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July 9, 2020

Seema Verma, MPH

Administrator

Centers for Medicare & Medicaid Services

Attention: CMS-1735-P

P.O. Box 8013

Baltimore, MD 21244-1850

RE: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals (CMS-1735-P)

Dear Administrator Verma:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2021 Hospital Inpatient Prospective Payment Systems proposed rule published in the *Federal Register* on May 29, 2020.

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 CMS' Inpatient Prospective Payment System (IPPS) and related hospital quality improvement efforts. With our 100-year history in developing policy recommendations to optimize the delivery of surgical services, lower costs, improve program integrity, and make the U.S. healthcare system more effective and accessible, we believe that we can offer insight to the Agency's proposed modifications to the 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

As of October 1, 2015, 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 instead of the ICD-9-CM coding system, which was used through September 30, 2015. 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.

### ***MDC 6 (Diseases and Disorders of the Digestive System): Acute Appendicitis***

CMS received a request to add ICD-10-CM diagnosis code K35.20 (*Acute appendicitis with generalized peritonitis, without abscess*) to the list of complicated principal diagnoses that group to MS-DRGs 338, 339 and 340 (*Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively*) so that all ruptured/perforated appendicitis codes in MDC 6 (*Diseases and Disorders of the Digestive System*) group to MS-DRGs 338, 339, and 340. ICD-10-CM diagnosis code K35.20 currently groups to MS-DRGs 341, 342, and 343 (*Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively*).

The requestor also noted that diagnosis code K35.32 (*Acute appendicitis with perforation and localized peritonitis, without abscess*) currently groups to MS-DRGs 338, 339, and 340; however, diagnosis code K35.20, which describes a generalized, more extensive form of peritonitis, does not. The requestor highlighted that ICD-10-CM diagnosis code K35.20 is the only ruptured appendicitis code not included in the list of complicated principal diagnosis codes for MS-DRGs 338, 339 and 340 and indicated that it is clinically appropriate for all ruptured/perforated appendicitis diagnosis codes to group to MS-DRGs 338, 339 and 340.

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CMS identified all diagnosis codes describing acute appendicitis within the ICD-10-CM classification under subcategory K35.2 (*Acute appendicitis with generalized peritonitis*) and subcategory K35.3 (*Acute appendicitis with localized peritonitis*) and reviewed their respective MS-DRG assignments for clinical coherence. The applicable codes are listed in the table below.

ICD-10-CM Code	Code Description
K35.20	Acute appendicitis with generalized peritonitis, without abscess
K35.21	Acute appendicitis with generalized peritonitis, with abscess
K35.30	Acute appendicitis with localized peritonitis, without perforation or gangrene
K35.31	Acute appendicitis with localized peritonitis and gangrene, without perforation
K35.32	Acute appendicitis with perforation and localized peritonitis, without abscess
K35.33	Acute appendicitis with perforation and localized peritonitis, with abscess

CMS stated that, while the average costs for cases reporting diagnosis code K35.20 are similar to cases in MS-DRGs 338, 339, and 340, diagnosis codes describing acute appendicitis that do not indicate the presence of an abscess should remain in MS-DRGs 341, 342, and 343 (*Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively*) for clinical consistency. Therefore, CMS does not propose to reassign diagnosis code K35.20 from MS-DRGs 341, 342, and 343 to MS-DRGs 338, 339, and 340.

The Agency also stated that cases reporting ICD-10-CM diagnosis codes describing “with abscess” are associated with higher severity of illness and resource consumption because of extended lengths of stay and treatment with intravenous antibiotics. Therefore, CMS proposes to reassign diagnosis code K35.32 from MS-DRGs 338, 339 and 340 to MS-DRGs 341, 342, and 343 for clinical consistency, and also to remove code K35.32 from the complicated principal diagnosis list in MS-DRGs 338, 339, and 340 as listed in the ICD-10 MS-DRG Version 37 Definitions Manual.

**The ACS opposes CMS’ proposal to maintain the current MS-DRG assignment for ICD-10-CM diagnosis code K35.20 (*Acute appendicitis with generalized peritonitis, without abscess*).** We agree with the requestor that all ruptured/perforated appendicitis diagnosis



codes should group to MS-DRGs 338, 339 and 340 and believe that the condition described by code K35.20 can be associated with risk of post-operative abscess formation and extended length of hospital stay, thereby warranting classification as a complicated diagnosis. **We urge CMS to reassign code K35.20 from MS-DRGs 341, 342, and 343 (*Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively*) to MS-DRGs 338, 339 and 340 (*Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively*).**

We also believe that that the condition described by ICD-10-CM diagnosis code K35.32 (*Acute appendicitis with perforation and localized peritonitis, without abscess*) represents a complicated diagnosis, and do not support CMS’ proposal to reassign this code from MS-DRGs 338, 339 and 340 to MS-DRGs 341, 342, and 343. **We ask CMS to maintain the current complicated diagnosis classification for code K35.32.**

**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 procedure code, 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.

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

- Endoscopic Revision of Feeding Devices. CMS received a request to designate three ICD-10-PCS codes that describe endoscopic revision of feeding devices as non-O.R. procedures. The applicable codes are listed in the table below.

ICD-10-PCS Code	Code Description
0DW08UZ	Revision of feeding device in upper intestinal tract, via natural or artificial opening endoscopic
0DW68UZ	Revision of feeding device in stomach, via natural or artificial opening endoscopic
0DWD8UZ	Revision of feeding device in lower intestinal tract, via natural or artificial opening endoscopic





The requestor noted that these procedures do not require the resources of an O.R. and that they consume resources comparable to related ICD-10-PCS procedure codes describing the endoscopic insertion of feeding tubes that currently are designated as non-O.R. procedures. CMS agreed with the requestor’s recommendation and proposes to remove codes 0DW08UZ, 0DW68UZ, 0DWD8UZ from the FY 2021 ICD-10 MS-DRGs Version 38 Definitions Manual Appendix E (Operating Room Procedures and Procedure Code/MS-DRG Index) as O.R. procedures.

The ACS believes that endoscopic revision of feeding device procedures do not typically require the resources of an O.R and can be safely performed in non-O.R. settings such as interventional radiology or endoscopy suites. Therefore, **we support CMS’ proposal to reclassify ICD-10-PCS codes 0DW08UZ, 0DW68UZ, 0DWD8UZ as non-O.R. procedures for FY 2021.**

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

- Percutaneous/Endoscopic Biopsy of Mediastinum. CMS received a request to designate all procedures performed within the mediastinum by an open or percutaneous endoscopic approach as O.R. procedures. The applicable codes, one of which was identified by the requestor (0WBC4ZX) and the remainder by CMS, are listed in the table below.

ICD-10-PCS Code	Code Description
0WBC0ZX	Excision of mediastinum, open approach, diagnostic
0WBC0ZZ	Excision of mediastinum, open approach
0WBC3ZX	Excision of mediastinum, percutaneous approach, diagnostic
0WBC3ZZ	Excision of mediastinum, percutaneous approach
0WBC4ZX	Excision of mediastinum, percutaneous endoscopic approach, diagnostic
0WBC4ZZ	Excision of mediastinum, percutaneous endoscopic approach

CMS noted that, in the ICD-10 MS-DRGs Definitions Manual Version 37, procedure codes 0WBC0ZX, 0WBC0ZZ, 0WBC3ZZ,



and 0WBC4ZZ are currently designated as O.R. procedures, however, procedure codes 0WBC3ZX and 0WBC4ZX are not recognized as O.R. procedures for purposes of MS-DRG assignment. CMS agreed with the requestor that procedure code 0WBC4ZX, along with procedure code 0WBC3ZX as identified by the Agency, typically require the resources of an O.R. CMS therefore proposes to add these two procedure codes to the FY 2021 ICD-10 MS-DRGs Version 38 Definitions Manual in Appendix E (Operating Room Procedures and Procedure Code/MS-DRG Index) as O.R. procedures, assigned to MS-DRGs 166, 167 and 168 (*Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively*) in MDC 04 (Diseases and Disorders of the Respiratory System); MS-DRGs 628, 629, and 630 (*Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively*) in MDC 10 (*Endocrine, Nutritional and Metabolic Diseases and Disorders*); MS-DRGs 820, 821, and 822 (*Lymphoma and Leukemia with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively*) and MS-DRGs 826, 827, and 828 (*Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively*) in MDC 17 (*Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms*); and to MS-DRGs 987, 988, and 989 (*Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively*).

**The ACS supports CMS' proposals to reclassify ICD-10-PCS codes 0WBC4ZX (*Excision of mediastinum, percutaneous endoscopic approach, diagnostic*) and 0WBC3ZX (*Excision of mediastinum, percutaneous approach, diagnostic*) as O.R. procedures for the purposes of MS-DRG assignment for FY 2021.** We believe that surgeries performed within the mediastinum by an open or percutaneous endoscopic approach, regardless of whether it is a diagnostic or therapeutic procedure, typically require the resources of the O.R. to control for possible damage to the structures contained within the mediastinum, including loose connective tissue, the heart and great vessels, esophagus, trachea, nerves, and lymph nodes. The invasive nature of these procedures also necessitates the sterile environment of an O.R. to limit the risk of secondary infection.

- Percutaneous Endoscopic Excision of Stomach. CMS received a request to designate an ICD-10-PCS code that describes excision of

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stomach via a percutaneous endoscopic approach as an O.R. procedure. During its review of this service, CMS noted that the ICD-10-PCS code describing diagnostic percutaneous endoscopic excision of stomach was also not currently recognized as an O.R. procedure. The applicable codes are listed in the table below.

ICD-10-PCS Code	Code Description
0DB64ZZ	Excision of stomach, percutaneous endoscopic approach
0DB64ZX	Excision of stomach, percutaneous endoscopic approach, diagnostic

CMS agreed with the requestor that procedure code 0DB64ZZ, along with procedure code 0DB64ZX as identified by the Agency, typically require the resources of an O.R. CMS therefore proposes to add these codes to the FY 2021 ICD-10 MS-DRG Version 38 Definitions Manual in Appendix E (Operating Room Procedures and Procedure Code/MS-DRG Index) as O.R. procedures assigned to MS-DRGs 326, 327, and 328 (*Stomach, Esophageal and Duodenal Procedures with MCC, with CC, and without CC/MCC, respectively*) in MDC 6 (*Diseases and Disorders of the Digestive System*); MS-DRGs 619, 620, and 621 (*Procedures for Obesity with MCC, with CC, and without CC/MCC, respectively*) in MDC 10 (*Endocrine, Nutritional and Metabolic Diseases and Disorders*); and MS-DRGs 820, 821, and 822 (*Lymphoma and Leukemia with Major Procedure with MCC, with CC, and without CC/MCC, respectively*), MS-DRGs 826, 827, and 828 (*Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major Procedure with MCC, with CC, and without CC/MCC, respectively*), and MS-DRGs 829 and 830 (*Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedure with CC/MCC and without CC/MCC, respectively*) in MDC 17 (*Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms*).

**The ACS supports CMS' proposals to reclassify ICD-10-PCS codes 0DB64ZZ (*Excision of stomach, percutaneous endoscopic approach*) and 0DB64ZX (*Excision of stomach, percutaneous endoscopic approach, diagnostic*) as O.R. procedures for the purposes of MS-DRG assignment for FY 2021.** We concur with the requestor's statement that similar procedures such as percutaneous endoscopic excisions of gastric lesions and percutaneous endoscopic partial gastrectomies are currently

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classified as O.R. procedures, and that the two listed stomach excision codes should be designated as O.R. procedures due to comparable costs and resource use. The invasive nature of such procedures also necessitates the sterile environment of an O.R. to limit the risk of secondary infection.

- Percutaneous Endoscopic Drainage. CMS received a request to designate six ICD–10–PCS codes that describe laparoscopic drainage of peritoneum, peritoneal cavity, and gallbladder as O.R. procedures. The applicable codes are listed in the table below.

ICD-10-PCS Code	Code Description
0D9W4ZZ	Drainage of peritoneum, percutaneous endoscopic approach
0D9W40Z	Drainage of peritoneum with drainage device, percutaneous endoscopic approach
0W9G4ZZ	Drainage of peritoneal cavity, percutaneous endoscopic approach
0W9G40Z	Drainage of peritoneal cavity with drainage device, percutaneous endoscopic approach
0F944ZZ	Drainage of gallbladder, percutaneous endoscopic approach
0F9440Z	Drainage of gallbladder with drainage device, percutaneous endoscopic approach

CMS agreed with the requestor that these six procedure codes typically require the resources of an O.R., and therefore proposes to add codes 0D9W4ZZ and 0D9W40Z as O.R. procedures assigned to MS-DRGs 356, 357, and 358 (*Other Digestive System O.R. Procedures, with MCC, with CC, and without CC/MCC, respectively*) in MDC 06 (*Diseases and Disorders of the Digestive System*); and MS-DRGs 907, 908, and 909 (*Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively*) in MDC 21 (*Injuries, Poisonings and Toxic Effects of Drugs*). CMS also proposes to add codes 0W9G4ZZ and 0W9G40Z as O.R. procedures assigned to MS-DRGs 356, 357, and 358 (*Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively*) in MDC 6 (*Diseases and Disorders of the Digestive System*); MS-DRGs 420, 421, and 422 (*Hepatobiliary Diagnostic Procedures, with MCC, with CC, and without CC/MCC, respectively*) in MDC 7 (*Diseases and Disorders of the Hepatobiliary System and Pancreas*); 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); MS-DRGs 749 and 750 (Other Female Reproductive System Procedures with and without CC/MCC, respectively) in MDC 13 (Diseases and Disorders of the Female Reproductive System); MS-DRGs 802, 803, and 804 (Other O.R. Procedures of the Blood and Blood Forming Organs, with MCC, with CC, and without CC/MCC, respectively) in MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders); MS-DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major Procedure with MCC, with CC, and without CC/MCC, respectively) and MS-DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major Procedure with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); and MS-DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs). Lastly, CMS proposes to add codes 0F944ZZ and 0F9440Z as O.R. procedures assigned to MS-DRGs 408, 409, and 410 (Biliary Tract Procedures Except Only Cholecystectomy with or without C.D.E., with MCC, with CC, and without CC/MCC, respectively) in MDC 7 (Diseases and Disorders of the Hepatobiliary System and Pancreas).*

**The ACS supports CMS' proposals to reclassify ICD-10-PCS codes 0D9W4ZZ (Drainage of peritoneum, percutaneous endoscopic approach), 0D9W40Z (Drainage of peritoneum with drainage device, percutaneous endoscopic approach), 0W9G4ZZ (Drainage of peritoneal cavity, percutaneous endoscopic approach), 0W9G40Z (Drainage of peritoneal cavity with drainage device, percutaneous endoscopic approach), 0F944ZZ (Drainage of gallbladder, percutaneous endoscopic approach), and 0F9440Z (Drainage of gallbladder with drainage device, percutaneous endoscopic approach) as O.R. procedures for the purposes of MS-DRG assignment for FY 2021.** We concur with the requestor's statement that similar procedures such as percutaneous endoscopic inspection of gallbladder, percutaneous endoscopic excision of peritoneum and percutaneous endoscopic extirpation of matter from peritoneal cavity are currently classified as O.R. procedures, and that the six listed procedure codes should be designated as O.R. procedures due to comparable costs and resource use. The invasive nature of such procedures also

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necessitates the sterile environment of an O.R. to limit the risk of secondary infection.

## **PAYMENT ADJUSTMENT FOR MEDICARE DISPROPORTIONATE SHARE HOSPITALS FOR FY 2021**

### **Uncompensated Care Payments**

Medicare disproportionate share hospital (DSH) uncompensated care payments are provided by CMS to qualifying hospitals with the intent to offset costs incurred by hospitals treating a large or disproportionate number of indigent patients. Such payments are computed using three factors: (1) CMS' estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, (2) an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and (3) each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals.<sup>1</sup>

Using this methodology, the Office of the Actuary (OACT) estimates that the uninsured rate for calendar years (CYs) 2020 and 2021 is 9.5 percent. However, given the significant impact of the Coronavirus (COVID-19) public health emergency (PHE) on business operations in various sectors throughout the country, the ACS does not believe that this estimate is an accurate reflection of the rate of uninsured individuals in the United States for CYs 2020/2021. As of July 1, 2020, the national unemployment rate is 11.1 percent—this rate does not account for the effects of the surge of COVID-19 infections and related business shut-downs at the end of June 2020, which will undoubtedly result in even more individuals losing insurance coverage.<sup>2</sup> Models produced by the Robert Wood Johnson Foundation and the Urban Institute predict that, if the U.S. unemployment rate reaches 15 percent, an *additional* 5 to 8 million individuals may be left without insurance, even *after* accounting for those who lose employer-based plans and find coverage elsewhere (e.g., Medicaid, ACA Exchange subsidies, COBRA).<sup>3</sup> **We urge CMS and the OACT to consider the**

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<sup>1</sup> Social Security Act §1886(r)(2)

<sup>2</sup> Bureau of Labor Statistics. The employment situation—June 2020. <https://www.bls.gov/news.release/pdf/empsit.pdf>. Published June 2020.

<sup>3</sup> Garrett, B., & Gangopadhyaya, A. How the COVID-19 recession could affect health insurance coverage. The Robert Wood Johnson Foundation and Urban Institute. [https://www.urban.org/research/publication/how-covid-19-recession-could-affect-health-insurance-coverage/view/full\\_report](https://www.urban.org/research/publication/how-covid-19-recession-could-affect-health-insurance-coverage/view/full_report). Published May 4, 2020.

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unprecedented disruption in health insurance coverage during the PHE and produce a new estimate of the uninsured rate within the context of the COVID-19 pandemic so the DSH payment calculations more accurately reflect such circumstances.

## MARKET-BASED MS-DRG RELATIVE WEIGHT PROPOSED DATA COLLECTION AND POTENTIAL CHANGE IN METHODOLOGY FOR CALCULATING MS-DRG RELATIVE WEIGHTS

CMS seeks comment on an alternative methodology for calculating IPPS MS-DRG relative weights using hospitals' reported median payer-specific negotiated charges to develop market-based IPPS payments, which the Agency believes would better reflect the relative hospital resources used to provide inpatient services to patients. CMS indicates that it may adopt this new methodology—which would be implemented beginning in FY 2024—in the FY 2021 IPPS final rule. **The ACS believes that changing the Medicare MS-DRG relative weight calculation methodology could have a significant impact on hospital payment rates under the IPPS, and we question why CMS would finalize any alternative methodology three years before it would become effective, particularly in the absence of any details regarding the fundamentals of its implementation. As such, we urge the Agency to delay the adoption of any new methodology for calculating IPPS MS-DRGs using information collected through FY 2021 rulemaking at this time.**

## QUALITY, VALUE AND INTEROPERABILITY REPORTING REQUIREMENTS AND RELATED PROVISIONS

### Overview

In the FY 2021 IPPS proposed rule, CMS proposes a number of updates to the Hospital Readmissions Reduction Program (HRRP), Hospital Value-Based Purchasing Program, Hospital Acquired Condition (HAC) Reduction Program, Hospital Inpatient Quality Reporting (IQR) Program, and Medicare and Medicaid Promoting Interoperability (PI) Programs. Many of the proposals focus on aligning reporting requirements and data validation criteria across programs to support the Agency's initiatives to reduce administrative burden. The ACS appreciates the Agency's effort to align reporting requirements and improve programmatic mechanics across the hospital-based quality programs but believes that the structural elements of these measures

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miss the mark in establishing a program for quality. Instead, the ACS urges CMS to reevaluate its current quality programs and leverage the lessons learned from the COVID-19 pandemic to drive the development and implementation of programs that support quality improvement cycles and a learning healthcare system.<sup>4</sup> The College has not seen evidence to support that the current programs drive improvement in surgical care. The programs do not appreciate measures that are proven to reflect improvement and assist patients in making quality and value-based decisions about their care. Instead, they pose an unnecessary burden on the healthcare system.

The need for hospital quality programs to be meaningful and actionable has never been more apparent than it has been during the COVID-19 pandemic. ***The pandemic provided an excellent example of what the healthcare system can do—and how fast it can be done—when resources are pulled together to understand a disease, its care model, and resource challenges.*** Medical information such as pandemic treatment and safety protocols which usually take years to translate to practice, often after publication, were disseminated worldwide within days or weeks.

Although we lacked adequate testing in the early phases of the pandemic, making it hard to predict disease projections, the infrastructure now exists to permit reliable short-term forecasting. We have also been quick to appreciate informing COVID-19 patients at the point of care, supported with near real-time data. We must leverage these COVID-19 lessons learned for other conditions to create alignment and to improve our current fragmented health care system, as well as strategically rethink how to optimize care. Just as there are opportunities to learn during a pandemic, there are still many opportunities for lessons learned in the daily routines of surgical care. For example, in surgery, how do we know the steps we take in a care pathway are correct for patients over the long-term? Do we have the proper pathways to ensure a trusted environment for patients and clinicians during and after the pandemic?

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<sup>4</sup> A learning health system is system in which science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience. (National Academies of Medicine, available at <https://nam.edu/programs/value-science-driven-health-care/learning-health-system-series/>.)





Our comments in the sections below pertain to the various quality reporting and value-based payment programs that are discussed in this rule and the on impact inpatient hospitals, including:

- HRRP;
- The Hospital IQR Program;
- The Hospital VBP Program;
- The HAC Reduction Program; and
- The Medicare and Medicaid PI Programs for Hospitals.

### ***Current IPPS Quality and Value Programs Should Incentivize Comprehensive Quality Programs***

Although we appreciate CMS efforts to better align quality and value-based programs, the current system is a payment program based in fee-for-service which does not inform patients about important value-based care decisions essential to the lifecycle of their condition. Again, COVID-19 emphasized the importance of prevention, early detection, and effective and ineffective treatments—all providing necessary information needed to track quality and safety during a pandemic. Imbedded in more comprehensive quality programs are the elements of structure, process, and data management for outcome measures. To be effective, when the focus is on reporting rare adverse events, a quality program must be trusted and face many challenges to ensure a high level of measure rigor. Clinical outcome measures using event rate reporting—although important to track—are difficult to use for performance measurement in value assessments because without standards to define, aggregate and normalize the data, they lack reliability and show little variation for most events. The siloed nature of sporadic process measures untethered from a care management lifecycle, as implemented by CMS, have shown that clinicians can easily “pass the test” and therefore top out easily—making it difficult to show variation and causing disruptions to long-term and consistent measurement. Furthermore, both process and clinical outcome measures currently being used only reflect a fragmented picture of care and don’t follow the patient’s care journey. And, although patient reported outcome measures (PROMs) have great potential to improve value for patients, more work is needed to develop condition or disease-specific PROMs that can be implemented with little burden for patients and clinicians. Lastly, regardless of the type of measures, a sole source to aggregate the data is needed to ensure reliability and validity. Since IPPS measures are not driving true quality improvement cycles, clinicians and hospitals have learned how to report simply for the sake of compliance to ensure that their payment is not adversely affected and

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therefore there is little impact on improving value. **In summary, the fundamental problem with the current incentive programs is that they incorrectly measure quality as a disconnected set of measures—but quality is not just a set of measures, quality is a comprehensive, condition-specific program.**

Importantly, during COVID-19 this was illustrated when the data collected under the HRRP, HVPB, HAC and IQR provided us with little to no insight into how to drive high quality care or assure that hospitals had the proper structure or resources available to prepare for hospital surge. Instead, hospitals relied on (and will continue to rely on) information from clinical data registries that were well-established and could quickly and more fluidly ascertain COVID-19 variables. For surgery, Department of Health and Human Services (HHS) also relied on ACS leadership to leverage data and help the Agency determine whether to shut down elective surgery,<sup>5</sup> and when it was safe to resume. However, despite their importance, programs like the ACS quality programs are in jeopardy of being discontinued by hospital systems due to the financial turmoil that resulted from COVID-19. The ACS quality programs define a condition, track the important aspects of its lifecycle of care, and report on both patient-reported outcomes (PROs) and risk-adjusted event rates. However, payers have failed to recognize the true impact of implementing ACS-type quality programs within their payment reward systems and toss them aside as too burdensome for a health system to provide. Instead, payers prefer using the sporadic metrics similar to those used by CMS. Without better alignment of quality programs with payment programs, successful ACS quality programs could be lost by the fiscal challenges thrust upon hospitals in a pandemic situation.

**Therefore, we encourage CMS to make evidence-based policy decisions when considering how to learn from the pandemic and consider a comprehensive quality model to measure quality as a program which is inclusive of valuing the standards for verification of resources and structures needed for a condition or disease.** This is how ACS has structured our successful model for quality which is

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<sup>5</sup> While the term “elective” may sound to some like “optional,” this term covers a wide range of essential services such as joint replacements, cancer biopsies, and most procedures that are scheduled in advance because they do not involve an immediate emergency. Delay of elective procedures therefore can have consequences such as additional pain and suffering, delayed diagnosis, or worse outcomes when care is finally received.

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based largely on the Donabedian model.<sup>6</sup> The Donabedian elements (structure, process, and outcomes) are captured using standards. Through these standards we have demonstrated great strides in patient care improvement. In addition to defining standards and infrastructure required to deliver high-quality care, a foundational element of ACS quality programs are clinical registries that are industry-leading via rigorous data collection, leading analytics, and are validated. Research utilizing these databases has resulted in over 2,000 publications. Each database evaluates the quality of care at local, regional, and national levels, and has been utilized in public reporting and in the policy setting.

Each of the ACS condition-specific quality programs are built on a four-part model, known as the ACS Quality Model, that includes 1. Standards, 2. Infrastructure, 3. Data, and 4. Verification. Applying Donabedian elements within the ACS Quality Model and verifying their implementation in a health care system yields the greatest opportunity to drive improvement.

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. There is well-established evidence supporting the ACS Quality model, as illustrated in the following examples. Mortality in verified trauma centers is statistically lower than the mortality rate in non-verified centers which is true for the overall population, as well as in subgroups analyses, including the highest acuity patients (i.e. highest abbreviated injury score (AIS)).<sup>7</sup> The literature also demonstrates improved care in verified breast cancer centers. Since over 80% of breast cancer patients have survival of over 10 years, it is important to recognize that measuring quality of breast cancer care is arguably best achieved with measuring a comprehensive set of evidence-based processes. In this regard, peer-reviewed publications have demonstrated that breast cancer care is statistically superior in verified breast cancer centers where there is higher compliance with receipt of chemotherapy when appropriate criteria are met, a higher compliance of receipt of radiation therapy when appropriate criteria are met, and a higher compliance of

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<sup>6</sup> Donabedian A. Evaluating the quality of medical care. 1966. *Milbank Q.* 2005;83(4):691-729. doi:10.1111/j.1468-0009.2005.00397.

<sup>7</sup> MacKenzie, E.J., Rivara, F.P., Jurkovich, G.J., et al. A national evaluation of the effect of trauma-center care on mortality. *New England Journal of Medicine.* 2006;354(4):366-78. <https://www.ncbi.nlm.nih.gov/pubmed/16436768>.

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appropriate screening techniques.<sup>8,9,10</sup> Lastly, 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).<sup>11,12,13</sup>

### ***ACS Response to the COVID-19 Pandemic: Leveraging Expertise from the ACS Quality Model***

Part of the ACS response to the pandemic was to leverage the ACS Quality Model expertise in clinical data registries to quickly scale up and begin the capture of COVID-19-related data. ACS has formal relationships with over 2,000 hospitals which participate in at least one of the ACS Quality Improvement Programs – this includes 1,500+ cancer hospitals, 900+ bariatric hospitals, 800+ trauma hospitals, and 800+ National Surgical Quality Improvement Program (NSQIP) hospitals. The communication channels that exist between the ACS and these hospitals across the United States will be used to facilitate data collection and may prove essential in dissemination and possibly implementation in a response to future pandemics or epidemics. To safely reopen surgical services, outcomes tracking at the institutional level for all surgical services is needed. This is accomplished by selecting from two general registry approaches. ACS has developed a low burden/low cost registry, and included COVID-19 variables in our high-fidelity registries, including NSQIP registry:

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<sup>8</sup> Berger, E.R., Wang, C.E., Kaufman, C.S., et al. National Accreditation Program for Breast Centers Demonstrates Improved Compliance with Post-Mastectomy Radiation Therapy Quality Measure. *Journal of the American College of Surgeons*. 2017;224(3):236-244. <https://www.ncbi.nlm.nih.gov/pubmed/27993697>.

<sup>9</sup> Miller, M.E., Bleicher, R.J., Kaufman, C.S., et al. Impact of Breast Center Accreditation on Compliance with Breast Quality Performance Measures at Commission on Cancer-Accredited Centers. *Annals of Surgical Oncology*. 2019;26(5):1202-1211. <https://www.ncbi.nlm.nih.gov/pubmed/30684159>.

<sup>10</sup> Winchester, D.P. The National Accreditation Program for Breast Centers: quality improvement through standard setting. *Surgical Oncology Clinics of North America*. 2011;20(3):581-6. <https://www.ncbi.nlm.nih.gov/pubmed/21640922>.

<sup>11</sup> Nguyen, N.T., Nguyen, B.S., Nguyen, V.Q., et al. Outcomes of Bariatric Surgery Performed at Accredited vs. Nonaccredited Centers. *Journal of the American College of Surgeons*. 2012;215(4):467-474. <https://www.ncbi.nlm.nih.gov/pubmed/22727608>.

<sup>12</sup> Morton, J.M., Garg, T., Nguyen, N. Does Hospital Accreditation Impact Bariatric Surgery Safety? *Annals of Surgery*. 2014;260(3):540-8. <https://www.ncbi.nlm.nih.gov/pubmed/25115426>.

<sup>13</sup> Baidwin, N.K., Bachiashvili, V., Mehta, T. A meta-analysis of bariatric surgery-related outcomes in accredited versus unaccredited hospitals in the United States. *Clinical Obesity*. 2019;e.12348. <https://www.ncbi.nlm.nih.gov/pubmed/31713328>.

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- Low Cost/Low Burden Registry:

The low-cost low-burden registry is used to track certain aspects of care and event rates generally associated with COVID-19 status of patients and their overall outcomes, regardless of other co-morbidities or a recognized comparative group (control). This is the “some data are better than none” scenario needed to learn about a novel disease which tracks all COVID-19 patients, not just surgical patients. Because the country will want to capture as much relevant data as possible during the pandemic, we needed a registry that can scale up very quickly, is free or low cost where every hospital is given the opportunity to report. To do this, ACS utilized our extensive history of developing and maintaining clinical data registries in developing the ACS COVID-19 Registry. Cases can be batched for analysis and communicated to participating sites to inform them of their unadjusted event rates.

However, the core registry has limited value since it is unadjusted event rate reporting. Such a registry would truly limit the ability to understand the risk to patients having elective surgery. The majority of the cases in this registry will be non-operative patients. This registry will lack surgical discrete variable definitions and lack the ability to adjust by comorbid conditions and surgical procedures. In the absence of data needed for reliable and valid risk adjustment, we will not have the ability to reliably distinguish confounding factors when considering what we need to know to safely perform procedures and inform patients of their risks when they are making the decision for surgery. A “core” registry such as the ACS Core COVID-19 Registry is scalable, free and will provide unadjusted event rate reporting, but it is not adequate for complex understanding of the uncertainties which surround surgical services during the pandemic.

- ACS Risk-adjusted COVID-19 Registry in NSQIP with High Fidelity for Determining Risk of Surgery in COVID-19 Patients:

Our experience tells us that the preferred approach is to generate a COVID-19, risk-adjusted clinical data registry which meets trusted criteria for a meaningful and actionable registry from a sole source to aggregate the data. This registry should be multispecialty to limit the burden on hospitals and facilities for data aggregation. NSQIP is in 800 hospitals capturing all inpatient cases which will be the best option for understanding COVID-19 risks in surgical patients. Leveraging the existing NSQIP registry during the pandemic will allow NSQIP hospitals to use the training, resources, and infrastructure already in place with minimal added burden. Collecting all COVID-19 patient data in NSQIP will also result in a large sample of patients across all

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surgical specialties to understand risk of elective and urgent surgeries during the COVID-19 pandemic. This can serve as the inpatient source for understanding the risk of surgery during the COVID-19 pandemic with real-time reporting and data remodeling on a quarterly basis. With trained data collectors, this registry will reliably track surgical patients for 30-days post-discharge which will effectively capture any post-operative COVID-19 events. This information will be critical for shared decision making with patients considering the risks associated with surgery during the pandemic.

Moving forward, ACS will also focus the evaluation of hospital processes, quality of care, and patient outcomes as essential in order to better resume “elective” or essential surgery and recover following the pandemic. The ACS recognizes the common use of the term “elective” operation when referring to non-urgent, essential surgical services. The essential surgical services were postponed by many patients during the pandemic lockdown and shuttering of surgical care. It is difficult to know the impact of delayed or postponed surgical care during a pandemic. How many cancers progressed to more advanced stages? Did patients suffer from disabling pain when delaying surgical joint replacements? Were dialysis catheters in limited supply? And so forth. We are collecting needed information to better understand local protocols, the impact on care delivery, and the associated patient outcomes and harms. Without population surveys from community sources, we can speculate about the impact based on historical trends, but more reliable tracking would come from survey vehicles. Therefore, we assert that both types of registries are needed during the pandemic to track COVID-19 cases. The least burdensome approach for hospitals and surgical facilities would be a limited number of registry options with multi-specialty capability during this reopening timeframe for surgical services.

### ***Next Steps for Managing Knowledge During a Pandemic and Eventually all Conditions***

As previously mentioned, we strongly urge the Agency to consider how we can leverage lessons learned during the COVID-19 pandemic to fundamentally change the foundational elements of the current IPPS quality and value-based incentive programs in order to better assess value. We described the ACS response to COVID-19 that informed key learnings from the surgical experience. An improved framework to prioritize essential surgery will help optimize the balance between resource conservation and provisions of care to patients without

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COVID-19, and likely lead to better “health” (financial and otherwise) of the local, regional, and national healthcare system.

The first key takeaway is that the incentives of payment models and other mechanism(s) used for implementation must recognize that care is delivered to a patient by a multidisciplinary team. This team-based care is focused on the patient for their specific condition and informed by a learning health system based on the intense and reliable exchange of knowledge. These truths are the scientific method of modern care and extend beyond the silos of payment models. Collecting data quickly and across a large population was the best we could do during the pandemic. We need to have the structure-process-outcome measurement system in place and to do this for many diseases and conditions, during and outside of pandemics. Therefore, we must focus on crafting a journey from the current state of siloed quality metrics to the future state of quality programs and shared knowledge management.

- **Current State:** As we discuss extensively in this letter, the current state must rely on the utilization of clinical data registries, including a single high-fidelity source of truth (or a limited number of registry options) for a condition or disease. In the current pandemic, using the existing digital infrastructure for surgical care, we must appreciate the value of a single source of truth for a given disease or condition. For surgery, the single source is NSQIP to aggregate data across NSQIP hospitals for a reliable and actionable source when reopening surgery in a COVID-19 environment. NSQIP can serve as the “sole source” to reopening surgery in the current pandemic.
- **Future State:** The future state must move to national standards-based data. Standards-based data require data element definitions as well as a standard means to aggregate and normalize the data before inclusion into a common data model. It also implies the standardization of the analytics used for benchmarking across institutions. To automate data flows across data sources (beyond registries), we must transition toward a sole set of open-source, standardized, patient-centered knowledge that is accessible to all members of the team involved in the prevention model, the therapeutic care model, the resource model, and the informational data model. In surgery, knowledge management experts for surgical conditions should define the sole source of standards for surgical care. This is further discussed in our response to the *Request for*

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*Information: Future of the Medicare/Medicaid Promoting Interoperability Program, below.*

**Request for Information: Future of the Medicare/Medicaid Promoting Interoperability Program**

CMS seeks comment on how Medicare can best support HHS goals to reduce administrative burden, align with the Quality Payment Program (QPP), and 21<sup>st</sup> Century Cures Act, advancing interoperability and the exchange of health information, and promoting innovative uses of health information technology (health IT). The Agency specifically mentions how they can support areas of overlap in the 21<sup>st</sup> Century Cures Act final rule, such as information blocking, transitioning from the Common Clinical Data Set (CCDS) to the United States Core Data for Interoperability (USCDI), finalization of a new certification criterion for a standards-based application programming interface (API) using Fast Healthcare Interoperability Resources (FHIR), and other updates to 2015 Edition health IT certification criteria and Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program.

The ACS urges CMS to study modern care models to better understand how to transition dated fee-for-service payment into value-based payment models, as reducing administrative burdens in fee-for-service does little to move payment into a modern value-based era. First, the preferred approach to reduce administrative burden involves generating a quality payment program which aligns with modern care models and meaningful and effective quality of care programs, such as the ACS Quality Programs built on a four-part model, known as the ACS Quality Model, that includes 1. Standards, 2. Infrastructure, 3. Data, and 4. Verification, as previously discussed on page 15. Physicians are far more inclined to engage in quality measurement when the metrics are meaningful and inform the patient and care team.

Secondly, the ACS recognizes we are entering more information into medical systems about a patient than in previous generations. The administrative burden for turning this information into useable knowledge requires moving digital information about a patient from over reliance on electronic health records (EHRs) to mid-tier clouds of data that can assemble patient-centric common data models for APIs to expose knowledge to the right clinical team at the right time.

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The ACS appreciates the Agency’s efforts to support the Medicare and Medicaid PI programs with ONC’s initiatives to modernize health IT and implement standards for increased interoperability. However, we continue to challenge the agencies to move away from over reliance on an EHR-centric system and instead move toward a patient-centered system, which includes multiple sources of digital information. The College envisions a system where the USCDI and FHIR functionalities are expanded to other systems that host electronic health information, such as health information exchanges (HIEs), clinical data registries, etc. to allow a more complete view of the patient’s overall health. For example, in this environment EHRs would not only be able to provide information from the patient record maintained within its system, but could also access and share data collected in HIEs and registries, etc. The initial interoperability efforts based on FHIR are “pull-based,” where query/request and response systems are used for knowledge sharing. This would allow physicians to query and gather information from devices, smartphones, registries and every physician that treated a patient through the lifecycle of their condition. Expanding beyond an EHR-centric system, is the next step in supporting a health system that is continuously learning and advancing based on real-time data. With increasing movement to mid-tier clouds for knowledge management, the ability to enhance workflow orchestration with “push” technologies will allow for delivering guidelines directly into care pathways for patients and their clinicians to follow. This requires a shift in focus where digital services are used to track and inform patient conditions or episodes of care, rather than relying on systems which were built for purposes of payment and reimbursement.

As discussed in the introductory comments of this letter, the ACS has a long history of implementing registry-based programs that demonstrably improve the safety and reliability of surgical care. ACS registries are multidisciplinary and comprehensive, including trauma services, bariatrics and metabolic care, cancer, pediatric surgery, and more, and have been implemented in more than 3,000 hospitals in the United States and abroad. The ACS NSQIP is a nationally validated, risk-adjusted, outcomes-based program designed to measure and improve the quality of surgical care, and provides participating hospitals with analyses, reports, and other tools that have shown to be effective in improving the quality of surgical care while also reducing complications and costs. While NSQIP has a track record of proven success, registries such as this can be difficult and costly to maintain, because they require considerable investments of time from highly skilled and expensive labor. The ACS has recently taken steps to reduce

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registry burden and costs, actively involve patients, and facilitate the aggregation of outcome data across the full continuum of care through plans to define and standardize NSQIP registry data elements to FHIR resources and FHIR profiles to more easily collect and share data elements through FHIR-based APIs. The ACS is committed to this work, as it will provide clinicians with timely access to data that can be analyzed and turned into actionable knowledge that can inform patient care decisions, drive quality improvement cycles, and support a learning health system.

As mentioned in prior sections, the COVID-19 pandemic has shed light on the need for increased interoperability and real-time data sharing. In the early stages of the pandemic, we learned very slowly that most of the therapeutic interventions did not work, due in-part to our nation's reliance on a patchwork of observational data collected haphazardly in separate, proprietary data models. **The pandemic environment emphasizes how standards-based data exchange is necessary, even in non-pandemic environments, to support a learning health system where patient outcomes, treatment information, and medical knowledge can disseminate continuous feedback and inform the development of a care model in real-time.** If these data were standards-based across the U.S., we would have been able to continuously collect more usable and accurate data on the successes or failures of COVID-19 treatments to safely and effectively deliver high-quality care to patients.

Finally, the ACS believes that as electronic health information sharing expands, we should be concurrently working to develop a solution, such as a unique patient identifier (UPI) that allows unique patient information to move between clinicians, in a secure and private manner. In today's patient care environment, we know that an individual patient is treated across a care continuum by several clinicians over a variable amount of time, and data sharing is essential to coordinate, optimize care, and reduce costs. Without a UPI, the industry is forced to use work-around methods to match patient data, which can put patient's sensitive health information at risk for inaccurate patient matching. Inaccurate patient matching can lead to a number of adverse events, such as compromised safety and privacy, inappropriate and unnecessary care, unnecessary burden on both patients and physicians to correct misidentifications, time consuming and expensive burden on health systems to detect and reconcile duplicate patient records and improper record merges, increased health care costs, and poor oversight of fraud and abuse. The ACS is

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extremely supportive of legislative efforts to allow HHS to explore and adopt a UPI, as it would serve as a safe, accurate, and consistent strategy to link patients to their health information across the entire care continuum.

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, Regulatory Affairs Manager, at [vmujumdar@facs.org](mailto:vmujumdar@facs.org), or Jill Sage, Quality Affairs Manager, at [jsage@facs.org](mailto:jsage@facs.org).

Sincerely,

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