse.

Understanding the quality of care being delivered and creating mechanisms to incentivize continuous improvement play an important role in achieving value for patients, the care team, and payers. For participation in the TEAM to be meaningful, the quality model and cost model for each episode must be aligned. This is the only way to truly understand if the model is incentivizing the delivery of team-based coordinated care, improving efficiency and resource use, promoting transparency to inform improvement, and achieving higher-value care overall. Selecting the proper quality indicators for each episode is also essential to supporting patients, accountable care organizations (ACOs), referring physicians, and others when they seek high-quality specialty care. Without this information, there is potential for unintended consequences, such as misdirecting care to facilities or providers who cannot adequately care for the specific needs of patients. If CMS finalizes the requirements for mandatory participation in TEAM, they must closely monitor for unintended consequences.

The design of the TEAM initiative has several major flaws that have potential to erode the integrity of the pilot. Some aspects are helpful and would be worthwhile for learning and future design, while other aspects will become critical points of failure in care—saving money at patients' expense and diluting trust in the system. A fair design in an episode system relies on properly defining the episode for inclusions and exclusions. This works well in narrowly-scoped episodes but not in episodes where inclusions are highly variable and diagnoses are unrelated. Limiting the sites of care for inclusion may simplify the overall design but the consequence may be to avoid those sites of care and potentially limit patients for inclusion, which can impact access to care. Finally, as previously mentioned, when quality measures are applied to cost for interpretation of overall value, quality metrics must match the episode.

As proposed, the TEAM is better suited for optional participation—voluntary participation is necessary until CMS has evidence that the elements of the model are optimally working to achieve their goals for high-quality value-based care. An optional model that is properly designed will naturally create market forces to attract participants who want to share in the benefits and foster innovation.

Financial Accountability of a TEAM Participant

The Agency discusses that through its experience implementing the CJR model, they continue to believe it is best to identify a single entity to bear financial accountability for participation in order to avoid challenges of having multiple providers or suppliers in a single model initiate an episode. The rationale is that it would simplify episode attribution and make it easier for the single entity to identify beneficiaries that may be included in the model. Given this, CMS proposes to make the TEAM participants financially accountable for making repayment if quality and spending performance metrics are not met to CMS under the model after reconciliation has been performed. Within the proposed rule, CMS also states that they considered splitting financial accountability between the TEAM participant and other providers and suppliers that provide items and services to the TEAM beneficiary. However, the Agency was concerned about the accuracy of a reasonable sharing methodology that reflects the portion of spending the TEAM participant or the physician group practice (PGP) should be financially accountable for and therefore did not move forward. The Agency asks for comments on approaches to splitting financial accountability when multiple providers or suppliers care for a single beneficiary in an episode.

While the ACS can understand the complexities of splitting financial accountability, we are concerned that the business model proposed for the TEAM does not map to the care model. We believe the administrative complexities and system-wide preferences will outweigh the benefits. The focus will be on the hospital and how hospital metrics can dilute any potential risk presented by the program. The risk-bearing entity (RBE) must be laser-focused on the episode under consideration. While this is a welcome change from the focus on volume, what considerations did CMS have for the RBE other than the hospital, such as hospital-PGPs or clinically integrated networks (CINs)? Examples of this exist in some cardiac and musculoskeletal programs. These stakeholders are amenable to serving as an RBE because they are highly-focused, team-based, and able to construct an episode-directed quality program and track episode costs—regardless of site of care. It seems this pilot selected a hospital-based program out of payer convenience and efficiency rather than optimal care model. The impact, as designed, lacks the patient-centered protections necessary to assure high-value care and draws more attention to the impact on hospitals.

Proposed Episodes

CMS proposes testing five surgical episodes in the model: CABG, LEJR, SHFFT, Spinal Fusion, and Major Bowel Procedures. The Agency explained that these were chosen because they are time-limited with well-defined triggers, have clinically similar patient populations with common care pathways, and have sufficient spending or quality variability, particularly in the post-acute period, to offer participants the opportunity to improvement.

Episode Category Definition

CMS proposes to define episodes as including all Medicare Part A and Part B items and services with some exceptions, beginning with an admission to an acute care hospital stay (hereinafter "the anchor hospitalization") or an outpatient procedure at a hospital outpatient department (HOPD) (hereinafter "anchor procedure"), and ending 30-days following hospital discharge or anchor procedure.

Major Bowel Procedure Episode Category

The Agency proposes to include the Major Bowel Procedure episode category for beneficiaries undergoing inpatient major small bowel and large bowel procedures. They state that this episode was chosen because it was the fifth-highest volume and fourth-highest cost BPCI Advanced surgical episode performed in the inpatient setting using 2021 data. CMS seeks comment on its proposed definition and inclusion of Major Bowel Procedure episode.

The ACS recommends that CMS consider Major Bowel Procedures through a different lens than the other episodes included in the TEAM due to the broad nature of the procedures and complex diagnoses included. For example, the LEJR episode encompasses three services: knee, hip, ankle replacement. In contrast, the procedures within the Major Bowel Procedure episode represent components of a complex gastrointestinal (GI) surgery service line, which includes episodes for stomach procedures, pancreas procedures, small bowel procedures, colon procedures, and more.

The LEJR episodes are narrowly focused and typically associated with limited relevant diagnoses, such as osteoarthritis. This is similar to the CABG and spinal fusion episodes that are also defined with focused relevant diagnoses for inclusion in defining the episode definitions. In contrast, the Major Bowel Procedures episodes represent a more complicated set of procedures and a complex array of associated diagnoses. Therefore, the ACS recommends that small bowel procedures should be excluded from the episode. If excluding small bowel is not possible, the Major Bowel Procedures should be split into at least two subsets of service episodes: small bowel episodes and large bowel episodes. Small bowel and large bowel procedures have distinctly different diagnoses, surgical treatment, clinical outcomes, and attendant risks. In addition, we advise that only elective procedures should be included in the episode.

The goal of episode groups should be more than similar price points. The optimal set of goals should be to help patients find the care they seek and for care teams to focus on improving safety, outcomes, and the quality of care. To attain these goals, episodes work best when the diagnoses and grouped clinical services are aligned. Since we see CMS has done this with the other non-bowel episodes, we ask for the same consideration on behalf of patients and care teams for major bowel.

To illustrate this with one example, the goals for managing inflammatory bowel disease in small bowel surgical care are related to resolving the clinical problem while preserving small intestine. Loss of small intestine may lead to nutritional deficiencies that are harmful to patients.

In large bowel surgical care, the primary goal for treating inflammatory bowel disease is to resect the disease. There are no similar concerns about the risk of nutritional deficiencies.

Grouping episodes by small bowel and large bowel procedures and only including elective procedures better align with clinical care and would be better suited for determining the value of an episode, assigning quality metrics, informing patients, providing information to referring PCPs, and aiding health plans seeking to contract for episodic-specific services. Merging major bowel procedures into one episode limits the utility of the episode approach to alternative payment systems. Ultimately, the goal should be to create episodes that are meaningful and actionable to the various stakeholders and not to primarily serve payment systems.

Additionally, we strongly recommend that the episode exclude urgent/emergent bowel procedures.

We ran a cost analysis of 2023 Medicare fee-for-service rate and average cost of small bowel versus large bowel procedures and elective versus emergent procedures, showing a major variation in cost per episode in elective versus emergent cases for both small and large bowel services. These results are illustrated below in *Figure 1*. Our analysis demonstrates that urgent/emergent cases are roughly \$15,000-\$20,000 more compared to elective. The current model does not account for the dramatic difference in cost in elective versus urgent/emergent major bowel procedures.

Figure 1. TEAM Major Bowel Episodes

Census Division 1: (CT-ME-MA-NH-RI-VT)

	Elective		Urgent/	Emergent
	Count	Cost	Count	Cost
Large	1943	\$23,699	989	\$40,909
Small	336	\$22,473	637	\$38,065

Census Division 2: (NJ-NY-PA)

	Elective		Urgent/	Emergent
	Count	Cost	Count	Cost
Large	4277	\$24,295	2263	\$41,764
Small	790	\$24,072	1391	\$39,885

Census Division 3: (IL-IN-MI-OH-WI)

	Elective		Urgent/Emergent	
	Count	Cost	Count	Cost
Large	4988	\$24,548	2492	\$42,103
Small	947	\$24,752	1586	\$40,173

Census Division 4: (IA-KS-MN-MO-NE-ND-SD)

	Elec	tive	Urgent/	Emergent
	Count	Cost	Count	Cost
Large	3011	\$24,508	1299	\$41,391
Small	579	\$25,627	805	\$40,796

Census Division 5: (DE-DC-FL-GA-NA-SC-VA-WV)

	Elec	tive	Urgent/	Emergent
	Count	Cost	Count	Cost
Large	6864	\$23,757	3491	\$40,976
Small	1100	\$23,545	2108	\$38,744

Episode Length

CMS proposes that episodes end 30 days after discharge from the anchor hospitalization or anchor procedure and that day one of the 30-day post-acute portion of the episode is the date of the anchor procedure or the date of discharge from an anchor hospitalization. If services included in an episode span a period that extends beyond the episode duration, CMS proposes that these payments would be prorated so that only the portion attributable to care during the fixed duration of the episode is attributed to the episode spending. The Agency states that they considered a longer episode duration, as used in the CJR and BPCI Advanced models, but determined that an episode length longer than 30 days poses a

greater risk for the hospital because of variability due to medical events outside the intended scope of the model. CMS believes that an episode duration of 30 days could sustain the spending reductions demonstrated in BPCI Advanced and CJR and mitigate some of the current challenges experienced between ACOs, hospitals, and other providers.

The ACS questions the effectiveness of the 30-day episode duration. Instead, we recommend that CMS look at the episode window on an episode-by-episode basis. For example, it will be difficult to capture meaningful information on the success of a knee replacement 30 days following operation—it is the avoidance of complication, reoperations, and long-term functional outcomes that will truly show success. Importantly, the model episode should align with appropriate quality measures, such as the 90-day CABG mortality measure.

Initiating Episodes

The Agency proposes that an episode would begin when a beneficiary is admitted for an anchor hospitalization or anchor procedure for one of the MS-DRGs or Healthcare Common Procedure Coding System (HCPCS) codes assigned to the TEAM episodes. We acknowledge that the TEAM is designed for hospitals; therefore, it only includes inpatient or outpatient hospital procedures, not procedures performed in ambulatory surgery centers (ASCs). We ask CMS if they have explored the impact of not including ASC-based procedures on savings, patient care, and access? Since procedures done in an ASC would not accrue shared savings under TEAM, will this create perverse incentives to shift care to or from ASCs (e.g., surgeons might be discouraged from performing appropriate surgeries in ASCs since none of the savings would be shared with the TEAM participant)?

It is possible to contemplate that certain procedures now performed in the hospital will be encouraged to move to the ASC and thereby avoid inclusion in the TEAM. Perhaps, the reverse is also true; that is, to encourage moving low-risk patients to the hospital to reduce and balance the overall results from high-risk patients. In other words, the episode of care that is patient-centric has the analytical ability to be inclusive of all sites of care and create targets consistent with patient risk and site of service.

The major concern is how this will impact care for Medicare beneficiaries? How will CMS track these activities for impact on patients or unintended consequences? Aligning incentives around the patient care journey—and not the setting of care or payment system—should be the goalpost for value-based care. The ACS believes it is better to build those incentives into the program from the outset. Allowing the clinical team to participate as an RBE could better align incentives around the patient because the team has responsibility for the care journey, including time in the hospital and time to discharge.

Quality Measures and Reporting

Within the proposed rule, CMS discusses the importance of performance metrics that incentivize improvements in patient outcomes while simultaneously lowering health care spending. It also states that it believes that improved quality of care, specifically achieved through coordination and communication among providers, patients, and their caregivers, can favorably influence patient outcomes. The Agency proposes that TEAM would incorporate quality measures that focus on care coordination, patient safety, and patient reported outcomes (PROs) that represent areas of quality particularly important to patients undergoing acute procedures.

Selection of Proposed Quality Measures

CMS proposes three measures to determine hospital quality of care and eligibility for a TEAM reconciliation payment. CMS is proposing the following measures for all TEAM episodes:

- Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356);
- CMS Patient Safety and Adverse Events Composite (CMS PSI90) (CMIT ID #135).

In addition, the Agency is proposing the Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618) for LEJR episodes. Beginning in Performance Year One and continuing for the duration of the model, CMS proposes to adjust reconciliation amounts by the TEAM participants' Composite Quality Score (CQS) based on their performance of quality measures previously listed. CMS proposes that the CQS baseline period would be CY2025 for the duration of the TEAM.

The ACS is extremely concerned with the lack of accountability for quality in the TEAM model. With the exception of the PRO-PM required for LEJR episode participants, the measures proposed will do little to show performance distinction due to their lack of relationship to the proposed episodes. The ACS supports the inclusion of the Hospital-Level THA/TKA PRO-PM in the LEJR episode of the TEAM. The PRO-PM acknowledges a patient's functional outcome following these procedures and therefore is well-suited to show the success of the episode for value assessment. In contrast, the first two measures (CMIT ID #356 and CMIT ID #135) are calculated for all hospital inpatients and do not specifically apply to the episodes included in TEAM. Therefore, it is possible that the patients receiving the surgeries included in TEAM could receive significantly lower quality care without reducing the overall average performance on the measures enough to be reflected in the reconciliation payment. The first two measures also only apply to inpatient care, so there would be no assessment of quality for outpatient procedures other than elective hip and knee replacements.

In addition, because two of the measures are hospital-wide measures, a hospital's performance on the measures will depend as much or more on how its readmission rate and patient safety performance compares to other hospitals for patients who are not eligible for TEAM than for the patients in TEAM episodes. Moreover, a hospital's performance on the quality measures could decrease under the TEAM, but the proposed quality score in TEAM does not assess whether a hospital's performance has changed; it merely compares each year's performance to the national average. As a result, a hospital might receive no penalty or only a small penalty if its lower performance was higher than the average of other hospitals nationally. We feel that this falls extremely short of incentivizing the delivery of high-quality care within the episodes in the model because it lacks the transparency needed to identify gaps in care within the episodes or incentivize improvement efforts. Without quality measures that map to the episode this is simply cost containment, which is a race to the bottom.

We also see the lack of alignment between the CQS baseline period and the baseline episode spending period as problematic, and seek clarity from the Agency. CMS proposes to use three years of baseline episode spending, rebased and shifted up annually to calculate benchmark prices. This results in different schedules for TEAM quality and cost assessments. For quality measures to be meaningful, benchmarks should be based on the most current data available and updated annually. We ask CMS why it chose this period for quality assessment, especially when it uses similar contemporaneous

or rolling baseline periods in other CMS quality programs, such as the Merit-based Incentive Payment System (MIPS)?

Among these issues, the proposed measures lack patient-centricity. As discussed in earlier sections, quality metrics should focus on centering the efforts of care teams around the patient and how to best meet their goals for care. Quality information should be transparent and serve the following objectives:

- Increase transparency and empower patients and caregivers to make effective decisions about where to receive care that best fits their needs.
- Support collaboration across the care team to meet a shared goal by defining and operationalizing a clinical unit-based system.
- Create resource and protocol standardization, evidence-based and data-driven processes, and functional strategies for hospitals to achieve improved care and outcomes.
- Provide payers with information that they can use to ensure their beneficiaries will receive high-quality care with the most efficient cost savings.

From the ACS perspective, measures that follow a quality program framework for a condition or episode provide clinical frameworks founded on evidence-based best practices to provide goal-centered, clinically-effective care for patients. Programmatic measures are designed to map to a condition or service line and focus the care team around the patient. Our experience with programmatic measures demonstrates applicability to diverse care settings, limited burden on care providers, and demonstrably better results. As CMS puts resources into building out the TEAM, developing a quality framework that maps to each episode is paramount. The TEAM will not move the needle in the way CMS intends if a better solution for quality is not defined. We strongly urge CMS to focus on developing the right measures and processes to drive improvement and engage subject matter experts in this effort before making this model mandatory.

CMS discusses the value of shared decision-making (SDM) measures but explains that implementing SDM measures is challenging in regard to the timing of patient/provider interaction and when the episode is initiated. Incorporating SDM measures aligns with a programmatic approach to care and is a step in the right direction to identify what matters to the patient up front in order to deliver care based on patient goals, including the decision to operate. Current risk calculators, such as the ACS National Surgical Quality Improvement Program (NSQIP) surgical risk calculator, can be used to discuss individual clinical risk, as a starting point. We encourage CMS to take next steps in building out how to identify and measure patient goal attainment. Models as they are today are based on assumptions of the appropriateness of care—instead we should have an assumption that we should realize patient goals of care which will vary based on an array of patient-specific factors such as quality of life, age, cultural background, race, ethnicity, past experience with the health care system, access to care and affordability, to name a few.

Programmatic Quality Framework for TEAM

We strongly recommend that CMS rethink how it views quality within the TEAM to acknowledge quality as program with a focus on meeting patient goals. Measures that follow a quality program, referred to as "programmatic measures," identify clinical frameworks based on evidence-based best practices to provide goal-centered, clinically-effective care for patients. CMS has taken steps to defining episodes for service lines—but in order to adequately deliver care within a service line, a team

of health care providers must work in coordination. CMS has also proposed the implementation of the Age Friendly Hospital measure in the IQR, which is the first measure that follows the program of care needed to care for elderly adults in the inpatient setting.

Programmatic quality measures 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 and follows the Donabedian framework. Programmatic measures focus on team-based care of patients including patient goals, drive quality improvement cycles with clinical data (can the team find their problems and fix them?), help guide patients seeking safe and good care, and reduce measurement burden since they are tied to optimal care delivery and improvement. The concept behind the programmatic measure is based on several decades of history implementing programs that demonstrably improve patient care provided by both the clinical team and the facility. Examples include ACS Trauma programs, Geriatric Surgery Verification, Bariatric Surgery Accreditation, ACS Cancer program, and more. Considering quality as a program quality is well-aligned to the goals of the TEAM.

Risk Adjustment and Normalization

CMS proposes the following methodologies for risk adjustment in TEAM.

- Calculate risk adjustment coefficients at the MS-DRG/HCPCS episode type level.
- Use the same age bracket risk adjustment variables (less than 65 years, 65 years to less than 75 years, 75 to less than 85 years, and 85 years or more) based on the participant's age on the first day of the episode, as determined through Medicare enrollment data.
- Use a hierarchical condition category (HCC) count risk adjustment variable (the "TEAM HCC count") that would look at the beneficiary's Medicare fee-for-service claims from a 90-day lookback period (beginning with the day prior to the anchor hospitalization or procedure) to determine which HCC flags to include in the count.
- Use a risk adjustment variable that accounts for potential markers of beneficiary social risk. The variable would be "yes" if one or more of the following apply: full Medicare/Medicaid dual eligibility status, being in a state or national Area Deprivation Index (ADI) percentile beyond a certain threshold (80th percentile for the national ADI and 8th decile for the state ADI), or Medicare Part D Low Income Subsidy (LIS). CMS would only adjust target prices if the coefficient on the beneficiary social risk adjustment variable is positive.
- Incorporate a prospective normalization factor into preliminary target prices, which would be subject to a limited adjustment at reconciliation based on the observed case mix, up to +/- 5%.

Risk adjustment is crucial for accurately comparing costs and outcomes of surgical procedures across different patient populations and providers. For CMS to effectively account for variances in price transparency for different surgical episodes, risk factors must first be identified. Figures 2 and 3 demonstrate this, showing how a patient's risk for complications and potential need for a longer hospital stay following a colectomy, can vary greatly based on just a few patient risk factors. Risk factors should account for demographic factors, clinical factors, and procedure-specific factors as described below.

- Demographic Factors: Age, gender, and socioeconomic status.
- Clinical Factors: Comorbidities (e.g., diabetes, hypertension), severity of illness, previous surgeries, and overall health status.
- Procedure-Specific Factors: Type and complexity of the colectomy, surgeon experience, and hospital characteristics.

Next, a risk adjustment model can be developed. This can be done by choosing an appropriate risk adjustment methodology (e.g., DRGs, HCCs, custom risk score models), then calculating risk scores by assigning risk scores to individual patients based on identified risk factors. These risk scores can be adjusted for clinical variability using statistical models (e.g., regression analysis) and applied to the base rate to predict expected costs based on patient risk profiles.

Surgical AMERICAN COLLEGE F SURGEONS Risk Calculator ACS NSQIP Website FAQ **ACS Website** About Procedure: 44140 - Colectomy, partial; with anastomosis Change Patient Risk Factors Note: Your Risk has been rounded to one decimal point. Average Outcomes 6 Risk Risk Outcome **Risk Factors:** Serious Complication 11.3% 16.9% Below Average Age: 50 Female 1.0% 2.7% Below Average Independent functional 0.5% 1.4% status Surgical Site Infection 9.3% 9.9% Average Mild Systemic disease **Urinary Tract Infection** 1.6% 1.8% Average Diabetes (insulin) 1.1% Hypertension Renal Failure 0.7% 1.2% Below Average BMI: 29.95 10.3% Colectomy Anastomotic Leak 2.4% 4.1% Below Average 9.6% 10.9% 4.1% Below Average 0.2% 1.5% 3.0% 4.2% Below Average Predicted Length of Hospital Stay: 4 days

Figure 2. Readiness for Partial Colectomy for a Low-Risk Patient

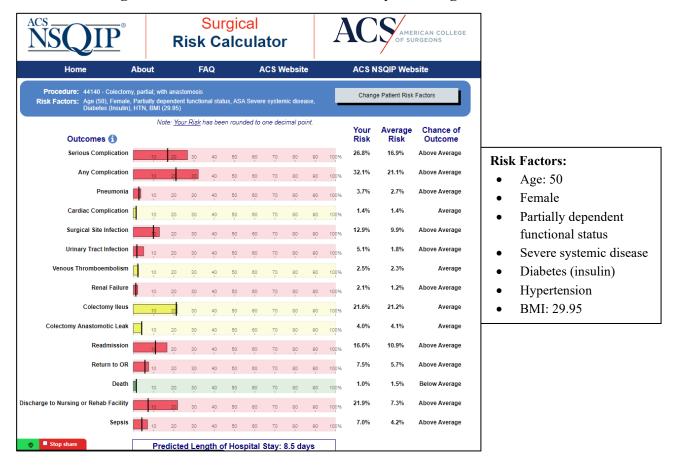


Figure 3. Readiness for Partial Colectomy for a High-Risk Patient

In another example, a recent surgical publication looked at frailty versus surgical procedural complexity. ¹⁰ The study used ACS NSQIP data and included nearly 60,000 surgical cases for review. The NSQIP data elements are aggregated in the most rigorous approach, providing trust in the data for its use in further analytics. The study showed the impact of frailty to be real and important; however, surgical complexity turned out to be even more critical. In conclusion, it is difficult to accept that a limited risk adjustment model, as used by the TEAM, will meet the necessary standards for rigor and trust to inform patients about the care they seek.

Health Equity

Proposed Methodology for Identifying Safety Net Hospitals

CMS proposes to use the CMS Innovation Center's Strategy Refresh definition for identifying safety net hospitals within TEAM, which it explains will allow for a consistent and streamlined approach to how the CMS Innovation Center plans to monitor safety net participation with CMS Innovation Center models. The definition uses two recognized measures of social risk to identify hospitals serving a higher proportion of beneficiaries that may face barriers to receiving or accessing care. Specifically, the CMS Innovation Center's Strategy Refresh defined safety net hospitals as short-term hospitals and critical

¹⁰ Zakhary B, Coimbra BC, Kwon J, Allison-Aipa T, Fireka M, Coimbra R. Procedure Risk vs. Frailty in Outcomes for Elderly Emergency General Surgery Patients: Results of a National Analysis. J Am Coll Surg. 2024.

access hospitals (CAHs) that serve above a baseline threshold of beneficiaries with dual eligibility or Part D LIS, as a proxy for low-income status. Under this definition, hospitals are identified as safety net when their patient mix of beneficiaries with dual eligibility or Part D LIS exceeds the 75th percentile threshold for all congruent facilities who bill Medicare.

CMS explains that Medicare beneficiaries and providers in rural and underserved areas can be underrepresented in voluntary models, whereas under a mandatory model they may include these entities, with safeguards as appropriate, for participation so that beneficiaries have equitable access to care redesign approaches intended to improve the quality care, and such providers gain experience in value-based care.

While we support innovation and redesign approaches to improve quality of care, ACS is concerned about mandating TEAM in rural and safety net hospitals when there are insufficient resources to support the changes to switch their business model. We also ask CMS how they plan to account for this as hospitals move into different tracks of TEAM and may be compared to other hospitals with very different resource availability over the 5-year pilot? The TEAM will require facilities to realign care to focus on episodes, meet patient goals and outcomes, be efficient in cost to value based care. These are all great strides in the transition toward value, but the complete redesign of clinical care, developing risk-based knowledge assets and dashboards, tracking benchmarks, and so forth are cultural changes and take real investment. These hospitals care for patients who lack chronic care management often coupled with complex social needs. Instead of putting these hospitals in a more difficult position, which may lead to hospitals closing, we ask CMS if they have considered how we help safety net hospitals capitalize the switch costs for these new elements of care when they lack the necessary resources? For example, one approach CMS could consider is funneling TEAM savings into incentives to support hospitals on the margins. The agency has invested in testing alternative payment models, running Physician-Focused Payment Model Technical Advisory Committee (PTAC) and building a test center in CMMI-these are the switch costs for a payer. Where are those resources in this effort? This is all happening simultaneously right after the COVID pandemic, with a nursing shortage, a physician shortage, and inflation.

Referral to Primary Care Services

CMS proposes to require TEAM participants during hospital discharge planning to make a referral to a supplier of primary care services for a TEAM beneficiary on or prior to discharge from the anchor hospitalization or anchor procedure. The ACS has been an advocate for team-based care and relationships between primary care and specialists are essential to the success of the patient. **To better support care coordination, we suggest CMS consider how it can leverage digital health tools for referrals between specialists and primary care physicians and the transfer of patient information between parties as the patient moves through the various phases of the episode.** These data can be aggregated in a digital platform and presented in a dashboard interface, which can display information about an existing relationship with a primary care provider or offer options for discharge referrals based on the patient's coverage and specific needs.

Maternity Care Conditions of Participation (CoP) RFI

There are currently no baseline care requirements for hospitals, CAHs, and rural emergency hospitals (REHs) that are specific to maternal-child services. Given the ongoing concerns about the delivery of

maternity care in Medicare and Medicaid certified hospitals, CAHs, and REHs, CMS plans to propose baseline health and safety standards for obstetrical services in the CY 2025 Outpatient Prospective Payment System (OPPS)/ASC proposed rule. CMS plans to propose a targeted obstetrical services CoP to establish baseline requirements for obstetrical care within participating facilities in the CY 2025 OPPS/ASC proposed rule based in part on public comments received in response to this RFI. Specifically, CMS is soliciting comments on what should be the overarching requirement, scope, and structure for an obstetrical services CoP. What types of facilities and care settings should such a CoP apply to (i.e., all hospitals, hospitals with/without obstetrics units, hospitals with/without emergency services, CAHs, REHs, outpatient settings, which may include inpatient and outpatient prenatal, postpartum, emergency, and birthing care services)?

The maternity crisis warrants exploring a CoP requirement, but we also recommend exploring other approaches to address the maternity crisis. At the moment, most efforts in maternity are plugging the leaks in care. These are great first steps, but to solve the conundrum of maternity care requires more work with further enrichment of the problem statement. A redesign of the clinical model will show how fragmented our business models have become and not focused adequately on the three major elements – the mother, the child, and the entire family setting. Most current efforts identify a failure point in care and focus on closing the gaps in care around that point.

What can be done to solve this problem and provide an ongoing solution that has continuous governance, oversight, and maintenance for optimal care? An alternative solution to CoP is to create a multi-tiered set of verification programs that cover the mother in the antenatal period, during the birthing episodes, and in the post-partum period for at least 1 year. Similar programs exist for neonatal care. However, these tend to be isolated, fragmented and lack a fully developed coordinated effort. The verification programs, from the maternal side as an example, should address the maternal challenges across reproductive ages of women. Specific work should focus on standards regarding high-risk patients, multi-morbid conditions, with a focus on behavioral health factors.

Maternity is a full-service line that includes mother and child. Within that service line are multiple episodes of care. The number of key role players extends beyond the obstetrician. Doulas, nurse midwives, social workers, lactation consultants, therapists, and others form a team that needs to be orchestrated in the best interest of the mother and child. However, there are many examples where business incentives have fragmented the care and challenged the handoffs across the trimesters, birth, postpartum and newborn needs, and beyond. Defining optimal care and how best to deliver it is work that needs to be formalized and placed into proper payment incentives. The aspects of neonatal services are just as complex and require linkage to the overall maternity service line. This is the rarest of clinical situations—there are at least two patients (mother and child) and even more to consider within the construct of a family.

If maternity care is to change, whether it is part of CoP or is a set of verification programs for mother, infant and family, the same high standards that highlight the elements of the ACS Levels of Trauma service are essential. The review is from top to bottom, including the board of directors, the executive administration, clinical leads in physicians and nurses, data systems, data driven improvement and public transparency and accountability. The formula for success and restoring trust in maternity care is among the most complicated.

Designating maternity care as a condition of participation in Medicare means that healthcare providers must meet specific quality, safety, and reporting standards for maternity services to participate in the Medicare program. This approach aims to improve maternal and neonatal outcomes, increase accountability, and enhance access to care, but it also presents challenges related to costs, administrative burden, and consistent implementation.

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 Jill Sage, Chief of Quality Affairs, at jsage@facs.org.

Sincerely,

Patricia L. Turner, MD, MBA, FACS

Executive Director and CEO