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633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org

Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

June 24, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1716-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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Ms. 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) proposed rule, *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 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals,* published in the *Federal Register* on May 3, 2019.

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for patients by setting high standards for surgical education and practice. Since a large portion of surgical care is provided in the inpatient hospital setting, the College has a vested interest in CMS' Inpatient Prospective Payment System (IPPS) and related hospital quality improvement efforts, and we believe that we can offer insight to CMS' proposed modifications to these policies for fiscal year (FY) 2020. Our comments below are presented in the order in which they appear in the proposed rule.

PROPOSED CHANGES TO MEDICARE SEVERITY DIAGNOSIS-RELATED GROUP CLASSIFICATIONS AND RELATIVE WEIGHTS

Proposed Changes to Specific MS-DRG Classifications

Review of Procedure Codes in MS-DRGs 981 through 983 and 987 through 989

Whenever there is a surgical procedure billed on a claim that is unrelated to the Major Diagnostic Category (MDC) to which the case was assigned based on the principal diagnosis reported, CMS assigns such cases to a Medicare Severity Diagnosis Related Group (MS-DRG) surgical class referred to as "unrelated operating room (O.R.) procedures" (i.e., MS-DRGs 981 through 983 (*Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively*) and MS-DRGs 987 through 989 (*Nonextensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively*)). The Agency conducts an annual review of ICD-10 Procedure Coding System (ICD-10-PCS) codes assigned to MS-DRGs 981 through 983/987 through 989 on the basis of volume by procedure to determine if it would be more appropriate to move cases reporting these procedure codes out of the unrelated O.R. procedure MS-DRGs and into one of the surgical MS-DRGs for the MDC into which the principal ICD-10- Clinical Modification (IDC-10-CM) diagnosis falls.

Adding Procedure Codes and Diagnosis Codes Currently Grouping to MS-DRGs 981 through 983 or MS-DRGs 987 through 989 into MDCs

Based on its analysis of the claims data from the September 2018 update of the FY 2018 Medicare Provider Analysis and Review (MedPAR) file, CMS proposes to move the following cases from the unrelated O.R. procedure MS-DRGs into more specific surgical MS-DRGs relative to the MDC assignments for the affiliated principal diagnoses.

- Gastrointestinal Stromal Tumors with Excision of Stomach and Small Intestine. CMS proposes to reassign cases reporting ICD-10-PCS procedure codes describing the open excision of the stomach or small intestine in conjunction with ICD-10-CM diagnosis codes for gastrointestinal stromal tumors (GIST) from MS-DRGs 981-983 in MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) to MS-DRGs 326-328 (Stomach, Esophageal and Duodenal Procedures with

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

MCC, with CC, and without CC/MCC, respectively) in MDC 6 (Diseases and Disorders of the Digestive System). The applicable diagnosis and procedure codes are listed in the table below.

MDC and MS-DRG Assignments for Open Gastrointestinal Excision Procedures Reported with a Principal Diagnosis of GIST						
ICD-10 GIST Diagnosis Code	**ICD-10 Procedure Code**	**ICD-10 Procedure Code Descriptor**	**FY 2019 MDC Assignment**	**FY 2020 MDC Assignment (Proposed)**	**FY 2019 MS-DRG Assignment**	**FY 2020 MS-DRG Assignment (Proposed)**
C49.A0 C49.A1 C49.A2 C49.A3 C49.A4 C49.A5 C49.A9	0DB60ZZ	Excision of stomach, open approach	MDC 8 (*Diseases & Disorders of the Musculoskeletal System and Connective Tissue*)	MDC 6 (*Diseases & Disorders of the Digestive System*)	MS-DRGs 981-983 (*Extensive O.R. Procedure Unrelated to Principal Diagnosis*)	MS-DRGs 326-328 (*Stomach, Esophageal & Duodenal Procedures*)
	0DB80ZZ	Excision of small intestine, open approach				

The ACS supports CMS' proposal to reassign cases reporting ICD-10-PCS codes 0DB60ZZ/0DB80ZZ with a principal diagnosis of GIST to MS-DRGs 326-328 in MDC 6. The Agency notes that the average length of stay and average costs of this subset of cases are similar to those of cases already mapped to MS-DRGs 326-328, and we agree with CMS that the proposed MDC and MS-DRG adjustments would better reflect the gastrointestinal nature of the underlying GIST disease and the resource use associated with this subset of cases relative to others within the same MDC/DRG groupings.

- Kidney Transplantation Procedures. CMS proposes to reassign cases reporting ICD-10-PCS kidney transplantation procedure codes in conjunction with ICD-10-CM diagnosis codes in MDC 5 (*Diseases and Disorders of the Circulatory System*)—specifically, those describing heart failure and chronic kidney disease as the principal diagnoses—from MS-DRGs 981-983 to MS-DRG 264 (*Other Circulatory O.R. Procedures*) in MDC 5. The applicable diagnosis and procedure codes are listed in the table below.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

MDC and MS-DRG Assignments for Kidney Transplantation Procedures Reported with a Principal Diagnosis in MDC 5					
ICD-10 Diagnosis Codes	**ICD-10 Procedure Codes**	**ICD-10 Procedure Code Descriptors**	**FY 2020 MDC Assignment (Proposed)**	**FY 2019 MS-DRG Assignment**	**FY 2020 MS-DRG Assignment (Proposed)**
I13.0 I13.2	0TY00Z0	Transplantation of right kidney, allogeneic, open approach	MDC 5 (*Diseases & Disorders of the Circulatory System*)	MS-DRGs 981-983 (*Extensive O.R. Procedure Unrelated to Principal Diagnosis*)	MS-DRG 264 (*Other Circulatory O.R. Procedures*)
	0TY10Z0	Transplantation of left kidney, allogeneic, open approach			

The ACS opposes the Agency's proposal to reassign cases reporting ICD-10-PCS codes 0TY00Z0 (*Transplantation of right kidney, allogeneic, open approach*) or 0TY10Z0 (*Transplantation of left kidney, allogeneic, open approach*) with an ICD-10-CM diagnosis code in MDC 5 (*Diseases and Disorders of the Circulatory System*) to MS-DRG 264 (*Other Circulatory O.R. Procedures*). We support and wish to reiterate the comments regarding this proposal that were submitted to the CMS by the American Society of Transplant Surgeons (ASTS), which indicate that such MDC/MS-DRG reassignments would reduce reimbursement for kidney transplantation procedures furnished to beneficiaries with severe cardiac comorbidities by approximately 33 percent; the resulting reimbursement rate would also be less than the amount paid for kidney transplantation procedures furnished to beneficiaries who *do not* have severe cardiac comorbidities.

The College does not believe that payment for transplant cases in which the patient presents with both chronic kidney disease and heart failure should be less than that for cases involving patients without serious comorbid conditions, and we thereby urge the Agency to assign cases reporting procedure codes 0TY00Z0/0TY10Z0 with a principal diagnosis in MDC 5 to MS-DRG 652 (*Kidney Transplant*). Assigning all kidney transplant cases to the same MS-DRG could facilitate the collection of hospital and transplant center cost data that could be then used to evaluate whether new severity-based kidney transplant MS-DRGs are needed; CMS' proposal to split such cases across different MS-DRG families would add unnecessary complications to the data collection and analytic processes needed to determine

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

whether the creation of additional severity-based MS-DRGs is warranted. **We also ask that the Agency review its MS-DRG grouper logic to ensure that other cases involving kidney transplantation procedures are not inappropriately assigned to miscellaneous O.R. MS-DRGs based solely on a patient's comorbidities.**

- Colon Resection with Fistula. CMS proposes to reassign cases reporting an ICD-10-PCS procedure code describing the open resection of the sigmoid colon in conjunction with ICD-10-CM diagnosis codes in MDC 11 (*Diseases and Disorders of the Kidney and Urinary Tract*) from MS-DRGs 981-983 to MS-DRGs 673-675 (*Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively*) in MDC 11. The Agency observed that the principal diagnosis most frequently reported with procedure code 0DTN0ZZ in MDC 11 is ICD-10-CM code N32.1 (*Vesicointestinal fistula*). The applicable diagnosis and procedure codes are listed in the table below.

MDC and MS-DRG Assignments for Colon Resection with Fistula Procedures Reported with a Principal Diagnosis in MDC 11

ICD-10 Diagnosis Code	ICD-10 Procedure Code	ICD-10 Procedure Code Descriptor	FY 2020 MDC Assignment (Proposed)	FY 2019 MS-DRG Assignment	FY 2020 MS-DRG Assignment (Proposed)
N32.1	0DTN0ZZ	Resection of sigmoid colon, open approach	MDC 11 (*Diseases and Disorders of the Kidney and Urinary Tract*)	MS-DRGs 981-983 (*Extensive O.R. Procedure Unrelated to Principal Diagnosis*)	MS-DRGs 673-675 (*Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively*)

CMS indicates that open resection of the sigmoid colon is the second most common procedure reported in conjunction with a principal diagnosis of vesicointestinal fistula, after procedure code 0TQB0ZZ (*Repair bladder, open approach*), which is assigned to both MDC 6 and MDC 11; according to the Agency, some procedures in MDCs 6 *and/or* 11 would be expected to relate to a principal diagnosis of vesicointestinal fistula because such fistulae involve the bladder *and* the bowel. CMS asserts that cases reporting code 0DTN0ZZ with vesicointestinal fistula as the principal diagnosis would best map to MS-DRGs 673-675 in MDC 11 given that these DRGs contain procedures performed on structures "other than kidney and urinary tract anatomy." The Agency notes that while procedure code

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

0DTN0ZZ does not currently map to MDC 11 when reported with a principal diagnosis of vesicointestinal fistula, the code is currently assigned to several other MDCs, which are listed in the table below.

MS-DRG Assignments for ICD-10 Procedure Code 0DTN0ZZ		
MDC	**MS-DRG**	**MS-DRG Description**
6	329-331	Major Small and Large Bowel Procedures
17	820-822	Lymphoma and Leukemia with Major Procedure
17	826-828	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major Procedure
21	907-909	Other O.R. Procedures for Injuries
24	957-959	Other Procedures for Multiple Significant Trauma

The ACS opposes CMS' proposal to reassign cases reporting ICD-10-PCS code 0DTN0ZZ (*Resection of sigmoid colon, open approach*) with a principal diagnosis of vesicointestinal fistula to MS-DRGs 673-675 (*Other Kidney and Urinary Tract Procedures*) in MDC 11 (*Diseases and Disorders of the Kidney and Urinary Tract*). We urge the Agency to withhold any changes to MDC/MS-DRG assignments for code 0DTN0ZZ until it considers the following issues:

- MS-DRG Assignment. We do not believe that mapping code 0DTN0ZZ to MS-DRGs 673 through 675 is appropriate because such DRGs do not account for the disease's organ of origin: the intestine. Generally, there are three disease processes that can lead to the formation of a vesicointestinal fistula—intra-abdominal inflammation, neoplasm, and iatrogenic trauma—most commonly emanating from complicated diverticulitis of the large intestine (ICD-10-CM code K57.32) or Crohn's disease (ICD-10-CM code K50.013). While we acknowledge that vesicointestinal fistulae may sometimes originate in the bladder in certain clinical scenarios (e.g., cancer involving the rectum or colon by direct extension from the urinary bladder), we disagree with CMS that cases reporting open sigmoidectomy with vesicointestinal fistula as the principal diagnosis most suitably map to MS-DRGs describing kidney and urinary tract procedures. **The ACS recommends that CMS and its clinical advisors review claims data, including average length**

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

of stay and cost information, for cases that report procedure code 0DTN0ZZ and map to MS-DRGs 329 through 331 (*Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively*) to determine whether these DRGs, which include the organs where fistulae most commonly develop, would provide a more precise representation of the severity of illness and disease processes leading to open resection of the sigmoid colon.

- MDC Assignment. We do not believe that the classification of ICD-10-CM code N32.1 (*Vesicointestinal fistula*) as a principal diagnosis in MDC 11 (*Diseases and Disorders of the Kidney and Urinary Tract*) is appropriate. We are concerned that this grouping does not exemplify the relationship between vesicointestinal fistula as a diagnosis and the likely origin of the fistula process, which, as indicated above, usually occurs in the intestine. We wish to reiterate that the standard surgical intervention for vesicointestinal fistulae using an open sigmoidectomy approach primarily involves complex intraoperative resection or repair of the colon—the organ in which the fistula first formed—but does not typically entail significant surgical management of the bladder. **The ACS recommends that CMS engage the ICD-10 Coordination and Maintenance Committee to examine the overall classification of vesical fistulae as principal diagnoses within each applicable MDC to ensure that, to the fullest extent possible, such assignments accurately reflect the etiology of the disease and affected organ systems.**

- Gastrointestinal Stromal Tumors with Laparoscopic Bypass. CMS received a request to reassign cases reporting ICD-10-PCS procedure code 0D164ZA (*Bypass stomach to jejunum, percutaneous endoscopic approach*) in conjunction with GIST of the stomach as the principal diagnosis from MS-DRGs 981-983 to MS-DRGs 326-328 in MDC 6. The Agency agreed with the requestor and referred to its proposal to move ICD-10-CM GIST diagnosis codes to MDC 6, and states that such policy, if finalized, would result in procedure code 0D164ZA mapping to MDC 6 when reported with GIST as the principal diagnosis. **As noted in our comments above, the ACS supports the proposed**

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

MDC/MS-DRG reassignments for GIST diagnoses and related procedure codes.

- Gastric Band Procedure Complications or Infections. CMS received a request to reassign cases reporting ICD-10-PCS procedure codes 0DW64CZ (*Revision of extraluminal device in stomach, percutaneous endoscopic approach*) and 0DP64CS (*Removal of extraluminal device from stomach, percutaneous endoscopic approach*) in conjunction with a principal diagnosis of complications or infections due to gastric band procedures from MS-DRGs 987-989 in MDC 10 (*Endocrine, Nutritional and Metabolic Diseases and Disorders*) to MS-DRGs 326-328 in MDC 6. The Agency agreed with the requestor and proposes to map cases involving the revision or removal of an extraluminal device in/from the stomach reported with gastric band procedure complications or infections as the principal diagnosis to MS-DRGs 326-328 in MDC 6. **The ACS supports the proposed MDC/MS-DRG reassignments for ICD-10-PCS codes 0DW64CZ and 0DP64CS.**

Operating Room (O.R.) and Non-O.R. Issues
Review of O.R./Non-O.R. Designation Methodology

CMS announces in this rule that, given the long period of time that has elapsed since the original O.R. and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, the Agency plans to conduct a comprehensive, systematic review of its process for determining when a procedure is considered an O.R. procedure. CMS solicits comments on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD-10-PCS classification system for future consideration.

We agree with CMS that making such O.R./non-O.R. designations has grown more complex, in part due to the implementation of the ICD-10 classification system and overall changes in medical practice. **The ACS believes that it is critical for the Agency to account for the inherently higher costs of performing procedures in an O.R. compared to non-O.R. locations (e.g., interventional radiology suites) in its review of its designation methodology, and maintains that hospital reimbursement rates for ICD-10-PCS codes under IPPS should reflect the differences in resource intensiveness between these two care settings.** We

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

encourage CMS to seek guidance from the American Medical Association (AMA) RVS Update Committee (RUC), which represents all procedural specialties and subspecialties and has the capacity to develop consensus-based recommendations for the Agency to consider as it explores a potential restructuring of O.R./non-O.R. designations. The College, with its 100 year history in establishing standards for the national improvement of surgical care and patient safety, also stands ready to provide CMS with expert clinical guidance to inform its efforts to refine MS-DRGs to better recognize the complexity of surgical procedures and associated utilization of resources across various sites of service.

For FY 2020, CMS will maintain its current methodology to review stakeholder requests to change the designation of specific ICD-10-PCS codes from non-O.R. to O.R. procedures, or to the designation from O.R. procedure to non-O.R for FY 2020. 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

- Percutaneous Drainage of Pelvic Cavity. CMS received a request to designate one ICD-10-PCS code that describes the percutaneous drainage of the pelvic cavity as a non-O.R. procedure. The applicable code is listed in the table below.

ICD-10-PCS Code	Code Description
0W9J3ZX	Drainage of pelvic cavity, percutaneous approach, diagnostic

The requestor noted that while ICD-10-PCS code 0W9J3ZX is currently recognized as an O.R. procedure, code 0W9J3ZZ (*Drainage of pelvic cavity, percutaneous approach*) is recognized as a non-O.R. procedure. The requestor stated that **both** procedures should be designated as non-O.R. CMS agreed with the requestor's recommendation and proposes to remove code 0W9J3ZX from the FY 2020 ICD-10 MS-DRG Version 37 Definitions Manual in Appendix E (Operating Room Procedures and Procedure Code/MS-DRG Index) as an O.R. procedure.

The ACS does not believe that percutaneous drainage procedures of the pelvic cavity for both diagnostic and

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

nondiagnostic purposes typically require the resources of an O.R., and we thereby support CMS' proposal to reclassify ICD-10-PCS code 0W9J3ZX as a non-O.R. procedure in FY 2020.

- Percutaneous Removal of Drainage Device. CMS received a request to designate one ICD-10-PCS code that describes the percutaneous removal of drainage devices from the pancreas as a non-O.R. procedure. The applicable code is listed in the table below.

ICD-10-PCS Code	Code Description
0FPG30Z	Removal of drainage device from pancreas, percutaneous approach

The requestor noted that while ICD-10-PCS code 0FPG30Z is currently recognized as an O.R. procedure, code 0F9G30Z (*Drainage of pancreas with drainage device, percutaneous approach*)) is recognized as a non-O.R. procedure. The requestor stated that **both** procedures should be designated as non-O.R. CMS agreed with the requestor's recommendation and proposes to remove code 0FPG30Z from the FY 2020 ICD-10 MS-DRG Version 37 Definitions Manual in Appendix E (Operating Room Procedures and Procedure Code/MS-DRG Index*)* as an O.R. procedure.

The ACS does not believe that the percutaneous removal of a drain typically requires the resources of an O.R., nor would it be more intensive than the placement of the drain, and we thereby support CMS' proposal to reclassify ICD-10-PCS code 0FPG30Z as a non-O.R. procedure in FY 2020.

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

- Percutaneous Occlusion of Gastric Artery. CMS received a request to designate two ICD-10-PCS codes that describe the percutaneous occlusion and restriction of the gastric artery with intraluminal devices as O.R. procedures. The applicable codes are listed in the table below.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

ICD-10-PCS Code	Code Description
04L23DZ	Occlusion of gastric artery with intraluminal device, percutaneous approach
04V23DZ	Restriction of gastric artery with intraluminal device, percutaneous approach

The requestor indicated that the resource intensiveness of ICD-10-PCS codes 04L23DZ and 04V23DZ is similar to that of codes 04L33DZ (*Occlusion of hepatic artery with intraluminal device, percutaneous approach*) and 04V33DZ (*Restriction of hepatic artery with intraluminal device, percutaneous approach),* which are recognized as O.R. procedures. CMS noted that, contrary to the requestor's statement, code 04V23DZ is already recognized as an O.R. procedure, and did not propose any changes to its designation. However, the Agency agreed with the requestor's recommendation regarding code 04L23DZ and proposes to add such code to the FY 2020 ICD-10 MS-DRG Version 37 Definitions Manual in Appendix E (Operating Room Procedures and Procedure Code/MS-DRG Index) as an O.R. procedure assigned to MS-DRGs 270 through 272 (*Other Major Cardiovascular Procedures*) in MDC 5 (*Diseases and Disorders of the Circulatory System*); MS-DRGs 356 through 358 (*Other Digestive System O.R. Procedures*) in MDC 6; MS-DRGs 907 through 909 (*Other O.R. Procedures for Injuries*) in MDC 21 (*Injuries, Poisonings and Toxic Effects of Drugs*); and MS-DRGs 957 through 959 (*Other O.R. Procedures for Multiple Significant Trauma)* in MDC 24 (*Multiple Significant Trauma*).

The ACS supports CMS' proposal to reclassify ICD-10-PCS code 04L23DZ as an O.R. procedure in FY 2020. We believe that surgeries involving percutaneous occlusion and restriction of the gastric artery with intraluminal devices typically require the resources of an O.R. to control for possible acute gastrointestinal bleeding or chemical injuries of the stomach that cannot be safely managed in other clinical settings. The invasive nature of these procedures also necessitates the sterile environment of an O.R. to limit the risk of secondary infection. In addition, we concur with the requestor's statement that transcatheter endovascular embolization of the gastric artery with intraluminal devices uses comparable resources to transcatheter endovascular embolization of the gastroduodenal artery, and that both types of services should be designated as O.R. procedures for the purposes of MS-DRG assignment.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

Proposed Add-On Payments for New Services and Technologies for FY 2020

Request for Information on the New Technology Add-On Payment Substantial Clinical Improvement Criterion

Under IPPS, CMS has established policies to provide additional payment for eligible medical services and technologies that meet three criteria: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. CMS states in this rule that it has received requests from stakeholders for more specificity on what data can serve as the foundation for satisfying the substantial clinical improvement criterion, and solicits comment on specific details and guidance stakeholders would find useful in understanding the Agency's approach to evaluating such data.

The ACS thanks CMS for its efforts to identify and eliminate regulatory obstacles that could inhibit utilization of new medical technologies, including those obstacles related to coverage or reimbursement. We believe that add-on payments for new technologies under IPPS can reduce financial barriers to investment and adoption by hospitals; these products can often otherwise be cost prohibitive for hospitals when the fees associated with such technologies—which may be significantly more expensive than the technologies already used by the hospital—are bundled into the overall payment for a service, such that a new technology is paid for at the same fixed Medicare rate as an older technology, regardless of the difference in the cost of the two products. **The College encourages CMS to provide greater clarity on the types of evidence that may be considered by the Agency in assessing substantial clinical improvement is needed to ensure that ambiguities within the existing IPPS add-on payment criteria do not hinder access to new technologies that may significantly enhance the diagnosis and treatment of Medicare beneficiaries.**

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

OTHER DECISIONS AND PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS

Hospital Readmissions Reduction Program: Proposed Updates and Changes

The Hospital Readmissions Reduction Program (HRPP) requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. The reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG). In this proposed rule, CMS states that it will retain the six measures that are currently part of the HRRP program.

Current Measures and Proposed Measure Policies for FY2020 and Subsequent Years

Proposed Measure Removal Factors Policy

To align the HRRP with previously adopted removal factor policies in CMS' other quality reporting and quality payment programs, CMS proposes to adopt a measure removal factor policy. In the FY 2019 IPPS/LTCH PPS final rule, the following eight measure removal factors were finalized for inclusion in the Hospital Inpatient Quality Reporting (IQR) Program, Hospital Value-Based Purchasing (VBP) Program, PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program, and Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP):

- Factor 1: Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvement in performance can no longer be made ("topped-out" measures);
- Factor 2: Measure does not align with current clinical guidelines or practice;
- Factor 3: Measure can be replaced by a more broadly applicable measure (across settings or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Factor 4: Measure performance or improvement does not result in better patient outcomes;

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

- Factor 5: Measure can be replaced by a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6: Measure collection or public reporting leads to negative unintended consequences other than patient harm;
- Factor 7: Measure is not feasible to implement as specified; and
- Factor 8: The costs associated with the benefit of its continued use in the program

We will provide comment on Factor 1 below.

Factor 1: Topped-out Measures

In CMS' response to feedback on Factor 1 that was finalized in the FY 2019 IPPS/LTCH PPS final rule for the Hospital VBP program, CMS clarified that removal factors are intended to be considerations taken into account when deciding when to remove measures and are not firm requirements. CMS also restated these points in this proposed rule. To reiterate our comments on last year's proposed rule, **ACS continues to oppose the general removal of all measures based on topped out status.** While we understand the removal factors are not firm requirements, the College's concerns that the policy does not consider the potential importance of a "topped-out" measure remain. If CMS discontinues the collection of data on key measures, the Agency and stakeholders cannot determine whether performance regresses or the removal of the measure results in lower quality of care over time. **As an alternative, we strongly recommend retaining measures that meet the "topped-out" criterion and are considered "meaningful" by key stakeholders. The argument to retain these measures is built on efforts to pursue excellence and avoid system errors. The measures should be consolidated into various composite measures or included as an evidence-based standard in a verification program.** The Trauma, Cancer, and Bariatric Surgery verification and accreditation programs led by the College are based on maintaining key topped-out process measures that are foundational in the success of the programs. [1,2] We believe that an

[1]Committee on Trauma, American College of Surgeons. "Resources for Optimal Care of the Injured Patient." https://www.facs.org/~/media/files/quality%20programs/trauma/vrc%20resources/resources%20for%20optimal%20care.ashx

[2] Commission on Cancer, American College of Surgeons. "Cancer Program Standards: Ensuring Patient-Centered Care." 2016. https://www.facs.org/~/media/files/quality%20programs/cancer/coc/2016%20coc%20standards%20manual_interactive%20pdf.ashx

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

effective quality system attempts to identify and seek topped out performance in all critical measures.

For example, through the College's experience with hospitals that partake in the National Surgical Quality Improvement Program (NSQIP), we identified a need for more general standards that can be implemented in any institution, hospital, department, or practice to guide the development of quality and safety programs. To meet this need, the ACS developed the "Optimal Resources for Surgical Quality and Safety" or "Redbook Verification." The Redbook Verification was built upon the four ACS Principles for Continuous Quality Improvement: 1) tracking standards individualized to the patient and based on research, 2) using the right infrastructure including quality processes, checklists, equipment and staffing/specialists, 3) rigorous attention to highly reliable data, including post-discharge tracking, and 4) verification of overall program implementation at the point of care with an external peer-review process which creates public assurances. The twelve evidence-based standards listed below are the foundation of the Redbook Verification, and when applied in a verification program are instrumental in cultivating a culture of quality, safety, and improvement. [3]

1. Leadership Commitment
2. Culture of Safety & High Reliability
3. Surgical Quality Officer
4. Surgical Quality Committee
5. Team processes in Five Phases of Surgical Care
6. Disease Based Management
7. Data collection and surveillance in surgical domain
8. Data-driven quality improvement in surgical domain
9. Case Review
10. Peer Review
11. Credentialing & Privileging
12. Compliance with regulatory performance metrics

Hospitals or institutions who have taken part in the verification and accreditation process aim for 100% compliance with all twelve standards. Continuing to seek high performance in the above standards exhibits a facility's dedication to achieving high-level quality measurement while ensuring the appropriate resources are in place for continual improvement

[3] American College of Surgeons. "Standards Manual v 2.0: Resources for Optimal Care of the Metabolic and Bariatric Surgery Patient." 2016. https://www.facs.org/~/media/files/quality%20programs/bariatric/mbsaqip%20standards manual.ashx

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

in patient care. If the topped-out measure policy described in this proposed rule were applied instead, many critical measures would be eliminated, leaving major gaps in the institutions quality improvement efforts. Therefore, ACS believes the topped out policies miss the mark in measuring true quality improvement. ACS's decades of experience in building reliable quality programs have demonstrated that to achieve better outcomes, the right process and structural measures are essential because process and structure provide the foundation for optimal care. Therefore, ACS supports a multi-faceted framework which includes structural and process measures, PROs, improvement activities, and risk-adjusted clinical outcomes that form a continuous cycle of improvement.

Proposed Updated Definition of "Dual-Eligible" Beginning in FY 2021

In the FY 2018 IPPS/LTCH PPS final rule, CMS updated the definition of dual-eligible to state: "Dual-eligible is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in the State Medicare Modernization Act (MMA) files for the month the beneficiary was discharged from the hospital." In this proposed rule, the Agency proposes to update the previously finalized definition of "dual-eligible" to be defined as "a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in data sourced from the State MMA files for the month the beneficiary was discharged from the hospital, except for those patient beneficiaries who die in the month of discharge, who will be identified using the previous month's data sourced from the State MMA files." CMS explains that in the past it has identified two situations where dual-eligible patients are under-reported: the dual-eligible patient is not recorded in the month of death, and the dual-eligible status changes from dual in the months prior to death to non-dual in the month of death. CMS believes that updating the definition will account for underreporting and allow for the use of the most accurate data available to determine "dual-eligible" status. **The ACS has long advocated for increased reliability of data that differentiates CMS populations and supports the update to the definition of "dual-eligible." We applaud CMS' efforts to accurately capture patient data for this group.**

Confidential Reporting of Stratified Data for Hospital Quality Measures

In past years, CMS has sought feedback on adjusting the HRRP measures for social risk factors. The ACS has continually supported CMS' efforts to assess the impact of social factors on the HRRP and other inpatient quality reporting programs. We also believe that examining the social

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

determinants of health that affect Medicare beneficiaries and finding ways to capture these factors in quality measurement should be a priority for CMS and other HHS agencies. As discussed later in this rule, CMS plans to include data stratified by patient dual-eligible status for the six readmissions measures in confidential hospital-specific reports (HSR) beginning as early as spring 2020. These data will include two disparity methodologies, the Within-Hospital Disparity Method and Dual Eligible Outcome Method, which the Agency ensures will not place any additional data collection burden on hospitals. CMS will continue using the current stratified methodology which uses excess readmission ratios (ERRs) for program measures stratified by hospital peer groups to determine payment determinations. The methodology used for payment determinations is separate from the proposed methodology for HSRs and therefore the proposed disparity methods will not affect payment adjustment factor calculations. CMS believes that providing the results of both disparity methods in conjunction with a hospital's measure data allows for a more meaningful comparison and assessment of quality of care for patients with social risk factors.

The College has long advocated for confidential reporting of stratified data, and agrees that providing these data will increase transparency and allow hospitals to better compare the quality of care they are providing based on patient population. We also believe that CMS can avoid unfairly penalizing hospitals with a more vulnerable population, while allowing hospitals to identify relevant factors to improve outcomes of disadvantaged patients. **Therefore, we support the inclusion of the two new methodologies in the HSRs, but we encourage further study because more information may be needed to better understand the socioeconomic status (SES) factors that result in higher spending and/or poorer health outcomes. We hope CMS continues to make identifying the impact of social risk factors on clinical quality measurement a priority.**

Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes

Under the Hospital Value-Based Purchasing (VBP) Program, CMS calculates a VBP incentive payment percentage for a hospital based on its Total Performance Score (TPS) for a specified performance period. The total amount available for value-based incentive payments for a fiscal year is equal to the total amount of the payment reductions for all participating hospitals for such fiscal year, as established by the Secretary. Beginning FY 2020, the available funding pool for value-based incentive payments is

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

2.0 percent. For each payment year, CMS specifies a VBP measure set and a baseline and performance period for each measure through rulemaking. Measures available for inclusion in the VBP Program are those that have been included in the Inpatient Quality Reporting (IQR) Program and have been included on the Hospital Compare website for at least one year prior to the start of the relevant VBP Program performance period.

Scoring Methodology and Data Requirements

Proposed Administrative Policies for NHSN Healthcare-Associated Infection (HAI) Measure Data

The five Centers for Disease Control (CDC) National Health Safety Network (NHSN) Healthcare-Associated Infection (HAI) were removed from the Hospital Inpatient Quality Reporting (IQR) Program, but retained in the Hospital VBP Program and Hospital Acquired Condition (HAC) Reduction Programs in FY 2019 as part of CMS' efforts to de-duplicate measures across the hospital inpatient quality programs. Within this policy, the HAC Reduction Program adopted the same data collection and validation processes previously used in the Hospital IQR Program. To continue streamlining and simplifying processes across hospital programs, CMS proposes to use the same data to calculate the CDC NHSN HAI measures in the Hospital VBP program as will be used for CY 2020 data collection in the HAC Reduction Program beginning January 1, 2020. If finalized, the processes for collecting data for the CDC NHSN HAI measures under the Hospital VBP Program would begin with data for the FY 2022 program year performance period. In conjunction with the adoption of the data collection processes, CMS also proposes that the Hospital VBP Program will use the same processes adopted by the HAC Reduction Program for hospitals to review and correct data for the CDC NHSN HAI measures and will use the HAC Reduction Program's validation to ensure accuracy of measure data in the Hospital VBP Program. **The ACS supports CMS' efforts to align the data collection and validation processes for these measures and believes that removing redundancy will lead to more focused quality reporting and targets for hospitals, as well as reduced burden on physicians.**

General Feedback

ACS appreciates CMS taking steps to reduce reporting burden by aligning measures across programs, thereby limiting the number of separate programs in which hospitals have to report. Program and measure consolidation could result in streamlined workflows for physicians and

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

care teams, as well as reduced administrative burden. However, there are multiple measures that are still used across multiple hospital programs. We urge CMS to clarify if performance on measures that are shared between programs would result in penalization in both programs, and if so, how this could affect incentives.

Hospital Acquired Condition (HAC) Reduction Program

Section 3008 of the Affordable Care Act required CMS to implement a hospital-acquired conditions payment adjustment beginning in FY 2015. This requires CMS to reduce hospital payments by one percent for hospitals that rank among the lowest performing 25 percent with regard to HACs specified under this program. The payment adjustment will result in the applicable hospitals receiving 99 percent of the payment that would otherwise apply.

Measures Specifications and Technical Specifications

Proposed Measure Removal Factors

While CMS is not proposing to remove any measures from the HAC Reduction Program in this proposed rule, they do propose the adoption of a measure removal factor policy that aligns with many of the other CMS quality reporting programs. In the FY 2019 IPPS/LTCH PPS final rule, the following eight measure removal factors were finalized for inclusion in the Hospital Inpatient Quality Reporting (IQR) Program, Hospital Value-Based Purchasing (VBP) Program, PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program, and Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP):

- Factor 1: Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvement in performance can no longer be made ("topped-out" measures);
- Factor 2: Measure does not align with current clinical guidelines or practice;
- Factor 3: Measure can be replaced by a more broadly applicable measure (across settings or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topic;
- Factor 4: Measure performance or improvement does not result in better patient outcomes;

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
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- Factor 5: Measure can be replaced by a measure that is more strongly associated with desired patient outcomes for the particular topic;
- Factor 6: Measure collection or public reporting leads to negative unintended consequences other than patient harm;
- Factor 7: Measure is not feasible to implement as specified; and
- Factor 8: The costs associated with the benefit of its continued use in the program

We will provide comment on Factor 1 below.

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[5] Commission on Cancer, American College of Surgeons. "Cancer Program Standards: Ensuring Patient-Centered Care." 2016. https://www.facs.org/~/media/files/quality%20programs/cancer/coc/2016%20coc%20standards%20manual_interactive%20pdf.ashx

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
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facs.org

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Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

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Payments for Indirect and Direct Graduate Medical Education (GME) Costs

Proposed Policy Changes Related to Critical Access Hospitals as Nonproviders for Direct GME and IME Payment Purposes

Teaching hospitals' full-time equivalent (FTE) caps dictate the maximum number of residents for which the hospital is eligible to receive Medicare reimbursement for the direct and indirect GME costs associated with resident training. Under current CMS policy, a hospital is permitted to include residents training in a "non*provider*" setting in its FTE count if the hospital incurs the residents' salaries and fringe benefits while the residents are training at that site.[8] Separately, the Agency allows critical access hospitals (CAHs) the option to either function as a "non*hospital*" site or to incur costs for training residents in an approved program and be paid 101 percent of the costs incurred from the program.[9]

CMS notes in this rule that it has received concerns from stakeholders that CAHs are not considered "non*provider*" sites for purposes of direct and indirect GME payments, thereby creating barriers to resident training and physician practice opportunities in rural and underserved areas. Stakeholders also indicated that excluding CAHs from the "nonprovider" site designation could hinder collaboration between larger hospitals and

[8] 42 CFR 413.78(g); 42 CFR 412.105(f)(1)(ii)(E)
[9] 78 FR 50735

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

CAHs and that some CAHs may be too small to independently support residency training programs or may not be in a financial position to incur the costs associated with such programs.

The Agency acknowledges that, while a CAH is considered a "provider of services" under section 1861(u) of the Social Security Act, the term "nonprovider" is not explicitly defined in the statute. Furthermore, section 1861(e) of the Social Security Act omits CAHs from the definition of "hospital."[10] Given the lack of both an explicit statutory description of a "nonprovider" site and a definitive determination as to whether a CAH is considered a hospital, CMS proposes that a hospital may include FTE residents training at a CAH in its FTE count as long as such CAH meets the Agency's "nonprovider" setting requirements. CMS does not propose changes to its existing reimbursement policies for CAHs incurring the costs of training residents.

The ACS echoes stakeholders' concerns about the ambiguous status of CAHs and thanks CMS for providing flexibility within the current statutory language to consider a CAH as a "nonprovider" setting for direct and indirect GME payment purposes. We believe that it is extremely important to support residency training in rural and underserved areas, including at CAHs. If this proposal is finalized, the College encourages CMS to work with the Health Resources and Services Administration (HRSA) and Federal Office of Rural Health Policy to communicate such information to CAHs and residency programs, as well as to explore additional opportunities for regulatory flexibility that could further increase rural residency training.

Distribution of Additional Residency Positions

Section 5503 of the Patient Protection and Affordable Care Act (ACA) directed CMS to redistribute 65 percent of teaching hospital's unused direct and indirect GME slots to teaching hospitals. Under this unused slot redistribution program, CMS awarded 726 direct GME slots and 628 indirect GME slots to 58 hospitals in 2011. Of these slots, 70 percent were allocated to hospitals in states with resident-to-population ratios in the lowest quartile, and the remaining 30 percent of slots were allocated hospitals in rural or health professional shortage areas.
Hospitals that received slots under Section 5503 were required to meet certain criteria to avoid forfeiting such slots over the five-year redistribution period from July 1, 2011, through June 30, 2016. **The ACA**

[10] 42 USC 1395x

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

specified that a hospital must use 75 percent of the awarded slots for residency training in primary care or general surgery.

In light of growing evidence demonstrating a shortage of general surgeons, the ACS supported the implementation of the unused slot redistribution program and the requirement that 75 percent of the positions attributable to the cap increase be used for primary care or general surgery. While we believe that this 75 percent threshold was intended to bolster the primary care and general surgery workforce as part of healthcare delivery for current and future Medicare beneficiaries, CMS has not provided information on the effects of this program, such as: the specialties of the training programs that lost unused slots; how many of the redistributed slots were filled; how many of the redistributed slots were awarded to primary care programs compared to how many were awarded to general surgery programs; whether general surgery experienced a net loss or net gain of residency slots; and how CMS monitored hospitals' adoption of the 75 percent threshold.

Now that the five-year redistribution period has ended, we strongly urge CMS to release its findings regarding awardee hospitals' use of their Section 5503 slots and their compliance with the terms and conditions of the program. We remain concerned with the lack of consistent, unbiased statistics on physician supply and demand and believe that CMS can provide more accurate and actionable workforce data based on this initial round of unused residency slot redistribution. In the interest of transparency and accountability, we ask that CMS make public a comprehensive description of the specialties from which the unused slots were drawn and subsequently redistributed; the number of slots designated as primary care versus general surgery under the 75 percent threshold; how the Agency and its contractors tracked hospitals' participation and enforced the program's statutory and regulatory requirements; and, in the event that it was determined a hospital did not satisfy these requirements, how its awarded slots were redistributed to another hospital(s) pursuant to Section 5503.

PROPOSED QUALITY DATA REPORTING REQUIREMENTS FOR SPECIFIC PROVIDERS AND SUPPLIERS

Hospital Inpatient Quality Reporting (IQR) Program

Under the Hospital IQR program, hospitals must meet the requirements for reporting specific quality information to receive the full market basket update for that year, and hospitals that do not will receive a two

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

percentage point reduction in that year's inpatient hospital payment update factor.

Proposed New Measures for the Hospital IQR Program Measure Set

CMS proposes to adopt two new opioid-related electronic clinical quality measures (eCQMs) for the Hospital IQR Program eCQM measure set beginning with the CY 2021 reporting period/FY 2023 payment determination.

Proposed Adoption of Two Opioid-Related eCQMs

Safe Use of Opioids – Concurrent Prescribing eCQM

This measure assesses patients 18 and older who were prescribed two or more opioids, or an opioid and a benzodiazepine, concurrently at discharge from a hospital-based encounter. Given the existing exceptions that exclude patients with cancer, patients on palliative care, and patients with encounters of 120 days or longer, the ACS supports the inclusion of this measure for CQM measure set in 2021.

Hospital Harm – Opioid- Related Adverse Events eCQMs

To align with the continued focus on measures designed to reduce adverse events or harms associated with opioid use, CMS proposes the inclusion of the *Hospital Harm – Opioid-Related Adverse Events* eCQM in both the Hospital IQR and Promoting Interoperability (PI) programs beginning with the CY 2021 reporting period/ FY 2023 payment determination. The outcome measure assesses the proportion of patients who had an opioid-related adverse event during admission in the acute care setting, rather than opioid overdose events that happen in the community. CMS plans to do this by measuring the administration of naloxone after 24 hours from hospital arrival or during the first 24 hours after hospital arrival with evidence of opioid administration in the hospital prior to the Naloxone administration. Naloxone is an opioid reversal agent that has been used in a number of studies as an indicator of opioid-related adverse respiratory events (ORAREs). To account for cases where Naloxone is used as part of a sedation plan, CMS excludes the use of the drug in the operating room. CMS explains that the intent of the measure is for hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and avoid harm, such as respiratory depression, which can lead to brain damage and death.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

The ACS agrees with CMS that it is important to have the operating room (OR) exclusion, which acknowledges cases where Naloxone is used to reverse the effects of narcotic anesthesia. Because cases in the OR are excluded from the measure, adverse events caused by opioids requiring the administration of Naloxone in the hospital setting should be rare. Therefore, these rare events would be captured in the measure, allowing for future improvement and prevention of potential patient harm. **However, while we do see benefits of using Naloxone administration as an indication of an adverse event due to respiratory repression, we remain concerned that there may be the unintended consequence of physicians interpreting the measure as a deterrent to Naloxone administration. To address this, we suggest CMS develop an additional measure that captures patient outcomes post Naloxone administration.**

Proposed Adoption of Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data

For further alignment between the Promoting Interoperability and the Hospital IQR programs, CMS proposes adopting the Hybrid Hospital Wide Readmission measure with claims and EHR data for inclusion in the CY 2023 reporting period. CMS plans to add 13 clinical data elements from EHRs, shown in the below figure—six vital signs and seven laboratory test results—to the existing claims data in order to risk-adjust the measure population. Data pulled from claims includes patient comorbidities and diagnoses, which will also be factored into the risk-adjustment methodology.

Data Elements	Units of Measurement	Additional Accepted Units of Measurement
Heart Rate	Beats per minute	--
Systolic Blood Pressure	Millimeter of mercury (mmHg)	--
Respiratory Rate	Breath per minute	--
Temperature	Degrees Fahrenheit (F)	Degrees Celsius (C)
Oxygen Saturation	Percent (%)	--
Weight	Kilogram (KG)	Pounds (LB)
Hematocrit	Percent (%)	--
White Blood Cell Count	10^9 per liter (X10E+09/L)	Thousands of cells per microliter (K/MCL)
Potassium	Millimole per liter (MMOL/L)	MEQ/L
Sodium	Millimole per liter (MMOL)/L	MEQ/L
Bicarbonate	Millimole per liter (MMOL)/L	MEQ/L
Creatinine	Milligrams per deciliter (MG/DL)	--
Glucose	Milligrams per deciliter (MG/DL)	--

While the ACS generally supports the use of risk-adjusted methodologies in pay-for-performance programs, we do not think the above data points

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
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appropriately account for risk factors related to readmission, as the items selected are biologically variable, and therefore not reliable to determine risk of readmission. For example, a patient's blood pressure and heart rate can be higher in the hospital due to stress and may not ultimately be a risk or indication of future hospital admission. Additionally, many of these values are documented multiple times a day throughout the course of an inpatient stay. As such, not only are the results biologically variable, there are also multiple entries within the EHR, further diluting the usefulness of these data. ACS recommends retaining the claims-only version of this measure.

Potential Future Quality Measures

Hospital Harm – Pressure Injury eCQM

CMS requests feedback on the possible inclusion of the Hospital Harm – Pressure Injury eCQM in future years of the Hospital IQR and PI Programs. The measure intends to assess the rate at which new hospital-acquired pressure injuries occur during an acute care hospitalization. The rate of newly-developed pressure injuries, stage 2, stage 3, stage 4, deep tissue injuries, or unstageable pressure injuries that were not documented as present in the first 24 hours of hospital arrival are identified using direct extraction of structured data from the EHR. **The ACS supports the possible adoption of this measure and agrees that measuring the rates of hospital-acquired pressure injuries is important in addressing preventable harm. This may also assist in determining if a hospital has adequate resources to properly care for their patients.**

Accounting for Social Risk Factors: Update on Confidential Reporting of Stratified Data for Hospital Quality Measures

In the FY 2017 IPPS/LTCH PPS proposed rule, CMS initially solicited public comment on potentially publicly reporting Hospital IQR Program measure data stratified by social risk factors but did not finalize this proposal. Instead, in FY2018 CMS finalized that they would first consider confidentially reporting data prior to any future public display on the Hospital Compare website. Then, in the FY 2019 IPPS/LTCH final rule, CMS finalized the distribution of confidential hospital-specific reports (HSRs) containing stratified results of the Pneumonia Readmission measure by dual-eligibility status. CMS will continue distributing confidential reporting of disparity results for the Pneumonia Readmission measure in the spring of 2019, as was done in 2018. However, in the spring of 2020, CMS plans to include disparity results for the following

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

five additional claims-based condition- and procedure- specific readmission measures as part of confidential HSRs.

1. Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization
2. Hospital 30-Day, All-Cause, RSRR Following Coronary Artery Bypass Graft (CABG) Surgery
3. Hospital 30-Day, All-Cause, RSRR Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization
4. Hospital 30-Day, All-Cause, RSRR Following Heart Failure (HF) Hospitalization
5. Hospital-Level 30-Day, All-Cause, RSRR Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)

The ACS applauds CMS' for recognizing the importance of accounting for social risk factors as part of quality measurement. However, to reiterate our comments from past years, adjusting solely based on dual eligible status may be too blunt and could inaccurately measure physicians. More information may be needed to specify the socioeconomic status (SES) factors that result in higher spending and/or poorer health care outcomes. The ACS has long advocated for further study in this area. Most of the research conducted to date focuses on analyzing the information found in Medicare administrative claims data, which has limited information on social factors. Feedback from NQF's measure developers and other stakeholders expressed a concern for a lack of complete patient-level and community-level data sources for SES and a need for greater standardization of SES variables and methods to improve testing measures for SES risk adjustment.[11] The National Academy of Medicine report also indicated the need for research on additional SES factors.[12] ASPE noted the need for further research on SES factors not found in Medicare data, as well as the need to examine the impact of measuring and accounting for functional status or frailty.[13] For purposes of identifying and reducing disparities, performance measures should be stratified on the basis of

[11] National Quality Forum *Socioeconomic Status (SES) Trial Period*. http://www.qualityforum.org/ProjectDescription.aspx?projectID=80124.
[12] National Academies of Sciences, Engineering, and Medicine. *Accounting for Social Risk Factors in Medicare Payment: Criteria, Factors, and Methods*. National Academies Press. (2016).
[13] U.S. Department of Health and Human Services. Offices of the Assistant Secretary for Planning and Evaluation. *Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.* HHS.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

relevant SES factors when used to evaluate hospitals/facilities, as well as individual physicians.

The ACS recommends that CMS continue to refine the confidential feedback reports and their stratification methods based on stakeholder feedback in an effort to identify the SES factors that directly impact health outcomes.

PPS- Exempt Cancer Hospital Quality Reporting (PCHQR) Program

Proposed Refinement to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey: Removal of the Pain Management Questions

The HCAHPS Survey was adopted by the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program beginning with the FY 2016 program year, and the survey was first publicly reported in the PCHQR Program in CY 2016. CMS explains that in feedback received in previous years, stakeholders raised concerns about the linkage of the Pain Management dimension questions to the Hospital VBP Program payment incentives. Some stakeholders stated that there could be potential pressure on hospital staff to prescribe more opioids in order to achieve higher scores in this category. In this proposed rule, CMS proposes to update the HCAHPS Survey used for the PCHQR Program by removing the following three "Pain Management" domains, which have been removed from both the Hospital IQR and Hospital VBP Programs, beginning with October 1, 2019 discharges.

- Q12: During this hospital stay, did you need medicine for pain?
- Q13: During this hospital stay, how often was your pain well controlled?
- Q14: During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?

CMS also proposes to not publicly report the data collected on the Pain Management questions beginning with October 2019 discharges. While these data will not be publicly reported, the Agency plans to provide performance results to PCHs in confidential preview reports upon the availability of four quarters of CY 2018 data, as early as July 2019.

The ACS puts the welfare of our patients above all else, and believes surgeons, as prescribers, can play a role in optimizing pain management strategies that will decrease frequent and prolonged opioid use. Pain is an

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

inevitable, but undesirable, consequence of surgery and cancer, and cancer treatment. Cancer care is complex, multidisciplinary, and cancer patients vary widely in their needs and goals for disease and pain management. For post-operative cancer patients, opioid-based pain control is a therapy supported by numerous national medical specialty societies, but these prescriptions carry well-known risks (chronic usage, addiction, and overdose). Yet, for advanced stage cancer patients or those receiving end of life care, pain is the primary condition requiring treatment and addiction is less of a concern. The College strives to ensure cancer patients continue to receive adequate pain control to restore their overall health and avoid prescription opioid-related complications or to provide opioids when needed for end-of-life care. In order to assure patients achieve adequate pain control, frequent communication between a patient and their physician(s) is critical. **For these reasons, ACS supports the proposal to remove the three HCAHPS Pain Management questions from the PCHQR program.** Additionally, until further research is conducted on the impact and utility of the HCAHPS Pain Management questions, we agree CMS should not publicly report performance data on pain assessment.

We believe that patient-reported outcomes (PROs) which follow a patient through their care journey— assessing their pain at various touchpoints— can better capture a patient's experience. **We do not believe distributing a large retrospective survey to patients after their care allows for optimal pain management. A survey mechanism that includes fewer questions distributed more frequently to patients on easily accessible platforms (such as their smartphones) throughout the course of their cancer episode provides information that can be used to inform a patient's pain at the point of care.** The ACS believes soliciting patients' feedback more frequently also supports ongoing communication between patients and physicians, which can lead to better patient outcomes and more personalized pain management plans.

Proposed New Quality Measures Beginning with the FY 2022 Program Year

Surgical Treatment of Complications for Localized Prostate Cancer

CMS proposes the adoption of the Surgical Treatment of Complications for Localized Prostate Cancer in an effort to fill a gap in quality measurement for the PCHQR Program. The measure aims to identify urinary incontinence and erectile dysfunction (ED) among patients undergoing localized prostate cancer surgery and uses this information to

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

derive hospital-specific rates. The measure was reviewed by the MAP Hospital Workgroup during 2018-2019 pre-rulemaking, where the MAP recommended CMS resubmit the measure after the measure developer has better streamlined the reliability and validity testing methodologies.

While the ACS believes that measuring patient outcomes following the surgical treatment of localized prostate cancer is extremely important, we support the MAP's recommendations and agree that this measure should not be included in the PCHQR Program until it has been refined and adequately tested. Given that ED affects approximately 30 million people in the United States, we recommend adopting an additional exclusion for patients who have been diagnosed or treated for ED and/or urinary incontinence prior to undergoing surgery for prostate cancer to ensure accurate measurement. [14] Furthermore, in many cases it is normal for patients to experience complications with ED and urinary incontinence for up to 90 days as part of their post-operative recovery. We believe this outcome would be best measured as a patient reported outcome (PRO) where patients identify any symptoms of ED or urinary incontinence beginning 30 days and up to 90 days following the surgical procedure.

Proposed Changes to the Medicare and Medicaid Promoting Interoperability Programs

CMS is continuing to advance the Promoting Interoperability Program, with the end goals of stabilizing the program; continuing to advance interoperability through CEHRT; reducing administrative burden; ensuring use of 2015 Certified Electronic Health Record Technology (CEHRT); and improving the accessibility of Electronic Health Record (EHR) data to patients to assist in health management and decision-making.

Proposed Changes to Measures Under the Electronic Prescribing Objective

As part of the Electronic Prescribing objective in the FY 2019 IPPS/LTCH final rule for the Promoting Interoperability Program, CMS included two opioid measures: *Query of the PDMP* and *Verify Opioid Treatment Agreement Measure*. Both measures were optional for CY 2019, and *Query of the PDMP* was to be required in CY 2020. However, CMS now proposes to make changes to the below measures:

[14] Nunes KP, Labazi H, Webb RC. New insights into hypertension-associated erectile dysfunction. *Current Opinion in Nephrology and Hypertension.* 2012;21(2):163–170.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

- *Query of PDMP Measure:* Based on comments and stakeholder concerns regarding the lack of integration between EHRs and PDMPs and challenges in documenting the review of the PDMP, CMS is not requiring this measure for CY 2020. Instead, this measure will remain optional in CY 2020 and eligible for 5 bonus points.
- *Verify Opioid Treatment Agreement Measure:* CMS is proposing to remove this measure in CY 2020 due to feedback from stakeholders on the challenges with documentation that prevent the ability to adequately report on this measure.

ACS supports both of these changes, as the measures are challenging to electronically report, given that they require additional documentation and verification with an external system, creating administrative burdens for physicians. Due to new policies in the ONC and CMS 21st Century Cures interoperability proposed rules, ACS recommends postponing the creation of new measures that require integration with PDMPs until the finalization of those proposed regulations, as that will affect the integration of PDMPs and EHRs.

Proposed Changes to the Scoring Methodology for Eligible Hospitals and CAHs Attesting to CMS Under the Medicare Promoting Interoperability Program for an EHR Reporting Period in CY 2020

CMS proposes a point structure for each measure in the EHR reporting period in CY 2019, with the addition of a five-point bonus for reporting on the *Query the PDMP* measure. In contrast, for CY 2019, a Security Risk Analysis (SRA) is required, but not eligible for points. The SRA measure has been a requirement since the beginning of the Meaningful Use Program in 2011, though traditionally has had points associated with it.

The burden to appropriately conduct the SRA is beyond the technical capabilities of hospitals and physicians. Therefore, the technological, encryption, and other cybersecurity components of the SRA should be shifted toward the health IT vendor to be included in the CEHRT process and not a burden placed on hospitals or physicians. Vendors create CEHRT products and have better technical know-how than their customers for running SRA. Healthcare organizations would still need to attest to conducting an analysis of the human, natural, and environmental threats to their information systems that contain e-PHI. However, we have moved beyond the days where sending medical records via fax to the wrong recipient was a major risk. Today, hackers and ransomware

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

threaten our systems and require much more technical mitigation which requires the expertise of health IT vendors.

Clinical Quality Measurement for Eligible Hospitals and Critical Access Hospitals (CAHs) Participating in the Medicare and Medicaid Promoting Interoperability Programs

Previously finalized CY 2020 CQMs

The table below includes the CY 2020 eCQMs available for reporting under the Promoting Interoperability Programs.

Short Name	Measure Name	NQF ID
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients (ED-2)	0497
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372

The ACS asks for clarification from CMS on the inclusion of both the Venus Thromboembolism Prophylaxis and Intensive Care Unit Venus Thromboembolism Prophylaxis measures, as neither measure is currently endorsed.

Proposed CY 2021 CQMs

In order to align the Promoting Interoperability Program with the Hospital IQR Program requirements, the below opioid-related CQMs are proposed to be part of the Promoting Interoperability measure set, beginning in CY 2021:

- *Safe Use of Opioids – Concurrent Prescribing eCQM (NQF 3316e)*
  This measure assesses patients 18 and older who were prescribed two or more opioids, or an opioid and a benzodiazepine, concurrently at discharge from a hospital-based encounter. Given the existing exceptions that exclude patients with cancer, patients on palliative care, and patients with encounters of 120 days or longer, the ACS support the inclusion of this measure for CQM measure set in 2021.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

- *Hospital Harm – Opioid-Related Adverse Events eCQM*
  To align with the continued focus on measures designed to reduce adverse events or harms associated with opioid use, CMS proposes the inclusion of the *Hospital Harm – Opioid-Related Adverse Events* eCQM in both the Hospital IQR and Promoting Interoperability (PI) programs beginning with the CY 2021 reporting period/ FY 2023 payment determination. The outcome measure assesses the proportion of patients who had an opioid-related adverse event during admission in the acute care setting, rather than opioid overdose events that happen in the community. CMS plans to do this by measuring the administration of naloxone after 24 hours from hospital arrival or during the first 24 hours after hospital arrival with evidence of opioid administration in the hospital prior to the Naloxone administration. Naloxone is an opioid reversal agent that has been used in a number of studies as an indicator of opioid-related adverse respiratory events (ORAREs). To account for cases where Naloxone is used as part of a sedation plan, CMS excludes the use of the drug in the operating room. CMS explains that the intent of the measure is for hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and avoid harm, such as respiratory depression, which can lead to brain damage and death.

  The ACS agrees with CMS that it is important to have the operating room (OR) exclusion, which acknowledges cases where Naloxone is safely used to reverse the effects of narcotic anesthesia. Because cases in the OR are excluded from the measure, adverse events caused by opioids that require the administration of Naloxone in the hospital setting should be rare. Therefore, these rare events would be captured in the measure, allowing for future improvement and prevention of potential patient harm. **However, while we do see benefits of using Naloxone administration as an indication of an adverse event due to respiratory repression, we remain concerned that there may be the unintended consequence of physicians interpreting the measure as a deterrent to Naloxone administration. To address this, we suggest CMS add an additional measure that captures patient outcomes post Naloxone administration.**

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

Potential Adoption of the Hybrid Hospital- Wide Readmission (HWR) Measure with Claims and EHR Data (Hybrid HWR Measure) for Reporting Periods Beginning with CY 2023

For further alignment between the Promoting Interoperability and the Hospital IQR programs, CMS proposes adopting the Hybrid Hospital Wide Readmission measure with claims and EHR data for inclusion in the CY 2023 reporting period. CMS plans to add 13 clinical data elements from EHRs, shown in the below figure—six vital signs and seven laboratory test results—to the existing claims data in order to risk-adjust the measure population. Data pulled from claims includes patient comorbidities and diagnoses, which will also be factored into the risk-adjustment methodology.

Data Elements	Units of Measurement	Additional Accepted Units of Measurement
Heart Rate	Beats per minute	--
Systolic Blood Pressure	Millimeter of mercury (mmHg)	--
Respiratory Rate	Breath per minute	--
Temperature	Degrees Fahrenheit (F)	Degrees Celsius (C)
Oxygen Saturation	Percent (%)	--
Weight	Kilogram (KG)	Pounds (LB)
Hematocrit	Percent (%)	--
White Blood Cell Count	10^9 per liter (X10E+09/L)	Thousands of cells per microliter (K/MCL)
Potassium	Millimole per liter (MMOL/L)	MEQ/L
Sodium	Millimole per liter (MMOL)/L	MEQ/L
Bicarbonate	Millimole per liter (MMOL)/L	MEQ/L
Creatinine	Milligrams per deciliter (MG/DL)	--
Glucose	Milligrams per deciliter (MG/DL)	--

While the ACS generally supports the use of risk-adjusted methodologies in pay-for-performance programs, we do not think the above data points appropriately account for risk factors related to readmission, as the items selected are biologically variable, and therefore not reliable to determine risk of readmission. For example, a patient's blood pressure and heart rate can be higher in the hospital due to stress and may not ultimately be a risk or indication of future hospital admission. Additionally, many of these values are documented multiple times a day throughout the course of an inpatient stay. As such, not only are the results biologically variable, there are also multiple entries within the EHR, further diluting the usefulness of these data. ACS recommends retaining the claims-only version of this measure.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

General Feedback: Promoting Interoperability Program

ACS appreciates CMS moving towards reducing reporting burden by aligning measures across programs, thereby limiting the number of separate hospital reporting programs. Program and measure consolidation could result in streamlined workflows for physicians and care teams, as well as reduced administrative burden. However, we urge CMS to clarify if performance on measures that are shared between programs would result in penalization under both programs, and if so, how this may impact incentives.

Future Direction of the Promoting Interoperability Program

RFI on Potential Opioid Measures for Future Inclusion in the Promoting Interoperability Program

CMS seeks comment on the inclusion of the below NQF and CDC measures for OUD prevention and treatment in the Promoting Interoperability Program. CMS also solicits recommendations on additional opioid measures for future program inclusion. Specifically, CMS is looking for measures that meet the following characteristics:

- Are applicable to all hospital settings (for example, rural, urban, small hospitals, large hospitals);
- Are represented by a measure description, numerator/denominator or "yes/no" attestation statement, and possible exclusions;
- Include evidence of positive impact on outcome-focused improvement activities, and the opioid crisis overall;
- Leverage the capabilities of CEHRT, including: automatic calculation of measure elements to reduce reporting burdens;
- Are based on well-defined clinical concepts, measure logic and timing elements that can be captured by CEHRT in standard clinical workflow and/or routine business operations (e.g., clinical and/or claims vocabularies such as SNOMED CT, LOINC, RxNorm, ICD-10 or CPT);
- Align with clinical workflows so as not to require any additional steps or actions by the health care provider.

ACS appreciates the opportunity to propose opioid measures for future program inclusion. We recommend developing a measure titled *Observed versus expected opioid usage in post-surgical cases*. This measure concept would track the expected versus observed opioid usage, defined per surgical type and case, based on morphine equivalent dose (MED) over a

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

30-day period. CMS could identify expected opioid usage per surgical case based on existing claims and pharmacy data, while patient-reported and pharmacy data would provide actual opioid usage post-surgery. This measure would help physicians understand the volume of patients who exceed expected and recommended opioid doses post-surgery, and work to determine alternative pathways to better manage post-surgical pain in these patients.

RFI on NQF and CDC Opioid Quality Measures

CMS proposes adding the below NQF and CDC OUD measures to the Promoting Interoperability program in future reporting years. CMS seeks comment on the use cases for health IT implementation for the actions within the measures.

NQF:

1. Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940)
   The proportion of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120 mg Morphine Equivalent Dose (MED) for 90 consecutive days or longer.
2. Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950)
   The proportion of individuals without cancer receiving prescriptions for opioids from 4 or more providers AND from 4 or more pharmacies.
3. Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer (NQF #2951)
   The proportion of individuals without cancer receiving prescriptions for opioids with a daily dosage greater than 120 mg MED for 90 consecutive days or longer, AND receiving prescriptions for opioids from 4 or more providers AND from 4 or more pharmacies.

The ACS has no concerns about the above measures, given the definitions and exclusions of patients with cancer and patients receiving palliative care. In response to the solicitation for health IT use cases for the above measures, pharmacy and PDMP data will be vital in ensuring complete and accurate data. Better integrated pharmacy, PDMP, and EHR data will allow for streamlined reporting with little administrative burden on

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

physicians. With implementation of the ONC and CMS proposed interoperability rules over the next several years, there will be a shift in data exchange because standards will be required. At the end of the implementation timeline from the final rules, the EHR will have the technical ability to incorporate PDMP and pharmacy data, creating a complete record of patient medications. In this future state, the reporting for the above measures will be more accurate, complete, and contain important external data elements.

CDC:

1. Check PDMP Before Prescribing Opioids (Measure 2)
   The percentage of patients with a new opioid prescription for chronic pain with documentation that a PDMP was checked prior to prescribing.
2. Evaluate within Four Weeks of Starting Opioids (Measure 4)
   The percentage of patients with a follow-up visit within four weeks of starting an opioid for chronic pain.
3. Check PDMP Quarterly (Measure 11)
   The percentage of patients on long-term opioid therapy who had documentation that a PDMP was checked at least quarterly.
4. Counsel of Risks and Benefits Annually (Measure 12)
   The percentage of patients on long-term opioid therapy for whom the clinician counseled the patient on the risks and benefits of opioids at least annually.

The ACS appreciates additional opioid measures being considered for inclusion in the Program. However, the Program proposed the eCQM *Query the PDMP* measure be a bonus measure in 2020 due to the challenges with collecting accurate data. Because of similar concerns on data availability and PDMP integration, the ACS recommends Measures 2 and 11, which are both based on utilization of the PDMP, not be adopted by the program until PDMPs are more standardized and better integrated into EHR systems.

Generally, the ACS recommends that any additional measures are added with a clear programmatic goal and future outcome. If part of the PI program's overall goal is to ensure PDMP utilization, then PDMP measures will accomplish that goal after PDMPs and EHRs are better able to exchange and incorporate data. However, if the goal is to ensure appropriate usage of opioids in medically-necessary episodes and deter behavior and use that lead to Opioid Use Disorder (OUD), the ACS recommends the development of the measure proposed earlier (*Observed*

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

versus expected opioid usage in post-surgical cases). This measure will better demonstrate the percentage of patients who exceed expected doses in the management of post-surgical pain, assist physicians in identifying patients at risk for OUD, and gauge a patient's need for alternative pain management strategies.

Request for Information (RFI) on a Metric to Improve Efficiency of Providers within EHRs

CMS is seeking feedback on possible measures to demonstrate provider efficiency as a result of health IT. Specific questions include:

- What are useful ways to measure the efficiency of health care processes due to the use of health IT? What are measurable outcomes demonstrating greater efficiency in costs or resource use that can be linked to the use of health IT-enabled processes? This includes measure description, numerator/denominator or "yes/no" reporting, and exclusions.
- What are specific technologies, capabilities, or system features (beyond those currently addressed in the Promoting Interoperability Program) that can increase the efficiency of health care provider interactions with technology systems, for instance, alternate authentication technologies that can simplify health care provider logon? How could we reward health care providers for adoption and use of these technologies?
- What are key administrative processes that could benefit from more efficient electronic workflows, for instance, conducting prior authorization requests? How could CMS measure and reward health care providers for uptake of more efficient electronic workflows?

The ACS offers recommendations below on the above questions for processes, electronic workflows, digital tools, and integration that would improve physician efficiency within EHRs.

- *Technologies, capabilities, and system features that would increase efficiency:* The ACS appreciates CMS' goal of efficient and effective use of technology to improve quality of care, decrease costs, and reduce administrative burden. We believe that incentives for physicians and systems for early adoption of application programming interface (APIs) and standards, such as Fast Healthcare Interoperability Resources (FHIR) and US Core Data for Interoperability (USCDI), would encourage early uptake

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

of these standards, promote data exchange across the care continuum, and allow for EHRs to incorporate external data for a complete patient record. Additionally, integration of digital tools and external data within the surgical workflow could be incentivized to encourage early adoption of technology, and increase efficiency of EHRs for surgery. Surgical specific enhancements that could carry incentives include risk calculation within EHRs, electronic workflow integration of the Enhanced Recovery After Surgery (ERAS) protocols, telehealth and other digital care service options, making the Prior Authorization process electronic, and Electronic Prescribing for Controlled Substances (ECPS). Incentives would result in increased use of these technologies, and encourage physicians and hospitals to be innovative in their care options.

- *Inclusion of Cost Data:* Specific technologies and features to improve efficiency include better incorporation of cost data within existing workflows to support resource use stewardship. Price information for an individual patient that is integrated into physicians' clinical workflow through APIs would be useful information for referrals for additional care and prescriptions. We urge CMS to work with ONC and to support the development and use of platforms such as the product created by Gemini Health, which aims to reduce health care costs through drug cost transparency at the point of care in a clinical workflow integrated within EHRs.[15] The ability to access patient-specific drug and alternative cost and coverage information at the point of care reduces pharmacy call backs, prior authorizations, and patient frustration. If patients have increased information about comparative treatment options and medications, protections should be put in place to ensure that clinicians are not required to provide alternatives that the clinician does not deem appropriate, nor should clinicians be held liable for refusing to offer such alternatives.

  Better understanding of total cost and resource use for episodes of care through the integration of external data would allow for better decision making along the care continuum. This process could be aided through integration of the patient workflow within the clinician workflow, including the collection of patient-reported outcomes (PROs) in more frequent, but brief, occurrences

[15] http://www.gemini.health/our-solutions/

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

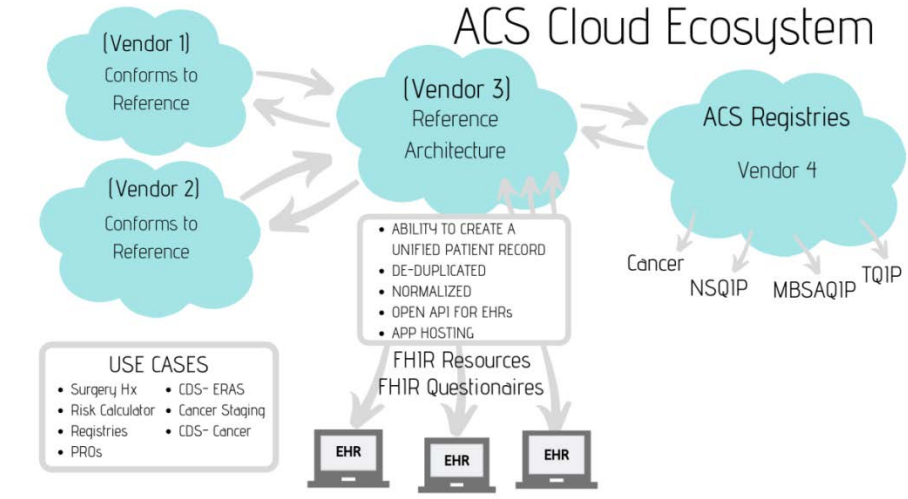
throughout their episode of care. Patient portals and third-party applications connected to EHRs through APIs could create additional options for PROs to become a part of clinical decision making.

- *Increased Efficiency for Prior Authorization through electronic workflow*: Surgeons across the country are facing setbacks in furnishing services to patients due to prior authorization processes that are antiquated, overly stringent, and inappropriately utilized by insurers. While many aspects of the clinical workflow have become automated, prior authorization remains a manual, paper-based task for many physicians. The exorbitant amount of time and resources practices must devote to prior authorization is due in part to the lack of automated prior authorization processes that integrate with EHRs. The encumbrance of inefficient prior authorization requirements represents unnecessary hours of lost clinical productivity, increased practice costs, and delays or interruptions in medically-necessary treatment. All processes needed to obtain prior authorization for medical services should be made available in EHRs or through connected digital technologies at the point of care to provide physicians with the real-time coverage information they need when making treatment decisions.

- *Streamlining standards and encouraging open source systems to ease burdens of interoperability:* Further reducing administrative burden, streamlining systems for sending and reporting data to Health Information Exchanges (HIEs), registries, and other databases through open source digital standards that meet criteria for clinical interoperability would better utilize existing technology and create efficiencies. This would greatly aid in data liquidity, which would largely eliminate data blocking, and enable patient cloud environments. Further, updated standards should include the ability for EHRs to ingest external data after clinical reconciliation, allowing for a complete health record for the patient within a physician's single system. Requiring data be sent and received in a single, standard format will better enable bidirectional exchange, particularly when facilitated through a single cloud platform. The figure below demonstrates that with standards in place, EHRs can both send and receive necessary data through a cloud platform, where the data can be processed, converted, and normalized as needed, before sending it to third-parties, such as registries, apps, state HIEs, or other EHRs, eliminating the need for EHRs to establish multiple connections in order to exchange data with a

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

variety of external parties. In the ACS Cloud Ecosystem example provided below, the cloud platform would receive EHR data using FHIR standards, the cloud would then run algorithms to normalize, de-duplicate, and risk adjust, before sending to a registry database where these data are used for quality reporting. This ecosystem simplifies data exchange through standards and plug-and-play connectivity.



PROs: Patient Reported Outcomes
CDS: Clinical Decision Support
MBSAQIP: Metabolic & Bariatric Surgery Accreditation and Quality Improvement Program
TQIP: Trauma Quality Improvement Program
NSQIP: ACS National Surgical Quality Improvement Program
ERAS: Enhanced Recovery After Surgery

RFI on Including Medicare Promoting Interoperability Program Data on Hospital Compare

CMS seeks comment on the following questions to better understand how and what timeline to post data on eligible hospitals' and CAHs' performance in the Promoting Interoperability Program on the CMS website:

- Of the six required measures and one bonus measure that would apply for an EHR reporting period in CY 2020, how many and which ones should CMS consider posting?
- What process should be in place to allow eligible hospitals and CAHs the opportunity to review the data prior to publication? This includes comment on how many days the preview period should be

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

for eligible hospitals and CAHs to review data prior to publication and a correction process for those who may have identified an error in their data.

ACS believes that a value *expression*, and not a value *score*, would better guide patients to find physicians and hospitals that meet their needs. A value expression is more than a conglomeration of measures with percentages that fail to give patients meaningful information regarding quality of care, available options for treatment, and access to their health information; rather, it includes multiple domains, further broken out into sub-domains, that allow patients to drill-down into information that matters most to them. A scalable tool of this sort can express value in surgery from two distinct perspectives: quality with an expression of production costs and quality with an expression of the total price for care for the episode, including costs from indirect care. These values would be represented as domains that would include interoperability, use of digital tools, reporting event rates, PROs, cost of services, and quality programs. This allows different end users to find the information that is most meaningful to them. The ACS is currently designing this expression for surgery, and welcomes collaboration with CMS to ensure the publicly available data is both accessible and meaningful.

RFI on the Provider to Patient Exchange Objective

CMS received feedback during the FY 2019 IPPS/LTCH comment period in support of creating a set of health IT activities that could be used as alternatives to the traditional Promoting Interoperability Program measures. Because the ONC and CMS recently released proposed rules on interoperability as part of the 21st Century Cures Act, CMS suggests using the technology and associated standards proposed within those rules as the possible alternatives. CMS is seeking feedback on the below activities as alternatives to traditional Promoting Interoperability Reporting:

- *Immediate Access:* CMS is proposing that data from eligible hospitals and CAHs be made available to patients no later than one business day.

ACS believes that this standard would create a disincentive for physicians to complete a patient's chart for it to be available for patient access. Instead, we believe two business days is a more realistic ask for data to be available for patients, as this allows time for physicians and the care team to discuss any sensitive results with patients before it is available electronically.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

- *Persistent Access and Standards-based APIs:* CMS is seeking comment on persistent and routine access for patients to their health information without needing to re-authorize their app and themselves.

While ACS agrees with CMS that patients should have routine access to their health information, we believe that this should apply only to certified applications. **As the FDA has a certification and regulatory process in place for mobile applications, the ACS strongly recommends that these criteria be adjusted and adopted in order to authenticate application developers. Additionally, just as critical is the 1) certification of the clinical logic used to ensure that the products are safe, accurate, and in alignment with clinical guidelines, and 2) privacy certification to ensure that apps meet privacy standards. We encourage CMS in collaboration with ONC to leverage the expertise of professional society organizations to certify the clinical logic.** Additionally, in the current marketplace, it is our understanding that some health IT developers employ hold-harmless clauses that protect them from liability if hospitals are later sued for medical errors that resulted from defects in the software. We strongly believe that third-party developers should be held responsible for medical errors caused as a result of use of their app—if this is not regulated, there could be grave impacts on patient safety and overall health. Certification of technology and clinical logic would largely eliminate this concern for users and developers of apps. In addition, ACS suggests that an EHR vendor's API check for the below three "yes/no" adoption & implementation attestations as a part of the certification requirements:

- (1) *Industry-recognized development guidance* (e.g., Xcertia's Privacy Guidelines);
- (2) *transparency statements and best practices* (e.g., Mobile Health App Developers: FTC Best Practices and CARIN Alliance Code of Conduct); and
- (3) *a model notice to patients* (e.g., ONC's Model Privacy Notice).

The certified app could then be acknowledged or listed by the health IT developer (e.g., in an "app store," "verified app" list). EHR vendors could also publicize app developers' attestations.

Furthermore, we support policies that require patients seeking access to their data using the app to authenticate themselves (using previously issued credentials by a health care provider or trusted source) and

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

authorize: 1) the app to connect to the FHIR server; and 2) specify the scope of the data the app may access. Once this process has been completed, the ACS agrees with persistent access for patients to their own data.

- *Available Data:* CMS seeks comment on measures that would require clinicians to use CEHRT in order to provide patients with EHI containing their complete electronic health data within an EHR.

In the recently proposed 21st Century Cures rule by the ONC, EHI is defined as all of the data that the health IT system produces and electronically manages for a patient or group of patients. This applies to the system's entire database, including but not limited to clinical, administrative, and claims/billing data. EHI also includes the oldest EHI available on that patient to the most recent, no matter the specific electronic format (e.g., PDFs are included).

The ACS appreciates that this proposal aims to provide patients and health IT users, including physicians, a means to efficiently export the entire electronic health record for a single patient or all patients in a computable, electronic format. We also appreciate that this criterion would provide additional assurances that a health IT developer supports, and does not inhibit, the access, exchange, and use of EHI. Importantly, this proposal also supports longitudinal data record development, which will help to foster better care coordination and more efficient care over time.

However, for the more immediate future, we are concerned that ONC is setting too ambitious of a goal with their proposal and failing to recognize important attributes that must first be in place to ensure successful implementation. We are also concerned that CMS is implementing related policies before the ONC releases a final rule. **For example, in the ONC proposed rule, the agency is not proposing that the export must be executed according to any particular standard. It is only requiring that the export must be accompanied by the data format, including its structure and syntax, to *facilitate* interpretation of the EHI**. It is critical that there are standards to export data in order to ensure the data are pulled consistently from every system, and that it could then be imported and integrated into other systems as needed.

The ACS strongly recommends uniform standards that certified health IT developers would have to adhere to in order to ensure that data can not only be exported, but also imported by the receiving entity. Limiting the

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

initial data set subject to this requirement to USCDI standards will result in a much more manageable mandate for health IT developers and help to minimize potential unintended consequences.

For measurements relating to EHI, ACS recommends providing incentives based on attestation for progress towards standard system extracts based on USCDI standards. Due to our existing concerns with the proposed definition of EHI, further suggestions of measures or the burden of those measures is unwarranted until a final, and updated, definition of EHI is published.

- *Patient Matching:* CMS is asking for innovative proposals and solutions to current issues regarding patient matching, without the use of a Universal Patient Identifier, or UPI. This issue will become more complex and of higher import through increasing interoperability.

In the RFI, CMS notes the critical importance of patient matching for interoperability to be successful. Inaccurate patient matching can lead to adverse events, compromised safety and privacy, inappropriate and unnecessary care, unnecessary burden on both patients and physicians to correct misidentification, 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. Inaccurate data matching poses a significant risk to patient safety because information may be unavailable when needed or records may be merged incorrectly, leading to inappropriate treatment choices. Errors in individual data matching will be compounded with the expansion of electronic health information sharing.

In the absence of a legislative fix mandating the creation of a Unique Patient Identifier (UPI) for this issue, the ACS recommends that CMS and ONC continue to explore alternative solutions for this problem. A standard algorithm hosted in a cloud platform that assesses and determines patient matches based on identifying information, such as name, date of birth, Payer ID, or other unique identifiers could be a stop-gap solution. Further, standard requirements for patient identifiers as part of the USCDI, such as number of digits and inclusion of hyphens, dashes, and apostrophes, could aid in this issue by standardizing the name field in EHRs and third- party applications. However, these options will not solve this problem completely, and ACS encourages a larger legislative fix for this issue, as it will only grow in size as digital technology and interoperability continues to increase in scope and practice.

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

RFI on Integration of Patient-Generated Health Data into EHRs Using CEHRT

As wearable devices and third-party health applications become increasingly common and available, the data generated from these products could introduce new ways to monitor and manage patient care between visits. While challenges with receiving and incorporating this information remain, CMS is interested in feedback on how the Promoting Interoperability Program could incorporate measures, activities, and elements that further the use and best practices on Patient-Generated Health Data (PGHD).

CMS asks for feedback specifically on the below questions:

- What specific use cases for capture of PGHD as part of treatment and care coordination across clinical conditions and care settings are most promising for improving patient outcomes? For instance, use of PGHD for capturing advanced directives and pre/post-operation instructions in surgery units.

ACS believes that the most beneficial PGHD are in the form of PROs. The integration of the patient experiences and milestones within the clinician workflow, including the collection of PROs in more frequent, but brief, occurrences throughout their episode of care, can provide meaningful information to physicians about progress on care goals, post-surgical recovery, pain management, and rehab and therapy. Patient portals and third-party applications connected to EHRs through APIs could create additional options for PROs to become a part of clinical decision making, and create a simple interface for users to respond to questions and share data back to their physicians.

- Should the Promoting Interoperability Program explore ways to include bonus points for health care providers engaging in activities that pilot promising technical solutions or approaches for capturing PGHD and incorporating it into CEHRT using standards-based approaches?

Incentives and bonus points are productive ways to encourage early adoption and use of PGHD incorporation into CEHRT. In early stages, attestation rather than measurement is a more effective way to measure uptake of PGHD, allowing physicians to test this incorporation out before being measured. Further, it is important that the applications and devices

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

used to capture PGHD are certified, both to ensure that they use data-exchange standards and that the data are validated and the clinical algorithms are verified before incorporation into the EHR. It will be important to learn from these early adopters, as the use and incorporation of PGHD into the EHR and clinical workflows remains in early stages. There are many lessons to be learned in the appropriate incorporation and utilization of these data.

- Should inpatient health care providers be expected to collect information from their patients outside of scheduled appointments or procedures? What are the benefits and concerns about doing so?

The ACS cautions against requiring physicians to collect information from patients outside of scheduled appointments and procedures. Given the proliferation of wearable devices and third-party applications and the challenges with these data, physicians should not be required to collect or share data with any device or application requested by a patient. Rather, there should be a certification process in place for these applications to ensure that the third-party is a safe steward of patient data, as described earlier. However, regardless of certification, there should not be a requirement to collect this data from patients, but rather it should be an option for patients and physicians to utilize devices and applications as a care management tool to maintain communication and care between visits. It is also important to recognize that not all patients have the resources, capacity, or ability to utilize technology that generates these data, and others will choose not to do so. As such, it cannot be required of physicians to use technology that patients may not be willing or able to utilize for care purposes.

- Should the Promoting Interoperability Program explore ways to reward health care providers for implementing best practices associated with optimizing clinical workflows for obtaining, reviewing, and analyzing PGHD?

As stated above, the ACS supports the concept of incentives to encourage early adoption of reviewing and incorporating PGHD. As the use of this data by clinicians remains new, evidence-based best practices are not yet well known. It is important that CMS and the ONC work together to understand the challenges physicians face as PGHD becomes more common, including challenges with volume of data, questions of accuracy, and increased communication and questions from patients. Working with physicians through these challenges to establish best practices will be an

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org

important step as the industry moves beyond adoption. ACS encourages CMS to work with specialty societies to develop these best practices.

RFI on Engaging in Activities that Promote the Safety of the EHR

CMS is seeking comments on strategies to further mitigating any risks to patient safety stemming from technology implementation, specifically on options that reduce clinical errors. CMS references the ONC SAFER guidelines as a possible tool to utilize for hospitals to complete and receive points towards their Program score. While the SAFER guides are comprehensive, several of the assessments contain information that should be the responsibility of the vendor to meet and complete, rather than the hospital, specifically the items in the High Priority Practices Checklist. Additionally, these criteria were last updated in 2016, and should be updated if they are used in the Program to ensure that they include patient safety threats that stem from increased interoperability and new technologies.

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 Ollapally, Regulatory Affairs Manager, at vollapally@facs.org, or Jill Sage, Quality Affairs Manager, at jsage@facs.org.

Sincerely,

David B. Hoyt

David B. Hoyt, MD, FACS
Executive Director

Chicago Headquarters
633 N. Saint Clair Street
Chicago, IL 60611-3211
Voice: 312-202-5000
Fax: 312-202-5001
E-mail: postmaster@facs.org
Washington Office
20 F Street, NW Suite 1000
Washington, DC 20001
Voice: 202-337-2701
Fax: 202-337-4271
E-mail: ahp@facs.org
facs.org