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Donald M. Berwick, MD, MPP
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1518-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year (FY) 2012 Rates

Dear Administrator Berwick:

On behalf of the over 75,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the proposed rule: *Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2012 Rates* that was published in the *Federal Register* on May 5, 2011.

The ACS was founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Because a large percentage of surgical care takes place in the inpatient hospital environment, we have a strong interest in the Centers for Medicare & Medicaid Services' (CMS) inpatient prospective payment system and hospital quality improvement efforts and can offer significant insight to CMS' proposed modifications to the program.

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

Preventable Hospital-Acquired Conditions, Including Infections

Since October 1, 2008, an inpatient hospital discharge is paid without a higher paying Medicare Severity Diagnosis-Related Group (MS-DRG) if a selected hospital-acquired condition (HAC) were not present on admission (POA). That is, the case will be paid as though the secondary diagnosis was not present. The selected HACs are among those that CMS determines: (1) are high cost, high volume, or both; (2) would result in the assignment of a case to a DRG that was

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a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through the application of evidence-based guidelines.

For FY 2012, CMS proposes to add contrast-induced acute kidney injury (a term that replaces “acute renal failure”) as a condition subject to the HAC payment provision. Specifically, this HAC would include discharges with ICD-9-CM diagnosis code 584.9 (Acute kidney failure, unspecified) that also have one or more of a specified list of 33 ICD-9-CM procedure codes.

We have concerns regarding this potential HAC. First, we believe that implementing this HAC via ICD-9-CM code 584.9 (a code that is non-specific for contrast-induced renal failure) in combination with the specified list of 33 ICD-9-CM procedure codes presumes that the only reason for renal failure in these cases is the use of the iodinated contrast media. While effective mechanisms exist for preventing renal failure in elective cases, there could be emergent cases where a patient suffers renal failure where there is a coincidental administration of contrast material that was not the *cause* of the renal failure. Examples of such cases include, but are not limited to, trauma, sepsis, and acute vascular occlusion of aorta or renal arteries. In fact, ICD-9-CM code 584.9 is most often associated with other conditions such as hypovolemia, which is not the result of contrast-induced kidney injury. As such, if CMS proceeds with implementing this HAC, the Agency should, at a minimum, include an exception for trauma and other life threatening cases where it might be medically necessary for a patient to receive a computed tomography (CT) scan or other administration of contrast material even though there might be no available information about the patient’s renal issues, or there might not be time to hydrate the patient properly or initiate renal protection protocols. In such cases, the benefit of the CT scan could outweigh the risk of kidney injury, and this risk/benefit analysis should be left to the treating physicians. Implementing this HAC without such an exception could result in patients being denied medically necessary treatment in order to avoid violation of the HAC.

Proposed Changes to Specific MS-DRG Classifications

MDC 5 (Diseases and Disorders of the Circulatory System)

Currently, two techniques are used for repair of thoracic aortic defects. These two techniques are described by ICD-9-CM procedure codes 38.45 (Resection of vessel with replacement, thoracic vessel) and 39.73 (Endovascular implantation of graft in thoracic aorta). These procedure codes are currently assigned to MS-DRGs 237 (Major Cardiovascular Procedures with MCC or Thoracic Aortic Aneurysm) and 238 (Major Cardiovascular Procedures without MCC). CMS received a request to remove codes 38.45 and 39.73 from MS-DRGs 237 and 238 and reassign them to a more clinically coherent set of MS-DRGs that also would reflect the higher resource consumption associated with these procedures. Therefore, CMS proposes to delete procedure codes 38.45 and



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39.73 from MS-DRGs 237 and 238 and to add these codes to MS-DRGs 216-221 based on findings of similar resource consumption and clinical coherence.

We support the proposed reclassification of thoracic aortic repair procedures 38.45 and 39.73 to MS-DRGs 216-221. While not representing a high-volume case load, patients requiring thoracic aortic repair, and the hospitals providing that care, face clinical challenges that are highly variable. Proof of this variability is demonstrated by the significant payment for outlier cases, an indicator that the current single-level MS-DRG is no longer adequate and appropriate. Improved alignment of payment to resources consumed is an inherent objective of the prospective payment system, and helps to ensure that short term incentives such as earlier discharge are not made at the cost of longer-term patient outcome.

MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue, and Breast)

CMS received a request to remove procedure code 86.22 (Excisional debridement of wound, infection, or burn) from the list of codes considered to be operating room (OR) procedures. The commenter stated that many inpatient excisional debridements are performed in a patient's room instead of in an OR. As a result, for the purposes of more accurate payment for both skin grafts and debridement, CMS proposes to remove excisional debridements (procedure code 86.22) from their current MS-DRG assignments within MS-DRGs 573 through 578 for skin grafts and assign them to new excisional debridement MS-DRGs. CMS proposes to maintain MS-DRGs 573 through 578 for skin grafts.

We have concerns regarding this proposal. Excisional debridement is not exclusively a bedside procedure. Rather, it can be performed in or out of the OR, based on the judgment of the surgeon. In many instances, this procedure cannot be performed at the bedside due to variables such as patient anxiety, the size of wound, bleeding risk, etc. Removing excisional debridement from their current MS-DRG assignments could also hurt many hospitals that perform procedures such as split thickness skin grafts for extensive wound or burns. Instead of removing excisional debridement from the current MS-DRG assignments, we recommend using a separate ICD-9 code for those wounds that require debridement in the OR due to anesthesia, equipment, or monitoring requirements.

Changes to the ICD-9-CM Coding System, Including Discussion of the Replacement of the ICD-9-CM Coding System with the ICD-10-CM and ICD-10-PCS Systems in FY 2014

The International Classification of Diseases, 10th Revision (ICD-10) coding system applicable to hospital inpatient services will be implemented on October 1, 2013. The ICD-10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-



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CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding, as well as the Official ICD-10-CM and ICD-10-PCS Guidelines for Coding and Reporting. In the January 16, 2009, ICD-10-CM and ICD-10-PCS final rule, there was a discussion of the need for a partial or total freeze in the annual updates to ICD-9-CM, ICD-10-CM and ICD-10-PCS codes. After multiple meetings, CMS announced at the September 15-16, 2010, ICD-9-CM Coordination and Maintenance Committee meeting that a partial freeze of both ICD-9-CM and ICD-10 codes would be implemented as follows:

Date	Activity
October 1, 2011	Last regular, annual update to both ICD-9-CM and ICD-10.
October 1, 2012	Limited code updates to both the ICD-9-CM and ICD-10 coding systems to capture new technologies and new diseases.
October 1, 2013	No updates to ICD-9-CM as the system will no longer be a HIPAA standard. There will only be limited code updates to ICD-10 code sets to capture new technology and new diseases.
October 1, 2014	Regular updates to ICD-10 will begin.

The ACS supports the implementation of the partial code freeze. We agree with CMS that there is a need to allow providers time to prepare for the implementation of ICD-10 and the accompanying system and product updates. The transition to ICD-10 will be quite costly to providers, and it comes at a time of tight budgets for healthcare entities, compounded with requirements to make sizable investments in other health information technologies. Accordingly, we support the limited freeze described above.

HOSPITAL INPATIENT QUALITY REPORTING PROGRAM

Under the Hospital Inpatient Quality Reporting (IQR) program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) 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 do so will receive a two percentage point reduction in that year's inpatient hospital payment update factor. We discuss specific proposals related to the Hospital IQR program below.



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Retirement of Hospital IQR Program Measures

Considerations in Retiring Quality Measures from the Hospital IQR Program

CMS describes the following seven criteria that should be used for retiring Hospital IQR program measures: (1) measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made; (2) performance or improvement on a measure does not result in better patient outcomes; (3) a measure does not align with current clinical guidelines or practice; (4) the availability of a more broadly applicable (across settings, populations, or conditions) quality measure for the topic; (5) the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic; (6) the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic; and (7) collection and/or public reporting of the measure leads to negative unintended consequences other than patient harm.

The ACS restates our previous recommendation that, in addition to the other criteria, CMS should add the criterion that a previous process measure should be retired in favor of a new risk-adjusted outcomes measure.

Proposed Retirement of Quality Measures Under the Hospital IQR Program for FY 2014 Payment Determination and Subsequent Years

CMS has proposed to retire several measures from the Hospital IQR program measure set for the FY 2014 payment determination, one of which is SCIP-Infection-6: Surgery Patients with Appropriate Hair Removal. As noted in previous years, we believe this measure should be retired because there is no evidence that clipping rather than other hair removal techniques reduces surgical site infections (SSI) across a broad spectrum of surgical procedures.

The SCIP program references the Centers for Disease Control and Prevention's (CDC) 1999 Guidelines for Prevention of SSI to justify its position that the use of razors is inappropriate. However, the CDC's recommendation on preoperative hair removal relies, in part, on the prevention of SSI following cardiac surgery by comparing razor shaving the night before surgery with electric clipping the morning of surgery. We believe it is inappropriate to draw broad generalizations about all surgical site preparation based on an improperly designed study that focuses on a single surgical specialty. For example, there is little to no data from well-designed, properly powered, carefully controlled studies of neurosurgical procedures to demonstrate that removing hair through methods other than razors decreases SSI. Furthermore, a 2007 study commissioned by the Agency for



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Healthcare Research and Quality (AHRQ) and performed through the Stanford-UCSF Evidence-based Practice Center observed that:

No conclusion can be reached regarding the effectiveness of QI strategies at promoting perioperative glucose control, perioperative normothermia, or decreasing operative site shaving. We were unable to determine any strategies effective at reducing SSI rates. In studies that did not have important methodologic flaws, surgical site infection rates were not consistently reduced, even when process measurements were improved.¹

Therefore, despite increased compliance with quality improvement strategies such as appropriate hair removal, AHRQ found no statistically valid demonstration of the reduction of SSI. Because the evidence for SCIP-Infection-6: Surgery Patients with Appropriate Hair Removal is based on suboptimal research design and the clinical evidence is either lacking or shows no real difference between clipping and using razors, we believe that it is inappropriate to require hospitals to report this measure in order to receive the full annual Medicare payment update. Therefore, the ACS supports CMS' proposal to retire the measure from the Hospital IQR program.

Proposed Measures for FY 2014 and FY 2015 Hospital IQR Payment Determinations

Proposed CDC/NHSN-Based Healthcare-Associated Infection Measures

CMS proposes to add two new healthcare-associated infection (HAI) measures to the Hospital IQR program for FY 2014 payment determination. The first measure is Central Line Insertion Practice Adherence Percentage (CLIP), which assesses the extent to which a facility employs practices consistent with CDC Healthcare Infection Control Practices Advisory Committee (CDC/HICPAC) recommendations that are known to reduce central line blood stream infections. The second measure is Catheter Associated Urinary Tract Infection (CAUTI). Both measures are currently collected by the CDC through the National Healthcare Safety Network (NHSN).

CLIP

We generally support the inclusion of the CLIP measure in the Hospital IQR program, but it is important that the measure incorporate exclusions for emergent cases such as when the central line is required in life threatening trauma cases, during a code, or any other time a central line is inserted

¹ Agency for Healthcare Research and Quality, Technical Review 9, *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies: Volume 6—Prevention of Healthcare-Associated Infections* (2007).



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while a patient is in the emergency room (ER). We also have concerns with one specific aspect of the CLIP protocol: the mask, sterile gown, sterile gloves, and large sterile drapes requirement. This requirement was part of a larger protocol that was instituted without examination of the individual components of the protocol to determine which of the components are effective. There is no evidence that this step is any more effective than the usual sterile precautions taken for other procedures such as Foley catheter insertion, Peripherally Inserted Central Catheter line insertion, chest tube insertion, etc. However, this additional step adds unnecessary cost, time, and inconvenience to central line insertion. As a result, we suggest excluding this particular step from the CLIP measure until Level I evidence shows that this is proven to be beneficial over the usual sterile precautions used for insertion of other items.

CAUTI

We also generally support the inclusion of the CAUTI measure in the Hospital IQR program, but we believe it is necessary to make certain revisions to this measure to avoid harmful unintended consequences. For example, in some cases, the urinary catheter is removed as soon as possible in order to comply with the measure, resulting in complications that are not tracked by the measure such as reinsertion and extreme patient discomfort. In some instances, patients have even developed cardiac arrhythmia and a distended bladder due to urinary retention because the catheter was removed too early and the patient was in too much pain to get up. Other types of patients should also be excluded, such as bedridden elderly patients whose urine output cannot be monitored otherwise, those who have had certain types of surgery such as colorectal anastomosis and complex pelvic surgery, and those with a history of urinary retention. The measure should also include a data capture point for catheter reinsertion to capture the rate of repeat instrumentation and infection risk for those with early catheter removal.

Proposed New Web-Based Structural Measure

CMS proposes to include a new structural measure, Participation in a Systematic Clinical Database Registry for General Surgery, in the Hospital IQR program beginning with the FY 2014 payment determination. This measure would indicate whether a hospital participated in a systematic clinical database registry for general surgery and if so, which one. This proposed measure is similar to previously adopted measures on registry participation regarding stroke care and nursing sensitive care. Data would be submitted annually beginning in July 2012 with respect to the time period January 1, 2012, through June 30, 2012.

The ACS supports the inclusion of this new structural measure indicating whether a hospital participated in a systematic clinical database registry for general surgery. We generally support the



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use of existing registries and data sources to expand and enhance quality reporting with little additional burden on hospitals and physicians. Participation in a systematic clinical database registry for general surgery should include rigorous clinical data collection that incorporates a data audit to ensure high quality data collection. In addition, the clinical data should ideally be collected by a trained and credentialed third party, not by the provider. This will lend rigor to the data collection effort. Finally, the data should be appropriately analyzed methodologically, and risk adjustment should be performed if outcomes are evaluated. An example of a general surgery database registry that meets the above requirements is the ACS National Surgical Quality Improvement Program (NSQIP). The ACS NSQIP is the first nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of surgical care. The program employs a prospective, peer-controlled, validated database to quantify 30-day risk-adjusted surgical outcomes, which allows valid comparison of outcomes among all hospitals in the program.

With respect to public reporting of data collected by general surgery database registries, we urge CMS to only include the highest level of rigor in terms of data collection, data analysis, and reporting. The reporting should utilize metrics that are meaningful and valid measures, including measures that have been vetted by a third party, such as the National Quality Forum (NQF).

Proposed New Chart-Abstracted Measures for the FY 2015 Payment Determination

CMS proposes to add an NQF-endorsed venous thromboembolism (VTE) measure set to the Hospital IRQ program for the FY 2015 payment determination. We provide comments on the proposed VTE measures below:

VTE-1: Venous thromboembolism prophylaxis

The ACS is concerned about the inclusion of this measure in the Hospital IQR program because the excluded population in the denominator of this measure is too limited. In addition to the current exclusions, patients who are bleeding, who have a brain aneurysm, or who are allergic or sensitive to the prophylaxis should also be excluded. Also, the measure should clarify the type of prophylaxis that is at issue (chemical, mechanical, or both). Furthermore, there are numerous guidelines for different surgical specialties that stratify within the specific populations at risk based upon the counter-balancing risk of VTE prophylaxis in those groups. In addition, this measure is a process, non-risk adjusted measure; however, we support outcomes over process measures, and risk-adjusted over non-risk-adjusted measures. Also, we recommend clarifying the documentation requirement in this measure, because it is not clear what exactly is required with respect to documentation as to why no VTE prophylaxis was given.



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VTE-2: Intensive care unit venous thromboembolism prophylaxis

The ACS is also concerned about the inclusion of this measure in the Hospital IQR program. Our comments to this measure are similar to our comments to VTE-1: Venous Thromboembolism Prophylaxis, above. In addition, we note that VTE-2 presumes that all patients admitted to the Intensive Care Unit (ICU) are bedridden; however, in many smaller hospitals, ICU beds are used for closer observation of patients who are unstable or potentially unstable, such as trauma patients. In the case of such patients, who may be ambulatory in their ICU room, or would not normally fit other criteria for VTE, this measure would penalize those smaller hospitals or encourage them to spend resources where there is no medical justification.

VTE-3: Venous thromboembolism patients with anticoagulation overlap therapy

We generally support the inclusion of this measure in the Hospital IQR program if the excluded populations are revised to include patients who are not being transitioned to Coumadin, for example, in cases where the patient is kept on Lovenox until a second surgery.

VTE-4: Venous thromboembolism patients receiving unfractionated heparin with dosages/platelet count monitoring by protocol

We generally support the inclusion of this measure in the Hospital IQR program, but the measure specification should more clearly describe the nomogram or protocol for monitoring patients' platelet counts following intravenous unfractionated heparin.

VTE-5: Venous thromboembolism discharge instructions

We generally support the inclusion of this measure in the Hospital IQR program. It would be somewhat burdensome to implement, but we recognize that it is a reasonable approach to improving patient safety. The implementation of this measure might be streamlined by directing the hospital pharmacy or patient education services to incorporate the measure as part of Coumadin management plan.

VTE-6: Incidence of potentially preventable venous thromboembolism.

This measure assesses the number of patients with confirmed VTE during hospitalization (not POA) who did not receive VTE prophylaxis between hospitalization and the day before the VTE diagnostic testing order date. The denominator of this measure excludes "Patients with reasons for not



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administering mechanical and pharmacological prophylaxis.” We agree with this exclusion, and we recommend that all the VTE measures exclude this patient population from the denominator as well.

Possible New Quality Measures and Measure Topics for Future Years

CMS invites comments on additional possible future measures and topics listed in the proposed rule. The ACS supports the continued development of future measures and topics. With respect to the five measures/topics below, we look forward to the opportunity to provide additional clinical input, and would consider supporting the inclusion of the following measures/topics in the Hospital IQR program only after further discussion regarding appropriate risk adjustment (especially risk stratification based on patient population), documentation of co-morbid conditions, appropriate exclusion criteria, interpretation of the collected data, and other standard measure development protocols including pending NQF or other third party endorsement.

- Mortality/Complications – Total Hip and Total Knee arthroplasty 30-day Complications
- Readmissions – Total Hip and Total Knee Arthroplasty 30-Day Risk Standardization Readmission Measure
- Patient Safety – Surgical checklist use for surgical procedures
- Healthcare-Associated Infections – Ventilator Associated Pneumonia, Post Procedure Pneumonia, Multi Drug Resistant Organisms
- SCIP – Short Half-Life prophylactic administered preoperatively redosed within 4 hours after preoperative dose

INDIRECT MEDICAL EDUCATION (IME) ADJUSTMENT

CMS proposes to continue the IME adjustment factor at 5.5 percent for every approximately 10-percent increase in the hospital’s resident-to-bed ratio. This adjustment factor is the result of a formula and multiplier that has remained unchanged since 2008. The ACS has a longstanding commitment to graduate medical education, the practice of academic medicine, and the successful training of surgical residents. Accordingly, we support the continued IME adjustment factor as IME Medicare payments are a crucial component of ensuring a strong general surgery workforce, which is currently experiencing a growing shortage.



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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 Bob Jasak in our Washington office. He may be reached at bjasak@facs.org or at (202) 672-1508.

Sincerely,

A handwritten signature in black ink that reads "David B. Hoyt". The signature is written in a cursive style.

David B. Hoyt, MD, FACS
Executive Director