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 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims

June 25, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1694-P
P.O. Box 8011
Baltimore, MD 21244-1850

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 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims published in the Federal Register on May 7, 2018.

The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Since a large proportion 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 programs. 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 the Medicare Code Editor

Following the 10th revision of the International Classification of Diseases (ICD-10) code set, CMS received requests from stakeholders to review specific ICD-10 diagnosis code edit lists that the requestors believed were incorrect and affected claims processing functions in the Medicare Code Editor (MCE), the software program that detects and reports errors in the coding of Medicare claims data. The MCE is used to determine the appropriate Medicare Severity Diagnosis-Related Group (MS-DRG) for a Medicare patient by examining medical records for coverage conflicts, clinical appropriateness, and inconsistencies in the use of diagnosis and procedure codes. The program checks each diagnosis and procedure code against a table of valid diagnosis and procedure codes contained in the MCE, and provides Medicare Administrative Contractors (MACs) processing inpatient claims an analysis of errors identified on bills submitted by hospitals.

Manifestation Code as Principal Diagnosis Edit

CMS states that, in the ICD-10 classification system, manifestation codes describe the manifestation of an underlying condition, not the condition itself and, therefore, should not be used as a principal diagnosis. The MCE contains listings of diagnosis codes identified as manifestation codes and will alert a MAC to return a claim to the submitting hospital if the medical record includes a designated manifestation code as a principal diagnosis. CMS encourages hospitals to review the returned medical records and enter the proper principal diagnosis code before resubmitting the claim to the appropriate MAC for payment.

For fiscal year (FY) 2019, CMS proposes to add two new ICD-10-Clinical Modification (CM) diagnosis codes K82.A1 (Gangrene of gallbladder in cholecystitis) and K82.A2 (Perforation of gallbladder in cholecystitis) to the Manifestation Code as Principal Diagnosis MCE edit code list, indicating that cholecystitis would be required to be reported first as the principal diagnosis. Gangrene of the gallbladder in cholecystitis and perforation of the gallbladder in cholecystitis would be considered an extension of the primary illness, and therefore rendered unacceptable principal diagnosis codes, under this code edit.
The ACS believes that the classification of gangrene of the gallbladder in cholecystitis and perforation of the gallbladder in cholecystitis as manifestation codes in the MCE is appropriate. We recognize that K82.A1 and K82.A2 are new ICD-10 codes, and we support the addition of these codes in CMS software to assist in assigning MS-DRGs reflective of both the underlying disease and additional complications of cholecystitis.

New ICD-10-CM Diagnosis Codes – Appendicitis

CMS lists in Table 6A of this proposed rule new diagnosis codes that have been approved by the Agency to be effective for discharges occurring on and after October 1, 2018. CMS assigned MS-DRGs to eight new ICD-10-CM diagnosis codes describing appendicitis with peritonitis, abscess, perforation, and/or gangrene. The applicable codes are listed in the following table.

<table>
<thead>
<tr>
<th>ICD-10 Diagnosis Code</th>
<th>Code Descriptor</th>
<th>MS-DRG</th>
</tr>
</thead>
<tbody>
<tr>
<td>K35.20</td>
<td>Acute appendicitis with generalized peritonitis, without abscess</td>
<td>371, 372, 373</td>
</tr>
<tr>
<td>K35.21</td>
<td>Acute appendicitis with generalized peritonitis, with abscess</td>
<td>338, 339, 340, 371, 372, 373</td>
</tr>
<tr>
<td>K35.30</td>
<td>Acute appendicitis with localized peritonitis, without perforation or gangrene</td>
<td>371, 372, 373</td>
</tr>
<tr>
<td>K35.31</td>
<td>Acute appendicitis with localized peritonitis and gangrene, without perforation</td>
<td>371, 372, 373</td>
</tr>
<tr>
<td>K35.32</td>
<td>Acute appendicitis with perforation and localized peritonitis, without abscess</td>
<td>338, 339, 340, 371, 372, 373</td>
</tr>
<tr>
<td>K35.33</td>
<td>Acute appendicitis with perforation and localized peritonitis, with abscess</td>
<td>338, 339, 340, 371, 372, 373</td>
</tr>
<tr>
<td>K35.890</td>
<td>Other acute appendicitis without perforation or gangrene</td>
<td>371, 372, 373</td>
</tr>
<tr>
<td>K35.891</td>
<td>Other acute appendicitis without perforation, with gangrene</td>
<td>371, 372, 373</td>
</tr>
</tbody>
</table>

The ACS believes that CMS has inappropriately assigned MS-DRGs 371, 372, 373 (Major Gastrointestinal Disorders and Peritoneal Infections with a Major Complication or Comorbidity (MCC), Major Gastrointestinal Disorders and Peritoneal Infections with a Complication or Comorbidity (CC), and Major Gastrointestinal Disorders and Peritoneal Infections without CC/MCC, respectively) to K35.20 (Acute appendicitis with generalized peritonitis, without abscess), and urges the Agency to assign additional MS-DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC,
Appendectomy with Complicated Principal Diagnosis with CC, and Appendectomy with Complicated Principal Diagnosis without CC/MCC, respectively) to this diagnosis code. We question why CMS assigned MS-DRGs 371, 372, 373 to K35.20 when its localized peritonitis counterpart, K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess), was assigned the additional MS-DRGs 338, 339, and 340.

Per the Agency’s FY 2019 ICD-10-CM Tabular List of Diseases and Injuries, the presence of generalized peritonitis as described in K35.20 indicates that the appendix has ruptured or perforated, which is a complicating diagnosis that will require additional care and a longer length of stay. We are concerned that the proposed MS-DRG assignments for this diagnosis code do not appropriately represent the complications of the underlying disease—nor the additional work and resources—associated with acute appendicitis with generalized peritonitis. Multiple retrospective, multivariate reviews of patients admitted with appendicitis conducted by Fellows of the ACS define “complicated appendicitis” as the presence of either generalized peritonitis due to perforated appendicitis or appendicular abscess. An appendix may perforate and cause generalized peritonitis without abscess if the perforation is walled off from the remainder of the peritoneal cavity because of its retroperitoneal location or by loops of small intestine or omentum. The College believes that any perforation resulting in generalized peritonitis should be considered a complicated principal diagnosis both clinically and for MS-DRG assignment and asks that CMS revise Table 6A to include MS-DRGs 338, 339, and 340—in addition to the MS-DRGs 371, 372, and 373 currently assigned—for K35.20.

Other Policy Changes: Other Operating Room (O.R.) and Non-O.R. Issues

CMS addresses stakeholder requests regarding the designation of specific ICD-10-Procedure Coding System (PCS) codes as non-O.R. or O.R. procedures based on typical resource use for such services. In cases where CMS proposes to change the designation of ICD-10-PCS codes from non-O.R. to O.R. procedures, the Agency also proposes one or more MS-DRGs to which the procedure code would be assigned.

Open Scrotum and Breast Procedures

CMS received a request to designate ten ICD-10PCS codes describing open

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drainage, open extirpation and open debridement/excision of the breast as O.R. procedures. The applicable codes are listed in the following table.

<table>
<thead>
<tr>
<th>ICD-10 Procedure Code</th>
<th>Code Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>0H9U0ZZ</td>
<td>Drainage of left breast, open approach</td>
</tr>
<tr>
<td>0H9T0ZZ</td>
<td>Drainage of right breast, open approach</td>
</tr>
<tr>
<td>0H9V0ZZ</td>
<td>Drainage of bilateral breast, open approach</td>
</tr>
<tr>
<td>0H9W0ZZ</td>
<td>Drainage of right nipple, open approach</td>
</tr>
<tr>
<td>0H9X0ZZ</td>
<td>Drainage of left nipple, open approach</td>
</tr>
<tr>
<td>0HCT0ZZ</td>
<td>Extirpation of matter from right breast, open approach</td>
</tr>
<tr>
<td>0HCU0ZZ</td>
<td>Extirpation of matter from left breast, open approach</td>
</tr>
<tr>
<td>0HCV0ZZ</td>
<td>Extirpation of matter from bilateral breast, open approach</td>
</tr>
<tr>
<td>0HCW0ZZ</td>
<td>Extirpation of matter from right nipple, open approach</td>
</tr>
<tr>
<td>0HCX0ZZ</td>
<td>Extirpation of matter from left nipple, open approach</td>
</tr>
</tbody>
</table>

The requestor stated that these breast procedures require making an open incision deeper than the skin under general anesthesia and that irrigation and/or excision of devitalized tissue or cavity are often necessary and inherent to such procedures. The requestor recommended that procedures involving open drainage, open extirpation and/or open debridement/excision of the breast be recognized as O.R. procedures for the purposes of MS-DRG assignment.

CMS agreed with the requestor’s recommendation and proposed to designate the ten ICD-10-PCS codes as O.R. procedures in the FY 2019 ICD-10 MS-DRGs Version 36 Definitions Manual Appendix E (Operating Room Procedures and Procedure Code/MS-DRG Index as O.R. Procedures), assigned to MS-DRG 584 (Breast Biopsy, Local Excision and Other Breast Procedures with CC/MCC) and MS-DRG 585 (Breast Biopsy, Local Excision and Other Breast Procedures without CC/MCC) in Major Diagnostic Category (MDC) 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast).

The ACS believes that procedures involving open drainage, open extirpation and/or open debridement/excision of the breast typically require the resources of an O.R. due to the complexity of the surgical intervention related to the extent of nonviable tissue present in the breast and the use of general anesthesia to control patient pain. The invasive nature of these procedures also necessitates the sterile environment of an O.R. to limit the risk of secondary infection. We thereby support CMS’ proposal to designate these ten ICD-10-PCS codes as O.R.
procedures, as well as the assignment of such breast procedure codes to MS-DRGs 584 and 585 in MDC 9.

Open Insertion of Totally Implantable and Tunneled Vascular Access Devices

CMS received a request to designate twenty ICD-10-PCS codes describing procedures involving open insertion of totally implantable and tunneled vascular access devices (VADs). The applicable codes are listed in the following table.

<table>
<thead>
<tr>
<th>ICD-10 Procedure Code</th>
<th>Code Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>0JH60WZ</td>
<td>Insertion of totally implantable vascular access device into chest subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JH60XZ</td>
<td>Insertion of tunneled vascular access device into chest subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JH80WZ</td>
<td>Insertion of totally implantable vascular access device into abdomen subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JH80XZ</td>
<td>Insertion of tunneled vascular access device into abdomen subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHD0WZ</td>
<td>Insertion of totally implantable vascular access device into right upper arm subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHD0XZ</td>
<td>Insertion of tunneled vascular access device into right upper arm subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHF0WZ</td>
<td>Insertion of totally implantable vascular access device into left upper arm subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHF0XZ</td>
<td>Insertion of tunneled vascular access device into left upper arm subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHG0WZ</td>
<td>Insertion of totally implantable vascular access device into right lower arm subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHG0XZ</td>
<td>Insertion of tunneled vascular access device into right lower arm subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHH0WZ</td>
<td>Insertion of totally implantable vascular access device into left lower arm subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHH0XZ</td>
<td>Insertion of tunneled vascular access device into left lower arm subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHL0WZ</td>
<td>Insertion of totally implantable vascular access device into right upper leg subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHL0XZ</td>
<td>Insertion of tunneled vascular access device into right upper leg subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHM0WZ</td>
<td>Insertion of totally implantable vascular access device into left upper leg subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHP0WZ</td>
<td>Insertion of totally implantable vascular access device into left lower leg</td>
</tr>
</tbody>
</table>
The requestor stated that open procedures to insert totally implantable VADs (TIVADs) involve implantation of a port by open approach, cutting through subcutaneous tissue/fascia, placing the device and then closing tissues so that none of the device is exposed. The requestor further explained that open procedures to insert tunneled VADs involve insertion of the catheter into central vasculature and then open incision of subcutaneous tissue and fascia through which the device is tunneled. The requestor also indicated that these procedures require two ICD-10-PCS codes: one for the insertion of the VAD or port within the subcutaneous tissue and one for percutaneous insertion of the central venous catheter that is connected to the device. The requestor recommended that the open insertion of both totally implantable and tunneled VADs be recognized as O.R. procedures for the purposes of MS-DRG assignment.

CMS agreed with the requestor’s recommendation regarding procedures involving open insertion of TIVADs and proposed to designate these ten ICD-10-PCS codes as O.R. procedures in the FY 2019 ICD-10 MS-DRGs Version 36 Definitions Manual Appendix E (Operating Room Procedures and Procedure Code/MS-DRG Index as O.R. Procedures). The Agency noted that TIVAD procedures already affect MS-DRG assignment, and indicated that such procedures will continue to be assigned to MS-DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) and MS-DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures, with CC, with MCC, and without CC/MCC, respectively) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). However, CMS stated that TIVAD procedures that are unrelated to the principal diagnosis will be assigned to MS-DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). CMS did not agree with the requestor’s recommendation regarding procedures involving tunneled VADs and proposed to maintain the non-O.R. designation for these codes.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0JHN0WZ</td>
<td>Insertion of totally implantable vascular access device into right lower leg</td>
</tr>
<tr>
<td></td>
<td>subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHN0XZ</td>
<td>Insertion of tunneled vascular access device into right lower leg</td>
</tr>
<tr>
<td></td>
<td>subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHM0XZ</td>
<td>Insertion of tunneled vascular access device into left upper leg</td>
</tr>
<tr>
<td></td>
<td>subcutaneous tissue and fascia, open approach</td>
</tr>
<tr>
<td>0JHP0XZ</td>
<td>Insertion of tunneled vascular access device into left lower leg</td>
</tr>
<tr>
<td></td>
<td>subcutaneous tissue and fascia, open approach</td>
</tr>
</tbody>
</table>
The ACS believes that procedures involving the open insertion of a TIVAD typically require the resources of an O.R. using maximum sterile barrier precautions and technique, as patients who need this type of device commonly have compromised immune systems and are predisposed to increased incidence of secondary infection. **We therefore support CMS’ proposal to designate the ten TIVAD ICD-10-PCS codes as O.R. procedures, as well as the assignment of such procedures to MS-DRGs 579-581 in MDC 9, MS-DRGs 673-675 in MDC 11, and MS-DRGs 981-983 for cases in which the insertion of the TIVAD was not related to the principal diagnosis.** While we also recommend that the insertion of tunneled VADs be performed in a sterile environment to minimize the risk of infection, such procedures are less invasive than open TIVAD insertion and can typically be performed safely in interventional radiology suites per the surgeon’s clinical judgment regarding the appropriate site of service. **We support CMS’ proposal to maintain the non-O.R. designation for the ten tunneled VAD ICD-10-PCS procedure codes.**

**QUALITY REPORTING PROVISIONS**

In this proposed rule, CMS has looked across all of its hospital quality incentive programs and proposes to remove all duplicative measures. The ACS commends CMS on this effort to reduce administrative burden. This will make it easier for patients and providers to understand hospital performance, and will keep hospitals from being penalized or rewarded for the same measure across multiple programs. We also applaud CMS on its continued efforts to consider how to best account for social risk factors, which could have a significant impact on how hospitals are measured across CMS performance programs. We recommend that the Secretary of the Department of Health and Human Services (HHS) encourage CMS to work with other HHS agencies to prioritize research that examines the broader social determinants of health.

There are some additional critical issues we would like to highlight regarding the overall direction and framework of CMS quality programs. We strongly believe that these recommendations will relieve many of the administrative challenges of the program while providing the framework for hospitals and clinicians to deliver exceptional care:

- **“Meaningfulness of measures” should be determined by multi-stakeholder experts.** In order to act impartially on behalf of patients and clinicians, we do not believe that CMS alone should determine which measures in these programs are meaningful. Instead, we recommend CMS makes determinations on the meaningfulness of measures in consultation with a team of multi-disciplinary, multi-stakeholder experts.
• **Value should be defined by the patient.** CMS measures the various providers and systems that care for the patient in separate programs (e.g., the Hospital Value-Based Purchasing Program (HVBP), the Merit-based Incentive Payment System (MIPS), etc.), across separate systems (e.g., electronic health records (EHRs), clinical data registries, etc.), with disparate measures—all which add to the administrative burden of reporting as well as the increased complexity of care. The current framework only tracks various sources of data and quality programs to focus on parts of the story, but unless the patient’s story is told across the spectrum of care, it will remain siloed and lack effectiveness in driving real improvements in quality and efficiency. The ACS strongly believes it is critical to holistically measure the quality of care a patient receives for a specific episode’s cost in order to make a value statement. Without this alignment, quality measurement might occur on a separate set of patient encounters than that on which cost is measured and will not result in meaningful data.

• **Consider a new measure framework that is less burdensome, episode-based, and patient-centric.** There is a great burden on CMS and hospitals to report and aggregate measures with clinical inputs across the Agency’s quality programs. As an alternative, CMS should consider a verification program framework which is driven by compliance with evidence-based standards, verified by patient-reported experience (PRE) patient-reported outcome (PRO) measures, augmented using administrative claims-based measures for low event rate complications in care and risk adjusted clinical outcomes for high event reporting in complex care across a patient’s care episode. Verification programs support a culture of quality and are designed to align with the clinical workflow. Hospital verification can be done periodically, which would also relieve the cost and burden associated with the current measurement system.

**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). Beginning with FY 2019 and mandated in the 21st Century Cures Act, CMS will compare peer groups of hospitals based on the
The number of dual-eligible beneficiaries in determining the extent of excess readmissions.

In the proposed rule, CMS states that it will retain the six current measures as part of the HRRP program, but will delete them from the Inpatient Quality Reporting (IQR) program to streamline the measure sets across inpatient quality programs. The ACS has long advocated for the deletion of duplicative measures and strongly supports this proposal. We believe that this will reduce administrative burden, be easier to understand for patients and providers, and will keep hospitals from being penalized or rewarded for the same measure across multiple programs.

**Accounting for Social Risk Factors in the HRRP**

CMS also provides a summary of the comments received in last year’s (FY 2018) proposed rule on adjusting HRRP measures for social risk factors. CMS explains that the results of the NQF’s 2-year trial period which aimed to assess whether adjustment for social risk factors is appropriate concluded that “measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship” between social risk factors and the outcomes measured. This discrepancy may be explained, in part, by the methods used for adjustment and the limited availability of robust data on social risk factors. ACS applauds CMS’ continued efforts in assessing the impact social factors may have on the measures used in the HRRP and other inpatient quality reporting programs and encourages CMS to further explore which social determinants of health affect Medicare beneficiaries and how these risk factors can be captured and used in quality measurement. ACS also recommends the Secretary encourage CMS to work with other HHS agencies to prioritize research efforts to examine the broader social determinants of health.

Specific to this program, we encourage CMS to examine the impact of the HRRP on disadvantaged hospitals and patients. There is substantial evidence in the literature that demonstrates that the lack of risk adjustment for socioeconomic and community factors are associated with 30-day readmissions. The risk adjustment methodology currently used in the HRRP program and other inpatient quality reporting and value-based payment programs is not sophisticated enough to account for factors and may be putting hospitals treating more vulnerable patients at an even greater disadvantage by reducing their payments. For

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example, in a recent study, Hong et al. concluded that vulnerable hospitals, including hospitals having a higher proportion of Medicaid patients and safety net hospitals, or hospitals which are both, have higher readmissions (all payer) after major cancer surgery despite the application of the current risk adjustment factors used in the HRRP. Another recent study by Chen et al, found that community factors of the U.S. Delta region are associated with higher readmission ratios, and these factors are not currently used for risk adjustment in HRRP.5 The U.S. Delta region is one of the most impoverished regions in the U.S and known for inadequate health systems and poor population health.6 To this end, we encourage CMS to carefully consider the impact of the HRRP program and other inpatient quality programs on disadvantaged hospitals and patients. As discussed above, the ACS encourages CMS to look at how social determinants of health affect Medicare beneficiaries and how social and community factors can be incorporated into measurement. We also recommend the Secretary encourage CMS to work with other HHS agencies to prioritize research efforts to examine the broader social determinants of health.

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

Under the HVBP Program, CMS calculates a VBP incentive payment percentage for a hospital based on its Total Performance Score 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. For FY 2019, the available funding pool for incentive payments is 2.0 percent. For each payment year, CMS specifies through rulemaking a VBP measure set and a baseline and performance period for each measure. Measures available for inclusion in the VBP Program are those that are 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.

To reduce cost and the duplication of measures across programs, CMS proposes to revise its regulations to clarify that once the Agency has met the statutory requirements for including a measure in the HVBP program, the measure will not have to remain in the IQR program as it has in the past. CMS explains that HVBP Program should focus on the measurement priorities not covered by the HRRP or

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the Hospital-Acquired Conditions (HAC) Reduction Program. The Hospital HRRP focuses on care coordination measures, and the HAC Reduction Program focuses on patient safety measures. The ACS supports efforts to remove duplicative measures across inpatient programs so that measures are more aligned with the program’s intent. We believe that this will allow for more focused quality improvement efforts, will be easier for the public to understand, and will reduce reporting burden for hospitals and providers.

Proposed Measure Removal Factors for the Hospital VBP Program

When determining which measures to remove from the HVBP program and other programs included in this proposed rule, CMS proposes to adopt the following removal factors. The first seven of these measure removal factors were previously finalized for the IQR program, and Factor 8 is newly proposed with an effort to align with proposals being made for other value-based purchasing programs:

- **Factor 1.** Remove topped out measures: statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤ 0.10
- **Factor 2.** A measure does not align with current clinical guidelines or practice
- **Factor 3.** The availability of a more broadly applicable measure (across settings, populations, or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic);
- **Factor 4.** Performance or improvement on a measure does not result in better patient outcomes
- **Factor 5.** The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic
- **Factor 6.** Collection or public reporting of a measure leads to negative unintended consequences other than patient harm
- **Factor 7.** It is not feasible to implement the measure specifications
- **Factor 8.** The costs associated with a measure outweigh the benefit of its continued use in the program

**Factor 1: Topped Out Measures**

The College generally supports the measure removal factors outlined by CMS and supports the adoption of these factors for the HVBP program. However, ACS opposes the general removal of all measures based on topped out status (Factor 1) because the policy does not consider the potential importance of a “topped-out” measure. If CMS discontinues the collection of data on key measures, the Agency and stakeholders will have no way of knowing whether performance regresses or whether the removal of the measure results in lower
quality of care over the long term. **As an alternative, we strongly recommend measures that meet the “topped out” criterion, but are still considered “meaningful” by key stakeholders, be consolidated into a composite measure or included as an evidence-based standard in a verification program.** In fact, the College’s verification programs are based on maintaining key topped out process measures which create the foundation for successful programs, including the verification programs we have in trauma, cancer, and bariatric surgery.\(^7\,8\,9\) ACS centers with certification have a culture of intense verification whereby they approach quality measurement with scientific rigor for data aggregation and with high fidelity. A general surgery example could be process measures that are topped out individually but collectively are meaningful components to an Enhanced Recovery After Surgery (ERAS) protocol verification program aimed at improving surgical outcomes.

If CMS does choose to completely remove a measure based on this factor, we strongly encourage the Agency to ask measure stewards for different data sources which may demonstrate a gap, as well as investigating whether the measures are topped out across all provider types and all sub-groups of patients as there may be certain groups of patients that experience differential performance or reporting rates, such as certain underserved populations.

**Factor 8: Cost**

CMS identified several different types of costs to help assess Factor 8: costs associated with a measure outweigh the benefit of its continued use in the program:

1. provider and clinician information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS;
2. the provider and clinician cost associated with complying with other quality programmatic requirements;
3. the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs;
4. the CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and

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\(^7\) American College of Surgeons Cancer Programs. https://www.facs.org/quality-programs/cancer.
\(^8\) ACS Verification, Review, and Consultation Program for Trauma. https://www.facs.org/quality-programs/trauma/vrc/about.
(5) the provider and clinician cost associated with compliance with other federal and/or state regulations (if applicable).

CMS states that its goal is to move the HVBP program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. The ACS generally agrees with the principal outlining the removal of measures if they are extremely resource intensive with little benefit, but we seek clarity on the process for stakeholder input when making the decision to propose a measure for removal. We worry that CMS may deem a measure too costly to implement, but providers find it meaningful. In the case of patient experience measures, CMS may find the implementation of the measures costly, but patients may value the measure for decision-making. To this end, we support the NQF MAP feedback that it is critically important that measures define value from the patient and from the clinician’s perspective.\(^\text{10}\)

We also support recommendations from the MAP regarding a measure’s importance and maintaining consistency across programs. CMS should balance removing measures with the importance of maintaining a focus on important quality and public health issues and ensuring progress among low performers; as well as the importance of consistency in the program measure sets because the costs associated with adapting to changing measures and shifting the focus of quality improvement efforts are extremely burdensome for providers and measure developers.\(^\text{11}\) It will be critical to gain the perspective of all key stakeholders early on in the measure process, prior to regulatory proposals, to ensure meaningful measures are retained and stakeholders are continually incentivized to invest in the development of innovative measures.

**Proposed Removal of Ten Measures from the HVBP Program**

As part of the effort to remove duplicative measures and align measurement priorities more specifically to the intent of the individual incentive programs, CMS proposes to remove 10 measures from HVBP program with the intent of focusing on clinical outcomes, patient experience, and cost. The removed measures will remain in either the IQR or HAC Reduction Program. The ACS **strongly supports the proposals to remove duplicative measures from the**


various hospital quality incentive programs and believes that aligning measures more closely with the measurement priorities of the various quality programs will lead to more focused quality targets for hospitals, less confusion for patients and providers, and reduced burden.

Medicare Spending Per Beneficiary Measure

CMS proposes to maintain the Medicare Spending Per Beneficiary Measure (MSPB) as part of the HBVP program to report on total payment. In the FY 2017 final rule, CMS implemented the following episode-based cost measures in the IQR program with the intent to have more granular information on episode-specific cost:

- Cellulitis Clinical Episode-Based Payment Measure (Cellulitis Payment);
- Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (GI Payment);
- Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure (Kidney/UTI Payment);
- Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure (AA Payment);
- Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure (Chole and CDE Payment); and
- Spinal Fusion Clinical Episode-Based Payment Measure (SFusion Payment)

However, in this proposed rule, CMS proposes to remove these cost measures from the IQR based on Factor 8: the costs associated with a measure outweigh the benefit of its continued use in the program. CMS also explains that these measures are not tied to clinical quality measures, and therefore, they do not provide an overall picture of providers’ clinical effectiveness and efficiency. CMS claims that providers would prefer to focus their improvement efforts on total payment with the MSPB measure rather than both total payment and the payments associated with these individual types of clinical episodes. The ACS agrees with CMS that cost measures, as currently defined by CMS, are not tied to clinical quality measures. Thus, a full quality/cost dashboard is not feasible, and patients and clinicians are not able to assess value. However, that does not imply MSPB would provide a proxy for value or that it drives waste from the system.

The College has long advocated that in order for resource use measures to be effective in driving value with higher quality and lower cost, it is critical for cost measures to have complementary quality measures. Year after year, we have heard from our members that the MSPB is not actionable or meaningful and
therefore does not drive improvements in cost efficiency. **We request that CMS publicly demonstrate large scale examples where MSPB has brought attention and change to specific episodes of care.** The ACS would readily assist in providing spread of any such knowledge to the surgical community. We are also interested to know more about the feedback CMS has received from providers who expressed a preference for focusing their improvement efforts on total payment with the MSPB measure.

In past comments, we have expressed concerns with the lack of a demonstrated linkage between spending and outcomes in regard to MSPB and considered the CMS episode-based measures a step in the right direction. Episode-based measures have the potential to improve coordination and transitions of care and thereby increase the efficiency of care across the full continuum. Additionally, public reporting of episode-based measures could assist patients with medical decision-making by providing more precise and contextual data versus broad-based spending measures, such as the MSPB. Because CMS is taking a step back with the removal of the episode-based measures in the IQR, and likely considering how to provide actionable and meaningful cost data in future years, **we strongly consider the Agency to define value from the perspective of the patient and move away from the fragmented silos of quality and cost measures.** Figure 1 illustrates the current state of fragmented measurement at the national level. CMS measures the various providers and systems that care for the patient in separate programs (HVBP, MIPS, etc.), across separate systems (EHRs, clinical data registries, etc.), with disparate measures—all which add to the administrative burden of reporting. The current framework only tracks various sources of data and quality programs to focus on parts of the story, but, unless the patient’s story is told, it will remain siloed and lack effectiveness in driving real improvements in quality and efficiency.
The ACS strongly believes it is critical to measure the quality the patient receives for that specific episode’s cost in order to make a value statement. There is currently no value proposition in the CMS quality incentive programs discussed in this proposed rule. Regardless of what federal program the measures are in, they should all link up to tell a story about the patient they touch. This concept aligns very well with CMS’ Meaningful Measures Initiative.

In our research with Brandeis University, the ACS has demonstrated one solution to this challenge of measurement by using the software known as the Episode Grouper for Medicare (EGM). The EGM groups Medicare claims into episodes of care, which can then be risk-adjusted based on the care the individual patient has received or is receiving to set a patient-specific target price or groups of prices. Reports from the CMS Bundled Payments for Care Improvement (BPCI) initiative reflect an early, primitive ability to demonstrate costs associated with an episode. However, the BPCI reports are limited by MS-DRG trigger points and miss the opportunities for episode reporting using CPT trigger points as developed in the Medicare EGM. Responsibility for care is automatically attributed to a patient and can have shared attribution to the various providers based upon their role in delivering health care services to the patient as determined through claims filed. The CMS EGM has been modernized by moving to ICD-10, and we are having discussions with key stakeholders to consider transitioning from SAS to a more efficient open source program language. The episode definitions data files are openly defined by the entire specialty community of medicine and could serve as an industry standard. This will

Figure 1. Current State of Performance Measures Across CMS Quality Incentive Programs
provide CMS with a grouper logic that shows variation across patients by all the
providers and exposes care to an opportunity for improvement. These data can
then be mapped to specific clinical quality and patient-reported outcome measures
for a more granular analysis of care. This would replace the MSPB measure, and
some of the measures currently used in the various CMS programs could map to
the specific episode. For more information on the ACS Brandeis project, visit
https://aspe.hhs.gov/system/files/pdf/253406/TheACSBrandeisAdvancedAPM-
ACS.pdf.

Proposed Changes to the HVBP Program Domains

CMS proposes to remove the Safety domain from the HVBP Program beginning
with the FY 2021 program year because there would no longer be any measures in
that domain if the Agency’s measure removal proposals are finalized (the Patient
Safety measures will remain in the HAC program but will be removed from
HVBP). Therefore, CMS proposes to re-weight the three remaining domains as
follows:

- Clinical Outcomes domain – 50 percent (increased from 25 percent)
- Person and Community Engagement domain – 25 percent; and
- Efficiency and Cost Reduction domain – 25 percent

CMS explains that the proposed weight domains are based on the number of
measures in each domain. The Clinical Outcomes domain would have five
measures of mortality and complications for the FY 2021 program year and six
measures beginning with the FY 2022 program year; the Person and Community
Engagement domain would have the HCAHPS survey with its eight dimensions
of patient experience; and the Efficiency and Cost Reduction domain
would include only the MSPB measure. ACS agrees with the proposal to
determine the domain weights based on the number of measures in the
domain initially, but we strongly encourage further development of measures
in the Person and Community Engagement domain, coupled with a heavier
weight for this category.12,13,14 For elective procedures, patient reported outcomes
or experience measures are more valuable than measuring low event rate clinical

12 Gale, S. C., Shafi, S., Dombrovskiy, V. Y., Arumugam, D., & Crystal, J. S. “The public health burden of emergency
general surgery in the United States: a 10 year analysis of the Nationwide Inpatient Sample – 2001 to 2001.” Journal of
Trauma and Acute Care Surgery 77, no. 2 (2014): 202-208.
burden to define operative emergency surgery.” JAMA 151, no. 6 (2016): e160480- e160480.
outcomes because the patient is the best source of success of the procedure. Patient outcomes will align with patient interest and will better define value from a patient-centric lens.

CMS also solicits feedback for accounting for social risk factors in the HVBP Program. Please see the discussion in the HRRP program on this topic.

**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.

CMS proposes to retain the measures currently in the HAC Reduction Program because they address a performance gap in patient safety and reduce harm caused in the delivery of care. As discussed in previous sections, these measures will be deleted in other programs where they are duplicative. As stated above, the ACS strongly supports the proposals to remove duplicative measures from the various hospital quality incentive programs and believes that aligning measures more closely with the measurement priorities of the various quality programs will lead to more focused quality targets for hospitals, less confusion for patients and providers, and reduced burden.

**Patient Safety and Adverse Events Composite (PSI 90)**

Previously known as PSI 90, for FY 2019 CMS adopted a modified version of this measure, the Patient Safety and Adverse Event Composite measure beginning with FY 2023 payment. The measure is a composite of 10 AHRQ PSIs:

- PSI 03 Pressure Ulcer Rate
- PSI 06 Iatrogenic Pneumothorax Rate
- PSI 08 In-Hospital Fall with Hip Fracture Rate
- PSI 09 Perioperative Hemorrhage or Hematoma Rate
- PSI 10 Postoperative Acute Kidney Injury Rate
- PSI 11 Postoperative Respiratory Failure Rate
- PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate
- PSI 13 Postoperative Sepsis Rate
- PSI 14 Postoperative Wound Dehiscence Rate
• PSI 15 Unrecognized Abdominopelvic Accidental Puncture/Laceration Rate

**PSI 06 Iatrogenic Pneumothorax Rate**

We have heard from our membership that many minor events are being reported as Iatrogenic Pneumothorax (PTX) and should not be included in the denominator, such as incidental or non-treated PTX. For example, a small PTX discovered after a subclavian or attempt at a pacemaker that is not treated (treatment includes overnight observation) should not be included in PSI 90. We recommend that AHRQ review the codes in the denominator and exclude incidental or non-treated PTX.

**PSI 11 Postoperative Respiratory Failure Rate**

The ACS believes the PSI 11 Postoperative Respiratory Failure Rate requires a more specific definition for what constitutes respiratory failure. As written, the measure is too subjective. For example, a patient who stays intubated because the anesthesiologist documents he/she is cold or coagulopathic or the surgery was longer than usual should not qualify as post-op respiratory failure. We recommend that CMS, in partnership with AHRQ, develop clinical criteria for this measure to establish a standard definition for post-op respiratory failure and subsequently provide coding guidance.

CMS also solicits feedback for accounting for social risk factors in the HAC Reduction Program. Please see the discussion in the HRRP program on this topic.

**PAYMENTS FOR INDIRECT AND DIRECT GRADUATE MEDICAL EDUCATION (GME) COSTS**

**Proposed Changes to Medicare GME Affiliated Groups for New Urban Teaching Hospitals**

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. To the extent that a hospital’s residency cap exceeds the number of slots CMS funds, the hospital will not receive any additional compensation. Two or more hospitals meeting certain requirements set forth by CMS may be authorized to form a Medicare GME affiliated group, through which such hospitals can contractually reapportion their collective FTE cap slots among themselves to reflect the rotation of residents within the affiliated group during an academic year. Hospitals may establish an affiliated group if they are located in the same geographic area, are
under common ownership, or are jointly listed as program sponsors or major participating institutions in the same program.

In a Medicare GME affiliation agreement, a hospital that has extra cap slots (i.e., the hospital is training fewer residents than allowed under its FTE cap) can share its unused slots with another hospital in the affiliated group that has exceeded its cap for GME reimbursement. While the aggregate number of FTE cap slots for all hospitals in an affiliated group remains the same, each hospital’s FTE counts may vary from year to year as residents rotate between the group’s facilities. Medicare GME affiliation agreements remain in place for the duration of one residency training year.

Under current CMS policy, a new urban teaching hospital in the process of building FTE caps is only permitted to join an affiliated group to receive slots and may not lend its own slots to hospitals with established medical residency training programs. New urban teaching hospitals were first approved to participate in an affiliated group in the FY 2006 IPPS final rule at which time CMS restricted new hospitals’ ability to share slots within its group with the intent to deter existing teaching hospitals—which CMS defines as hospitals whose GME caps were set in the 1996 base year—from circumventing their statutory FTE caps by creating new residency programs in the new hospitals solely for the purpose of affiliating with such hospitals to receive additional, Medicare-funded slots. The Agency asserts that the intent of a Medicare GME affiliation agreement is to promote the cross-training of residents at participating hospitals and to not provide for an unfair advantage of one participating hospital at the expense of another.

CMS states in this proposed rule that the Agency has received questions about whether two (or more) new urban teaching hospitals can form their own Medicare GME affiliated groups, considering that the provisions finalized in the FY 2006 IPPS rule only address groups involving existing teaching hospitals and new teaching hospitals. In recognizing that such provisions preclude affiliations that are designed to facilitate additional training at new hospitals, including smaller, community-based facilities, CMS proposes to allow new urban teaching hospitals to loan cap slots to other new urban teaching hospitals participating in the same affiliated group beginning July 1, 2019. The Agency would continue to prohibit these new hospitals from sharing their slots with existing teaching hospitals.

We appreciate CMS’ efforts to provide flexibility with regard to Medicare GME affiliation agreements while maintaining safeguards to avoid the formation of affiliated groups that only provide advantages to one of the participating hospitals. The ACS supports the Agency’s proposal to allow new urban teaching hospitals to create an affiliated group and believes that this policy can help such hospitals promote workforce development and provide residents with
both the required and more diverse educational experiences necessary to complete their training programs.

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 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

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15 I.e., general internal medicine, general pediatrics, family medicine, preventive medicine or osteopathic general practice
distribution. 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 REVISION OF HOSPITAL INPATIENT ADMISSION ORDERS DOCUMENTATION REQUIREMENTS UNDER MEDICARE PART A

Proposed Revisions Regarding Admission Order Documentation Requirements

CMS proposes to revise its inpatient admission order policy by removing the requirement that a written inpatient admission order be present in the medical record as a specific condition of payment for inpatient services under Medicare Part A. The Agency states that, while it has granted its contractors the discretion to determine that admission order information derived from the medical record constructively satisfies the requirement that a written admission order be present in the record, medically necessary inpatient admissions continue to be denied payment due to technical discrepancies (e.g., missing physician admission signatures, missing co-signatures or authentication signatures, signatures occurring after discharge) with the documentation of admission orders.

The ACS supports CMS’ proposal and thanks the Agency for removing this unnecessary and burdensome documentation requirement. We believe that medical record reviews should focus first and foremost on whether the inpatient admission was necessary and reasonable, rather than on technicalities unrelated to the medical necessity of the inpatient stay. Physicians and hospitals are already required to document all relevant orders—in addition to progress notes, treatment plans, certification statements, and other key clinical data—in the medical record to demonstrate clinical appropriateness and support Medicare coverage criteria. Minor documentation errors in the medical record, such as missing or delayed signatures, should not be the sole reason for the denial of payment for otherwise medically necessary services.

HOSPITAL INPATIENT QUALITY REPORTING (IQR) PROGRAM

Public Display of Quality Measures
Hospital Compare is a consumer-oriented website that provides the public with information about the quality of care in Medicare-certified hospitals. CMS currently reports data from the Hospital Readmissions Reduction Program, Hospital-Acquired Condition Reduction Program, and Hospital Inpatient Quality Reporting Program on Hospital Compare. In the FY 2018 IPPS final rule, CMS solicited comments across its quality reporting programs on the topic of accounting for social risk factors, including confidential reporting of measures stratified by patient dual eligibility to providers and future public reporting of measures stratified by patient dual eligibility on Hospital Compare.

CMS continues to seek feedback on accounting for socioeconomic status (SES). In the 2019 IPPS proposed rule, CMS stated they are planning to provide confidential feedback reports for the Pneumonia Readmission measure stratified by dual-eligibility status. CMS also seeks comment on: (1) expanding efforts to provide stratified data in hospital confidential feedback reports on measures; (2) including other social risk factors beyond dual-eligible status in hospital confidential feedback reports; and (3) eventually, making stratified data publicly available on Hospital Compare.

The ACS applauds CMS’ continued consideration of the impact social risk factors have on clinical quality measurement. However, as we pointed out last year, we would argue that adjusting solely based on dual eligibility status may be too blunt and could incorrectly measure providers while misinforming the public. More information is needed to specify the SES factors that result in higher spending and/or poorer health care outcomes. The ACS has long advocated for further study in this area. In the proposed rule, CMS acknowledged the work of the NQF and the HHS Assistant Secretary for Planning and Evaluation (ASPE). 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.\(^\text{16}\) The National Academy of Medicine report also indicated the need for research on additional SES factors.\(^\text{17}\) 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.\(^\text{18}\) For purposes of identifying and

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18 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.
reducing disparities, performance measures should be stratified on the basis of relevant SES factors when used to evaluate hospitals/facilities, as well as individual providers.

The ACS recommends CMS finalize its proposal to provide confidential feedback during the initial phase to gauge the appropriateness and accuracy of selected variables and methodologies among providers. CMS should also consider examining beyond its utility for providers. It is equally important to gauge the ability of the public to meaningfully comprehend and utilize stratified data before publicly reporting stratified measures on Hospital Compare.

**Meaningful Measures Initiative and the Hospital 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-percentage point reduction in that year’s inpatient hospital payment update factor.

CMS’ “Meaningful Measures Initiative” aims to promote improved health outcomes while minimizing several different types of costs, including:

- Provider and clinician information collection burden and related cost and burden associated with the submitting/reporting of quality measures to CMS;
- Provider and clinician cost associated with complying with other quality programmatic requirements;
- Provider and clinician cost associated with participating in multiple quality programs and tracking multiple similar or duplicative measures within or across those programs;
- CMS cost associated with the program oversight of the measure, including measure maintenance and public display; and
- Provider and clinician cost associated with compliance with other federal and/or State regulations (if applicable).

Although we applaud CMS’ effort in attempting to determine which measures are meaningful to promote improved outcomes while minimizing cost, we are concerned that this initiative is too heavily focused on cost burden. We encourage CMS to work to establish a return on investment (ROI) formula in quality measurement not just reducing cost. The ROI formula could establish whether the investment in measures are generating a return of better care from the patient.

perspective. Additionally, in order to act impartially on behalf of patients and clinicians, we do not believe that CMS alone should determine which measures in their programs are meaningful. Instead, we recommend CMS make determinations on the meaningfulness of measures in consultation with a team of multi-disciplinary, multi-stakeholder experts.

Proposed Removal of Hospital IQR Program Measures

CMS proposes to remove a total of 39 measures from the Hospital IQR Program across the FYs 2020, 2021, 2022, and 2023 payment determination. We discuss key measures below.

Safe Surgery Checklist Use

CMS proposes to remove the Safe Surgery Checklist Use measure from the IQR Program because the costs associated with this measure outweigh the benefit of its continued use in the program (removal Factor 8). In addition, CMS found no meaningful difference in performance and little room for continued improvement.

The ACS does not support the removal of this measure because of possible unintended consequences. Although CMS has not seen meaningful performance from this measure, the larger concern is that the removal of this measure may send the signal that the checklist is no longer important when, to the contrary, it is well-documented that surgical checklists improve patient safety. Taking an example from the aviation industry, a pilot’s pre-flight checklist is always performed at the moment before departure. Although performance on this pre-checklist process is typically high enough to satisfy CMS’ definition of “topped out,” pilots are still required to check these results every time before every flight. Medical care is complex and spans time, unique patients, and disparate care systems. It is every bit as crucial that we continue to incentivize the long-term tracking of key processes and outcomes—even those that CMS might define as “topped out.”

Clinical Episode-based Payment Measures

As discussed in the HVBP section of this letter, CMS proposes to remove 6 episode-based payment measures from the IQR program based on Factor 8 (associated costs outweigh the benefit of their continued use). CMS also explains that these measures are not tied to clinical quality measures, and therefore, they

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do not provide an overall picture of providers’ clinical effectiveness and efficiency. CMS claims that providers would prefer to focus their improvement efforts on total payment with the MSPB measure, rather than both total payment and the payments associated with these individual types of clinical episodes. The ACS agrees with CMS that cost measures as currently defined by CMS are not tied to clinical quality measures. Thus, a full quality/cost dashboard is not feasible, and patients and clinicians are not able to assess value. However, that does not imply MSPB would provide a proxy for value or that it successfully drives waste from the system.

We have long advocated that in order for resource use measures to be effective in driving value with higher quality and lower cost, it is critical for cost measures to have complimentary quality measures. Year after year, we have heard from our members that the MSPB is not actionable or meaningful and therefore does not drive improvements in cost efficiency. We welcome CMS to demonstrate large scale examples where MSPB has brought attention and change to specific episodes of care. The ACS would readily assist in providing spread of any such knowledge to the surgical community. We are also interested to know more about the feedback CMS has received from providers who expressed preference for focusing their improvement efforts on total payment with the MSPB measure.

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Figure 1. Current State of Performance Measures Across CMS Quality Incentive Programs

The ACS strongly believes it is critical to measure the quality of care the patient receives for that specific episode’s cost in order to make a value statement. There is currently no value proposition in the CMS quality incentive programs discussed in this proposed rule. Regardless of what federal program the measures are in, they should all link up to tell a story about the patient they touch. This concept aligns very well with CMS’ Meaningful Measures Initiative.

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providers and expose care to an opportunity for improvement. These data can then be mapped to specific clinical quality and patient-reported outcome measures for a more granular analysis of care. This would replace the MSPB measure and some of the measures currently used in the various CMS programs could map to the specific episode. For more information on the ACS Brandeis project visit https://aspe.hhs.gov/system/files/pdf/253406/TheACSBrandeisAdvancedAPM-ACS.pdf.

**Possible New Quality Measures, Measure Topics, and Other Future Considerations**

CMS also seeks comment on two potential future measures for the Hospital IQR Program

- Claims-Only, Hospital-Wide, All-Cause, Risk-Standardized Mortality measure (MUC17-195);
- Hybrid Hospital-Wide Mortality Measure Electronic Health Record Data (MUC17-196)

CMS explains that a measure of hospital-wide mortality captures a hospital’s performance across a broader set of patients and across more areas of the hospital. The ACS does not support the proposed hospital-wide mortality measures because the risk adjustment for these measures is not sophisticated enough to account for factors that may be putting vulnerable hospitals at an even greater disadvantage by reducing their payments. For example, the measure does not account for different types of trauma hospitals.

Measurement by itself is simply not enough and will result in misclassification of a high performing hospital. Just over a year ago, a Congressman sustained a gunshot wound and was taken to a local level 1 trauma center. The care the Congressman received was exceptional and saved his life. Yet, the press reported the Congressman was taken to an underperforming hospital by CMS standards. The ACS risk-adjusted trauma standards, had they been assessed, would have demonstrated the trauma center performed exceedingly well. This supports our assertions that CMS measures may misclassify a delivery center and misguide care. High-end trauma centers who gain ACS Trauma Certification have a culture of intense verification whereby they approach quality measurement with scientific rigor for data aggregation and with high fidelity. In uncertified centers the rigor of clinical aggregation is lacking and leads to under reporting of complications. Organizations with greater attention to measurement science and data aggregation suffer when classified by CMS measures which are less clinically valid measures. This measure would compare a trauma hospital, which sees the most complex and seriously injured patients, to a small community hospital, which does treat trauma patients. In this scenario, verified trauma centers provide the best care for trauma patients.
patients because they are well equipped to treat traumatic injury. Yet, this measure does not recognize or account for these varying levels of care and may unfairly penalize trauma centers or other hospitals that care for the most complex patients.

The ACS also supports MAP’s recommendation that these measures should not be considered for implementation until after they have been reviewed and endorsed by the NQF to ensure they have appropriate clinical and social risk factors in the risk adjustment models. ACS is concerned with measures that rely solely on claims data and therefore favor the use of the Hybrid Hospital-Wide Mortality Measure Electronic Health Record Data measure compared to the Claims-Only, Hospital-Wide, All-Cause, Risk-Standardized Mortality measure.

Potential Future Inclusion of the Hospital Harm – Opioid-Related Adverse Events Electronic Clinical Quality Measure (eCQM)

CMS is considering a newly specified Hospital-Harm Opioid Related Adverse Events eCQM for possible concurrent inclusion in future years of the Hospital IQR and Medicare and Medicaid Promoting Interoperability Programs. CMS explains that this outcome measure assesses, by hospital, the proportion of patients who had an opioid-related adverse event. The measure uses the administration of naloxone, an opioid reversal agent that has been used in a number of studies as an indicator of opioid-related adverse respiratory events, to indicate a harm to a patient. The intent of this measure is for hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and to avoid harm, such as respiratory depression, which can lead to brain damage and death. It focuses specifically on in-hospital opioid-related adverse events, rather than opioid overdose events that happen in the community and might bring a patient into the emergency department.

The ACS supports the measurement of opioid related adverse respiratory events (ORARE), which is a serious patient safety issue. However, as written, this measure could have the unintended consequence of deterring the use of naloxone, by incentivizing providers to withhold a narcotic antagonist. To avoid this unintended consequence, we do not support a measure that assesses whether naloxone was or was not administered. Rather, we support a measure that captures whether naloxone reversed and treated respiratory symptoms. We strongly advise the revision of this measure and then submission for NQF endorsement.

Accounting for Social Risk Factors in the Hospital IQR Program
CMS solicits feedback for accounting for social risk factors in the IQR Program. CMS also notes here that for the future, it is considering:

- Expanding its efforts to provide stratified data in hospital confidential feedback reports for other measures;
- Including other social risk factors beyond dual-eligible status in hospital confidential feedback reports; and
- Eventually, making stratified data publicly available on the Hospital Compare website.

In general, the ACS supports SES risk adjustment for measures used in accountability applications such as the IQR, HVBP, HAC Reduction Program, and Hospital Compare on a case-by-case basis. It is well established that without the use of appropriate risk adjustment for certain measures, clinical outcomes will be less reliable due to SES confounding variables. Closely evaluating the appropriate factors for SES confounding variables will lead to a deeper understanding of the relationship between these variables and clinical outcomes. Until there are further findings on the appropriate application of risk adjustment, including further study on social support services, the ACS supports the following methodology, when appropriate:

- For purposes of accountability (e.g., public reporting, pay-for-performance), SES factors should be included in risk adjustment of the performance score unless there are conceptual reasons or empirical evidence indicating that adjustment is unnecessary or inappropriate; and
- For purposes of identifying and reducing disparities, performance measures should be stratified on the basis of relevant SES factors when used in a confidential report to be analyzed by individual providers, policymakers, researchers, and the public working to reduce disparities.

By providing both the risk adjusted and the stratified results, CMS can avoid unfairly penalizing hospitals with a more vulnerable patient population, while also allowing hospitals to drill down on relevant SES factors to improve the outcomes of disadvantaged patients. However, stratified data will likely have limited utility on Hospital Compare and could lead to further confusion for the public. The ACS encourages a pilot study to test the use of data stratified by social risk factors on Hospital Compare.

For other comments related to adjusting for social risk factors, please see the discussion in the HRRP program on this topic.

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20 National Quality Forum. Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors Draft Report. NQF, 2014
PPS-EXEMPT CANCER HOSPITAL QUALITY REPORTING PROGRAM

The PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program began in 2014 as a pay-for-reporting program, and there is no penalty or consequence if a PPS-exempt Cancer Hospital (PCH) fails to meet the reporting requirements. Many of the PCHQR policies are similar to the IQR Program, including the principles for selecting and removing measures and the procedures for hospital participation in the program.

Possible New Quality Measure Topics for Future Years

Shared Decision-Making Process

CMS seeks comment on the Shared Decision-Making Process (NQF#2962) measures for future inclusion in the PCHQR program. Although the ACS strongly supports patient reported outcome (PRO) measures, we do not support the adoption of this specific shared decision-making measure because it is too broad and does not account for procedure-specific information that gives the patient the necessary information about their condition. CMS explains that the measure assesses patient answers about three essential elements of shared decision making: (1) laying out options; (2) discussing the reasons to have the intervention and not to have the intervention; and (3) asking for patient input. Given these questions, we are concerned that the provider will not discuss other options. For example, a cancer patient may want information on prognosis if he or she chooses to not have surgery or whether radiation therapy is an option. Patients would also be interested in active surveillance if that is an alternative option in their particular circumstance. This measure does not include the incentive to have these types of true shared-decision making conversations. Alternatively, we strongly believe that this measure should require condition or procedure-specific questions. We support a measure that incentivizes a library of clinical decision support (CDS) with tools specific to a patient’s condition and then measuring if these CDS tools were used for shared decision making.

PROPOSED CHANGES TO THE MEDICARE AND MEDICAID EHR INCENTIVE PROGRAMS (now referred to as the Medicare and Medicaid Promoting Interoperability Programs)

Originally implemented in 2011 as the Medicare EHR Incentive Program, the newly renamed Promoting Interoperability (PI) program was created to incentivize eligible hospitals and critical access hospitals (CAHs) to adopt, implement, upgrade, and demonstrate “meaningful use” of certified EHR
technology (CEHRT) through a 3-staged approach. In the most recent 2018 performance year, eligible hospitals and CAHs were required to attest to either Stage 2 or Stage 3 requirements. This includes using 2014 Edition or 2015 Edition CEHRT, or a combination of the two, to report data on measures that demonstrate “meaningful use” of EHRs.

In the FY 2019 IPPS proposed rule, some of the major changes and requirements CMS proposes include:

- Changing the name of the EHR Incentive program to Promoting Interoperability.
- A new scoring methodology which would reduce the number of objectives, reduce the number of measures to report, and transition from a threshold-based scoring system to a performance-based scoring system.
- Removal of 8 of the 16 clinical quality measures (CQMs) which are currently in the program, starting with the 2020 reporting period.

The ACS supports many of CMS’ proposed changes to the PI program and encourages CMS to continue prioritizing interoperability on a national level, providing greater access to information to patients, and reducing regulatory burden. In particular, we applaud the proposals to reduce administrative burden including a reduction in the number of required measures, CMS’ effort to ensure greater alignment between facility and clinician level accountability through MIPS, and CMS’ interest in potentially recognizing a set of priority HIT activities that would serve as alternatives to the traditional EHR Incentive Program measures, such as participation in the Trusted Exchange Framework and Common Agreement (TEFCA).

Front-line medical staff are rapidly leveraging new technologies in their workflow to provide optimal patient care. While front-line staff are the users of these increasingly advanced technological tools, we would like to remind CMS that health information technology (HIT) products and services, and their ability to meet regulatory requirements, are not completely controlled by hospitals, and front-line medical staff have even less control over these products. These new technologies and the capabilities they are designed to achieve to advance the field in a safe and secure manner are largely dependent on the technology vendor’s ability and willingness to adapt to changes. In setting policies to further advance interoperability, it is important that CMS account for the considerable influence that HIT vendors have over whether hospitals and
CAHs can comply with constantly evolving regulatory requirements and more robustly exchange health information. CMS should strive to find a balance between program goals and technological/financial feasibility for both HIT vendors and hospitals in their future rulemaking.

Certification Requirements Beginning in 2019 and 2020

During the 2018 performance year, eligible hospitals and CAHs had the choice to attest to either Modified Stage 2 or Stage 3 requirements of the EHR Incentive Program. Modified Stage 2 required participants to use either 2014 or 2015 Edition CEHRT or a combination of both while Stage 3 required participants to use 2015 Edition CEHRT or a combination of 2014 and 2015 Edition CEHRT.

In the proposed rule, CMS proposes that, beginning with the EHR reporting period in CY 2019, the 2015 Edition of CEHRT will be required. While we recognize that 2015 Edition CEHRT provides more functionality, such as application programming interfaces (APIs), enhanced certification criteria, and standards that advance the interoperable exchange of health information, we do not believe 2015 Edition CEHRT should be mandated because the CEHRT requirements are aligned with a superficial timeline that is costly to comply with and is narrowly scoped to exchanging information between EHRs.

In this proposed rule, CMS cites ONC, confirming that “90 percent of eligible hospitals and CAHs have 2015 Edition available based on previous EHR Incentive Programs attestation data.” While this demonstrates that the majority of hospitals have adopted 2015 Edition CEHRT, it also highlights that 10 percent of eligible hospitals and CAHs have not. This leads us to believe these hospitals have made a conscious decision that they either cannot afford to update to 2015 Edition CEHRT or have concluded the costs outweigh the possible benefits.

Instead of creating a system of mandated requirements, the ACS encourages a system that offers bonus points for the uptake of HIT that advances the interoperable exchange of health information including, but not limited to, EHRs. We believe a regulatory system that provides rewards is superior to a system that mandates requirements based on a specious timeline because this will provide more autonomy for hospitals to make business decisions that reflect their needs, while moving in the future direction CMS envisions.

To attain steady progress toward the goal of interoperability in a non-prescriptive manner, we propose short-term and long-term solutions. In the short-term, we request CMS adopt a policy similar to the Advancing Care Information (ACI) category in MIPS in 2018, where no one is required to adopt 2015 CEHRT, but receives bonus points for adopting and using it. In the long-term, the ACS envisions an incentive-based PI program that promotes the bi-directional sharing
of information and functionality across the digital ecosystem—not exclusive to EHRs. This future vision is further detailed in the below section; “Promoting Interoperability Program Future Direction.”

**Proposed Scoring Methodology for Eligible Hospitals and CAHs Attesting Under the Medicare Promoting Interoperability Program**

**Proposed Performance-Based Scoring Methodology**

**Security Risk Analysis.** In previous years, the Security Risk Analysis (SRA) measure was required under the Protect Patient Health Information Objective. The SRA requires eligible hospitals and CAHs to attest “yes” to conducting or reviewing a security risk analysis, implementing security updates as necessary, and correcting identified security deficiencies. In this proposed rule, CMS plans to eliminate the Protect Patient Health Information Objective and make the SRA a standalone, unscored measure that must be performed during the CY in order to be eligible to earn any score for the PI program. CMS is seeking comment on whether the SRA measure should remain part of the program as an attestation with no score, or whether points should be associated with this measure.

If the SRA measure is kept as part of the PI program, the ACS believes organizations should receive credit for the work done and resources spent. Hospitals and providers recognize the importance of keeping their patient’s electronic public health information (e-PHI) secure, but have difficulty properly conducting an SRA because they are not cybersecurity experts, often requiring them to hire outside consultants to complete the SRA.21

**In the opinion of the ACS, the technological, encryption, and other cybersecurity components of the SRA should be shifted toward the health IT vendor and not a burden placed on hospitals or physicians.** Vendors create the products and have better technical know-how than their customers. 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 threaten our systems and require much more technical mitigation that only a health IT vendor has the expertise to address.

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Ideally, CMS would provide the standards that products would have to meet to pass the SRA to the IT vendors, and then the vendors attest to their customers that their product conforms to the CMS standard. For example, this can be similar to what is done in the automobile industry in regard to certifying catalytic converters. The vehicle owner is required to maintain their catalytic converter and may have a rough idea of its purpose, but they would not be able to evaluate if a catalytic converter is working properly—nor is it necessary to know the ins-and-outs of a catalytic converter to operate a vehicle. Rather, the automobile manufacturer tests and meets the requirements of the EPA certification process in order to be market-ready for customers to use, and when the vehicle needs maintenance it is brought to an automobile mechanic. CMS should consider adopting a similar process for CEHRT and HIT so technical experts are the ones ensuring not only the foundational security of the products they produce, but that the products are being implemented correctly in the field, that security updates are being deployed properly and when necessary, and that deficiencies are correctly identified and addressed. The ACS welcomes the opportunity to work with CMS on how they could implement our suggestion.

Proposed Measures for Eligible Hospitals and CAHs Attesting Under the Medicare Promoting Interoperability Program

Measure Proposals for the e-Prescribing Objective

CMS has identified two new measures which align with broader HHS efforts to increase the use of Prescription Drug Monitoring Programs (PDMPs) to reduce inappropriate prescriptions, improve patient outcomes, and promote more informed prescribing practices. CMS proposes to add two new measures to the e-Prescribing objective that are based on electronic prescribing for controlled substances (EPCS): “Query of PDMP” and “Verify Opioid Treatment Agreement.” For both measures, CMS proposes to define opioids as Schedule II controlled substances. CMS also proposes to apply the same policies for the existing e-Prescribing measure to both the Query of the PDMP and Verify Opioid Treatment Agreement measures, including the requirement to use CEHRT as the sole means of creating the prescription and for transmission to the pharmacy. Initially, these measures would be optional to report, but available for bonus points, given they may not be fully developed by their health IT vendor or not fully implemented in time for data capture and reporting in 2019.

Proposed Measure: Query of Prescription Drug Monitoring Program (PDMP).

Under the e-Prescribing Objective, CMS is proposing a new measure, Query of PDMP, which will measure the use of data from CEHRT to conduct a query of a PDMP for Schedule II opioid prescriptions. The ACS supports the intent of this
measure as we believe the use of PDMPs is a strong tool in the fight against the opioid epidemic, but we do not support the measure as written.

Refining the Measure to Limit Queries of the PDMP

CMS seeks comment on whether to further refine the measure to limit queries of the PDMP to once during the stay regardless of whether multiple eligible medications are prescribed during this time. In our opinion, limiting the measure’s queries to once per stay per patient will not have a meaningful impact on care coordination or patient safety since it fails to account for the reality of clinical practice in a hospital, where patients are handed off to various physicians during their stay. This measure, as written, assumes that information from a query of the PDMP was communicated during a patient hand-off at the hospital. We believe this measure would be more effective if it was physician-centric, in which each prescribing physician is required to query the PDMP at least once during the patient’s stay in order to ensure that each prescribing physician has all relevant information to make a clinically appropriate decision.

Challenges Associated with Querying the PDMP and the Adoption of Standards

In the proposed rule, CMS acknowledged that PDMP integration is not in widespread use for CEHRT, and that this measure will require many workflow changes at the point of care before eligible hospitals and CAHs can meet this measure without experiencing significant burden. CMS seeks comment on the challenges associated with querying the PDMP with and without CEHRT integration and whether this proposed measure should require certain standards, methods or functionalities to minimize burden. Additionally, CMS seeks comment on whether ONC should consider adopting standards and certification criteria to support the query of a PDMP.

The success of this measure will be dependent on the functionality of PDMPs, and their ability to be integrated within EHRs. Currently, there is wide variation in functionality, which may be related to the state laws that require physicians to register and check the PDMP. According to the National Alliance for Model State Drug Laws, as of 2016, 21 states do not require all prescribers to be registered to their state PDMP, and 15 states do not have legislation requiring prescribers to query the PDMP. This has led to wide variation in the sophistication of functionality for each state’s PDMPs. Each state also has their own standards for

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their PDMP which has resulted in limited interstate data sharing. **To combat this widespread issue, CMS and ONC should work towards making one national standard for PDMPs and reward hospitals that use the national standard.** As CMS and ONC work to implement national standards for PDMPs and to ensure that they are used more consistently and universally across the nation, the agencies should also work with vendors to amend the EHR certification process so that it includes rules about PDMP queries and data exchange. Until these issues are addressed, CMS should not mandate this measure.

**Proposed Measure: Verify Opioid Treatment Agreement.** CMS proposes to introduce another measure to the e-Prescribing Objective, *Verify Opioid Treatment Agreement (OTA)*. This measure is defined as, “For at least one unique patient for whom a Schedule II opioid was electronically prescribed by the eligible hospital or CAH using CEHRT during the EHR reporting period, if the total duration of the patient’s Schedule II opioid prescriptions is at least 30 cumulative days within a 6-month lookback period, the eligible hospital or CAH seeks to identify the existence of a signed opioid treatment agreement and incorporates it into CEHRT.” CMS requests public comment on the following: 1) limiting the exclusion criteria to electronic prescriptions for controlled substances, 2) whether there are circumstances which may require an additional exclusion for the Verify Opioid Treatment Agreement measure and 3) what those circumstances might be. CMS also requests comment on characteristics that should be included in an opioid treatment agreement and incorporated into CEHRT, such as clinical data, information about the patient’s care team, and patient goals and objectives.

**Circumstances Which May Require an Additional Exclusion for the Verify Opioid Agreement Measure**

The ACS supports the concept of this measure but believes there needs to be further refinement and testing before it is implemented. For instance, CMS stated that hospitals and CAHs do not typically prescribe opioid medications for more than a few days, but this measure does not consider a situation in which a patient is incoherent, non-responsive, or not communicative over the length of their stay. Based on how the measure is currently specified, patients would be captured in the denominator even though it would be unreasonable to expect them to consent to an OTA. **To strengthen this measure, an additional exclusion criterion should be adopted for patients that are incoherent, non-responsive, or not communicative.** Additionally, the measure should be tested for validity and reliability before it is required for reporting.

**Feasibility of Reporting the Verify Opioid Treatment Agreement**
CMS also raises many feasibility issues in regard to a hospital or CAH’s ability to meet the *Verifying Opioid Treatment Agreement* measure, including the lack of standardization and multiple State laws which may present barriers to the uniform implementation of this proposed measure. The ACS agrees that there are many feasibility issues with this measure that must be resolved before its implementation.

*Characteristics That Should Be Included in an Opioid Treatment Agreement*

The ACS believes that the *OTA* should be one part of a comprehensive treatment plan. This approach would include a patient’s opioid treatment plan into their general treatment plan, where the *OTA* is displayed as just one aspect of the totality of care. This approach will promote an *OTA*’s utility because it will be easier for the provider to use the OTA in the context of how they will communicate with their patients to foster shared decision making at the point of care. Overall, the ACS believes this measure needs further refinement and would benefit from a formal measure development review process where many of CMS’ feasibility concerns can be evaluated.

*Measure Proposals for the Health Information Exchange (HIE) Objective*

*Proposed Modifications to Send a Summary of Care Measure*

Document Template for Purposes of the Measures Under the Health Information Exchange Objective. CMS proposes that eligible hospitals and CAHs can use any document template within the Consolidated Clinical Document Architecture (CCDA) standard to meet the needs of the measures in the HIE Objective. As currently written, the measure provides the referring entity flexibility to determine what is the most relevant format and information to send, which can lead to useful information not being incorporated or for information to be overlooked because it is not in a familiar format. The ACS believes that the surgeon needs relevant and concise information but that the robustness of information needs to provide the full array of information in a predictable manner. The ACS believes a single, standard template that includes all the information from the common clinical data set (CCDS) would ensure that all relevant information is shared.

While the ACS supports using a single, standard template, we recognize the difficulties a one-size-fits-all document can create, as noted in the proposed rule. The ACS supports CMS’ proposal to allow the use of any CCDA template, but asks that CMS demonstrate if a single, common format is viable.

*Proposed Modifications to the Public Health and Clinical Data Registry Reporting Objective and Measures*
Currently under Stage 3 requirements, eligible hospitals and CAHs are required to attest to 3 measures in the Public Health and Clinical Data Registry Reporting Objective. Under the new, proposed scoring methodology, CMS will reduce attestation to two measures under the Public Health and Clinical Data Registry Reporting Objective. Additionally, in future rulemaking CMS intends to propose to remove the Public Health and Clinical Data Exchange Objective and measures no later than CY 2022, and seeks comment on whether hospitals will continue to share such data with public health entities once the Public Health and Clinical Data Exchange objective and measures are removed.

The ACS believes that many hospitals and providers will continue to share data with public health entities even after it is no longer part of the PI program because this information contributes to life-saving research and improved patient care. However, eliminating the Public Health and Clinical Data Exchange Objective could remove incentives for EHR vendors to communicate information seamlessly with registries. It is critical that CMS continue to incentivize investment in and EHR interoperability with registries because use of this robust data has and will continue to contribute to large advancements in the field of medicine. Clinical data registries and other registries included in the measure need to sustain and streamline the input of data to continue the mission of the larger medical field to advance public health research and provide safe, optimal patient care.

Request for Comment – Potential New Measures for HIE Objective: Health Information Exchange Across the Care Continuum

CMS is soliciting feedback on two new potential measures for inclusion in the HIE Objective: “Support Electronic Referral Loops by Sending Health Information Across the Continuum” and “Support Electronic Referral Loops by Receiving Health Information Across the Care Continuum.” The first measure is described as, “for at least one transition of care or referral to a provider of care other than an eligible hospital or CAH, the eligible hospital or CAH creates a summary of care record using CEHRT; and electronically exchanges the summary of care record.” The other measure, Support Electronic Referral Loops by Receiving Health Information Across the Care Continuum is described as, “for at least one electronic summary of care record received by an eligible hospital or CAH from a transition of care or referral from a provider of care other than an eligible hospital or CAH, the eligible hospital or CAH conducts clinical information reconciliation for medications, medication allergies, and problem list.”

CMS seeks comment on whether these two measures should be combined into one so that an eligible hospital or CAH engaged in exchanging health information
across the care continuum may include any such exchange in a single measure. CMS also seeks comment on whether additional settings of care should be considered for inclusion in the denominators and if a provider should be allowed to limit the denominators to a specific type of care setting based on their organizational needs, clinical improvement goals, or participation in an alternative payment model.

**Combining the Two New Potential Measures**

While the ACS supports the intention of these measures, the measures are not entirely parallel to one another. The measure regarding “sending health information” requires the full summary of care record; the “receiving information” measure requires just medication, medication allergies, and current problems list. Because of this inconsistency, we believe it would be more useful for these measures to be combined so that the information that is being sent is the same as the information that is received.

**Limiting the Potential New Measures to Transitions of Care and Referrals Specific to Long-Term and Post-Acute Care, Skilled Nursing Care, and Behavioral Health Care Settings**

CMS solicits comment on whether the denominator of the potential new measures should be limited to transitions of care and referrals to long-term and post-acute care, skilled nursing care and behavioral health care settings. We believe this measure should not be limited to these points of care and should be available to all of the settings eligible hospitals and CAHs interact with in order to encourage the exchange of health information to all of the providers that care for a patient across the care continuum.

While we support the broadening of the denominator to ensure coordination with all types of settings, the ACS also supports allowing providers to limit the denominators to a specific type of care setting based on their organizational/clinical needs, as appropriate. This way, no setting is excluded, but providers will not be burdened with having to demonstrate this functionality in settings where they do not have adequate control over HIT choices and management.

**Incentivizing Write Functionality Within EHRs**

These measures also bring a larger issue to light that affects the measures’ ability to be implemented in a meaningful way for patients and providers. EHRs currently allow end users to use “receive” functions, like reading their allergy or medication list, but there is a lack of willingness of HIT vendors to allow users to
use “write” functionalities within their EHR. Write functionalities within the EHR allow end users to more easily add, display, and share information to other end users. **CMS should seek policy levers to incentivize EHR vendors to integrate “write” functionalities in their products.**

**Promoting Interoperability Program Future Direction**

*HIT Activities in Lieu of Reporting on Measures*

We applaud CMS for moving in the right direction to promote interoperability and believe the changes in this proposed rule can help reduce burden through more efficient exchange of information through HIT. **In future iterations of this program, we encourage CMS to adopt a set of priority HIT activities in lieu of traditional PI measures**, similar to the Improvement Activities category for MIPS, where there is a large set of activities that hospitals and CAHs can choose to attest to rather than providing data on a rigid set of mandatory measures. Some examples the ACS supports include: participation in TEFCA which could meet the Health Information Exchange Objective, and piloting emerging technology standards could meet the Public Health and Clinical Data Exchange Objective.

Activities that help attain widespread health data interoperability, not only between meaningful users of CEHRT but more broadly throughout the wider clinical data ecosystem, should be awarded. This approach will create greater autonomy and provide stronger incentives to adopt technology that promotes interoperability and meet the business needs of healthcare organizations. This approach will ultimately reduce regulatory burdens associated with reporting measures that many hospitals and providers do not feel are meaningful. This non-prescriptive approach will allow for attestation instead of the burden of uploading large sets of data and will allow healthcare organizations to earn points for the activities they already do or take actions that promote interoperability while aligning to their business needs.

**Measures that Promote Care Coordination and Interoperability**

As the new name of the Promoting Interoperability program suggests, CMS stated it is beginning a new phase of EHR measurement that has an increased focus on interoperability. In the opinion of the ACS, the PI program should focus on interoperability beyond just EHRs in order to leverage digital health information from any source, be it EHR or smart phones. During this new phase, EHRs should have to improve not only their read functionality, but their write functionality as well. **We recommend CMS adopt measures of functional interoperability that focus on read and write functionality in order to accomplish greater interoperability among EHRs and other HIT.**
Additionally, we recommend CMS require EHRs to go through an external review of their level of conformance and performance with open source implementation profiles and standards, such as CCDAs, Fast Healthcare Interoperability (FHIR), and HL7 Version 2 Messaging. This will ensure EHRs have the foundation necessary for the interoperable exchange of information that is vendor agnostic.

Furthermore, to have true interoperability the government, through its agencies such as AHRQ, NIH, NLM, or ONC needs to help promote the following: open source standards, repositories for shared logic models, development of patient-centric clinical logic models necessary for clinical care or care coordination, and clinical decision support (CDS) functions, such as CDS Hooks or CDS Connect. This will require a multi-pronged approach with coordination between the CDC, NLM, ONC, NIH, and AHRQ to build truly functional interoperability.

We suggest CMS consider a new approach for the PI program, which would create a tiered scoring methodology that divides use cases into four general categories that increasingly promotes the bi-directional sharing of information and functionality across the digital ecosystem. The tiers can start with EHR interoperability, with data streams moving bi-directionally across EHRs, then across mobile devices, then to registries and clouds where the data can be used to support Clinical Decision Support, and eventually result in artificial intelligence or computer adaptive learning:

1. EHR ↔ EHR
2. EHR ↔ EHR ↔ mobile device
3. EHR ↔ EHR ↔ mobile device ↔ registries/clouds with Clinical Decision Support guidelines
4. EHR ↔ EHR ↔ mobile device ↔ registries/clouds with Clinical Decision Support guidelines ↔ machine learning / artificial intelligence

**REQUIREMENTS FOR HOSPITALS TO MAKE PUBLIC A LIST OF THEIR STANDARD CHARGES VIA THE INTERNET**

CMS states that hospital disclosure guidelines will be updated to specify that, effective January 1, 2019, hospitals must make available a list of their current standard charges via the internet in a machine-readable format. CMS seeks comment on ways to improve price transparency and present cost information in a consumer-friendly format. The ACS welcomes CMS’ focus on price transparency and is encouraged by the Agency’s recognition of the complex nature of providing patients with actionable data. The information currently available to consumers on cost—particularly as it relates to out-of-pocket charges
for in- and out-of-network care—is sparse and inconsistent. We encourage CMS to consider the following issues as the Agency sets policies related to the communication of hospital charges.

**Standard Charges.** CMS requests feedback on what charge data hospitals should report, such as average rates for items on a hospital’s chargemaster, average rates for groups of services commonly billed together based on a hospital’s billing patterns, or the average discount off a hospital’s chargemaster amount across all payors. Hospital billing information is complicated and, even if averages were calculated for the billed rates of individual or groups of services, such averages would be different from what any one insurer would reimburse the hospital. The College believes that hospital charge data is not relevant to patients, as this information may not be in accordance with how a patient’s health plan will pay for hospital care. We remain concerned that patients will use information about hospitals’ average charges to estimate their out-of-pocket costs and that such an estimate would not be an accurate reflection of the patient’s actual bill.

**Provider Responsibilities.** CMS requests feedback on whether providers should be required to inform patients about how much their out-of-pocket costs for a service would be before furnishing the service. There is no single source of accurate information on patient out-of-pocket cost or total cost of care, as the contracted price of a given service can vary greatly depending on the insurer and a patient’s individual insurance policy. The prices for the same service can also vary depending on whether the service is provided in an office, an outpatient setting, an ambulatory surgery center, or on an inpatient basis in a hospital. For that reason, a physician—who is focused on providing the best quality of care for a patient—might not know the intricacies of differing contracted rates and site of service costs, and is therefore unlikely to know, or possibly even be able to quickly and accurately determine, how much a patient will have to pay out of pocket for a service. **We do not believe that physicians should be expected or required to inform patients of their out-of-pocket costs.**

**Accurate and Relevant Cost Data.** One potential way to fill the current gaps in information available to patients would be to provide narrow, but representative, ranges of expected costs based on the patient’s characteristics and diagnosis. For example, the ACS sees great promise in the kind of granular information that can be provided by the Episode Grouper for Medicare (EGM), which was developed for CMS by a team at Brandeis University to organize claims information into logical episodes of care. EGM consists of both a software suite and a set of clinical episode definitions that have benefited from multiple rounds of physician review over several years. While originally created to provide Medicare cost information to CMS, the technology is capable of providing remarkable insights to the care team, and, if built for this purpose, could be invaluable for patients
trying to determine potential costs for situations that are more complex than for a single service by a single provider. For cost information to be meaningful for consumers, it would need to be put into a proper format—such as an interactive rate book where patients could see estimated ranges based on historical claims of patients with similar comorbid conditions and other factors—to give them a precise estimation of what a patient with their concurrent care issues and medical history might expect.

PROPOSED REVISIONS REGARDING PHYSICIAN CERTIFICATION AND RECERTIFICATION OF CLAIMS

CMS proposes to revise its physician certification and recertification policies by removing the requirement that a physician statement that certifies or recertifies the medical necessity of covered services provided to a Medicare beneficiary specifically indicates where supporting information for the medical necessity statement is available elsewhere in the medical record (e.g., in the physician’s progress notes). The Agency states that, as currently worded, this policy has resulted in claim denials because the physician statement technically failed to identify a specific location in the medical record for the supporting information, even when such information nevertheless was readily apparent to the reviewer.

We support CMS’ proposal and thank the Agency for removing this unnecessary and redundant documentation requirement. Medical records already must contain adequate documentation of the necessity of the services or items being certified or recertified, and the College does not believe that it is necessary to require the location of this information be specified in the physician statement. To further reduce burden associated with certification and recertification, we urge CMS to standardize and streamline certification forms and limit the scope of certification requirements to physicians whose ordering patterns stray from clinical guidelines or suggest a pattern of overutilization.

REQUEST FOR INFORMATION ON PROMOTING INTEROPERABILITY AND ELECTRONIC HEALTHCARE INFORMATION EXCHANGE THROUGH POSSIBLE REVISIONS TO THE CMS PATIENT HEALTH AND SAFETY REQUIREMENTS FOR HOSPITALS AND OTHER MEDICARE- AND MEDICAID-PARTICIPATING PROVIDERS AND SUPPLIERS

CMS seeks feedback from stakeholders on how the Agency could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (i.e., the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for
Participation (RfPs)) to further advance electronic exchange of information that supports safe and effective transitions of care between hospitals and community providers. This Request for Information (RFI) describes a number of examples of potential revisions to current CMS CoPs, specifically related to electronic transfer of information to assist discharge. The RFI also poses several questions related to possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information.

Revisions to the CMS Patient Health and Safety Requirements

We appreciate CMS’ attention to the importance of electronic healthcare data exchange and eventually interoperability that would serve to inform care. **We do not believe that use of the CMS CoPs/CfCs/RfPs is an appropriate way to advance interoperability at this time.** Instead, CMS and ONC should focus on a more direct strategy to incentivize increased interoperability. Exchange of electronic patient data and interoperability will advance in stages as clinicians and facilities become more sophisticated and as technology improves. We also encourage HHS to translate the Office of the National Coordinator for Health IT (ONC) Interoperability Roadmap into an operational plan to provide clinicians with the tools they need to access interoperable digital health data. Prior to this, CMS could implement rewards and penalties to encourage the use of interoperability. But at this time, hospitals and providers should not be faced with exclusion from the Medicare and Medicaid programs due to failure to comply with CoPs/CfCs/RfPs intended to further advance electronic exchange of information.

Discharge Use Cases

One way to begin to expand interoperability is to examine specific use cases. If CMS intends to start with transitions of care or discharge as initial use cases, we urge the Agency to take into consideration the longitudinal needs of the patient and not to simply focus on electronic transmission of EHRs related to the admission at issue. For example, if an elderly patient with heart disease who had been living independently was admitted to a hospital for a broken hip and subsequently required skilled nursing facility (SNF) care, the data that are transmitted upon transfer to the SNF should not just be limited to information related to treatment of the ankle; rather, it should include information related to the treatment of all the conditions and diseases that the patient is being treated for in addition to historical information about the patient’s care prior to the admission so that the patient’s clinicians understand the needs of the patient prior to the broken hip. In addition, relevant data should not be limited to information recorded in EHRs but should also include pertinent information collected through
other means such as clinical registries, public health registries, cancer databases, labs, other healthcare facilities, and apps.

To further develop this use case, the ideal data for interoperable knowledge exchange related to a discharge should be in the form of a core set of post-discharge knowledge artifacts applicable to the majority of surgical patients. Such information would include: (1) the work that the surgeon did; (2) why the surgeon provided this care to the patient; (3) events that occurred during the hospitalization; (4) the status of the patient upon discharge (whether the patient is ambulatory, is the patient in pain, what are the patient’s baseline medications, etc.); and (5) subsequent care needed (for example, rehab, chemotherapy, or radiation). This information can be communicated to anyone who would need to understand the care that the patient received while in the hospital. In addition to the core set of surgical knowledge artifacts, additional procedure- and condition-specific knowledge artifacts should be defined as well. This information should be built using exchangeable standards and should comprise a library of artifacts that can be utilized in multiple use cases. Data that are transferred should not be limited to just EHRs; rather, relevant data from the wider clinical data ecosystem collected through a range of technologies should be incorporated. Finally, data should be shared in a way that is usable for the recipient, be it an EHR vendor, another type of vendor that is running an app, or the patient. It is not enough that data be transferred in a way that only EHRs can accept.

**Interoperability**

We would also like to take this opportunity to speak to the important topic of interoperability more generally. The ACS supports efforts to move toward a standards-based interoperable digital health information system that serves not only to ease documentation burdens, but also to inform care through clinical decision support tools and eventually through more advanced technologies such as machine learning and artificial intelligence.

The complexity of modern medicine has exceeded the ability of a single physician to provide all the care that a patient requires because there are limits to the amount of information one can process. The clinical care model is growing increasingly complex and the need for digital information to flow between all members of a team is critical to successful patient care and prevention of medical error. Such data must be captured or documented digitally, but also must be synthesized and represented back to the provider in a convenient and usable format. Without access to interoperable and usable digital health information, providers spend hours documenting and searching for information, which is extremely burdensome. In addition, without interoperability, providers lose the opportunity to truly leverage health care data available in the entire clinical data
ecosystem to enhance algorithms of care and treatment plans, analyze outcomes of therapy, and track resources.

The ultimate goal is to achieve an interoperable digital health information system. This would assimilate data from not only EHRs but also other patient data sources such as registries, performance measurement, smart devices, medical devices, research data systems, pharmacy data, and more. An essential point to stress is that data liquidity extends beyond a patient’s consolidated medical record and patient data should become available for a range of applications or services, thereby enabling a knowledge representation wherever needed. A digital health information system requires creation of HL7 digital standards for patient information to smoothly interoperate and be represented in a clinical workflow within and between EHRs and all the locations where patient data reside.

Need for both clinical and technical standards

One way to describe our view of interoperability in more granular terms is to start with use cases, which are libraries of ideas that involve all aspects of care. Use cases are designed by clinicians, government agencies, and others and are placed into the cloud to improve workflow and to achieve optimal patient care. Examples of use case ideas include clinical decision support, making guidelines or evidence available, automating registry exchanges, building outputs for performance measurement, and communicating across care delivery teams. This RFI appears to indicate that CMS considers the discharge use case as a potential starting point.

Although clinical and technical standards needed for interoperability are developed separately, the clinical experts must join with the technology experts to provide the context and contextual profiles needed for use cases and eventually to build apps. Development of clinical logic models requires understanding the details of clinical care and mapping them to specific computable terminologies. We believe that the clinical experts are best positioned to develop and maintain such clinical logic models. On the technical side, standards for how to define data, the value sets for the data, and the data models needed should be developed by technical experts such as those with expertise in HL7, FHIR, and open application program interfaces (APIs).

Once developed, use cases can be combined into a patient specific longitudinal care use case repository with help from clinical delivery systems, government agencies, specialty societies, payers and purchasers, and patient advocates. The objective is to develop a library of use cases that can be held in a use case repository. The use case repository would serve as one of the foundational elements for building the digital components of a learning health system. The
digital infrastructure of a learning health system lacks full development of its architecture but such a use case repository would serve as a first step toward building the infrastructure for standards-based interoperability.

**ACS Recommendations**

We believe that all related government agencies should work together to promote interoperability. Multiple government agencies have already shown interest in this area and can contribute to important effort of improving interoperability. The National Institutes of Health (NIH) is doing work in research interoperability, the Centers for Disease Control and Prevention (CDC) in clinical guidelines conformance, the Agency for Healthcare Research and Quality (AHRQ) in quality, and CMS in regard to clinical value. Given this activity, it would be helpful if clinical logic models and care mappings that we described above could be developed in the National Library of Medicine (NLM) as an open repository. It would also be helpful to have computable logic models as open source. Examples are those suggested, created, and shared through the Healthcare Services Platform Consortium (HSPC). Having a dedicated entity governing updates, availability, and version control of logic models would further promote trust and communication among stakeholders, and progress consensus-based standards for interoperability.

We appreciate the opportunity to comment on this proposed rule. The ACS 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, MD, FACS
Executive Director