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June 25, 2012

Ms. Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1588-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year (FY) 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers

Dear Ms. Tavenner:

On behalf of the over 78,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the proposed rule: *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year (FY) 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers* that was published in the *Federal Register* on May 11, 2012.

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 MEDICARE SEVERITY DIAGNOSIS-RELATED GROUP CLASSIFICATIONS AND RELATIVE WEIGHTS

Preventable Hospital-Acquired Conditions, Including Infections

Since October 1, 2008, an inpatient hospital discharge is not assigned to 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 were 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 a higher payment when present as a secondary diagnosis; and (3) could reasonably have been prevented through the application of evidence-based guidelines.

Proposed Additional Diagnosis Codes to Existing HACs

For FY 2013, CMS proposes two additional diagnosis codes, 999.32 (Bloodstream infection due to central venous catheter) and 999.33 (Local infection due to central venous catheter) to the Vascular Catheter-Associated Infection HAC category in order to better identify specific types of infections that occur as a result of central venous catheter placement. Currently there is only one diagnosis code, 999.31 (Infection due to central venous catheter) in the Vascular Catheter-Associated Infection HAC category.

We support the inclusion of the two additional diagnosis codes to the Vascular Catheter-Associated Infection HAC category. Due to local variation in coding for this condition, we agree with CMS that the addition of these two diagnosis codes would lead to further specificity as to the type of infection due to a central venous catheter. The variation in coding is a result of confusion as to the definition of vascular catheter-associated infections, also known as central line-associated bloodstream infections (CLABSIs). The use of uniform diagnosis guidelines would greatly improve the reliability of this HAC. As such, we recommend that CMS adopt and encourage hospitals and coders to use the Centers for Disease Control/National Healthcare Safety Network (CDC/NHSN) CLABSI definition for identifying and reporting the vascular catheter-

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associated infection HAC.¹ These rigorous guidelines will lend additional scientific validity to the determination of the existence of CLABSI.

Proposal to Add New HAC: Iatrogenic Pneumothorax with Venous Catheterization

For FY 2013, CMS proposes to add Iatrogenic Pneumothorax with Venous Catheterization as a new HAC category. CMS believes there are widely recognized guidelines for the prevention of this condition and that Iatrogenic Pneumothorax in the context of venous catheterization is reasonably preventable through the application of these evidence-based guidelines, in particular the recommended use of ultrasound for the placement of all central venous catheters.

We have concerns regarding the underlying assumptions for this HAC proposal. While ultrasound guidance for the placement of central venous catheters may be commonly used in some academic medical centers and Level 1 Trauma Centers, there is little to no data on how often ultrasound guidance is used in small community medical centers. Also, ultrasound guidance is less commonly used in procedures involving central venous access via the subclavian vein, and is often impossible to use in trauma cases. So although iatrogenic pneumothorax with venous catheterization might be greatly reduced through application of evidence-based guidelines that recommend the use of ultrasound, there are circumstances where a surgeon cannot comply with the guidelines. Furthermore, even with the application of evidence based guidelines, the incidence of iatrogenic pneumothorax can be reduced significantly, but can never be 100 percent preventable. Accordingly, we recommend that high frequency outliers, such as iatrogenic pneumothorax in emergency cases, be identified and excluded from this HAC.

Proposed Changes to Specific MS-DRG Classifications

Endovascular Implantation of Branching or Fenestrated Grafts in Aorta

CMS received a request to reassign procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta) that was created for use beginning October 1, 2011, from MS-DRGs 252-254 (Other Vascular

¹ Centers for Disease Control/National Healthcare Safety Network, Central Line-Associated Bloodstream Infection (CLABSI) Event, Jan., 2012, http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf.



Procedures with MCC, with CC, and without CC/MCC, respectively) to MS-DRGs 237 and 238 (Major Cardiovascular Procedures with MCC and without MCC, respectively). The request stated that the clinical coherence and consumption of resources were more similar to the major cardiovascular procedures. CMS is not proposing to reassign procedure code 39.78 and invites public comment.

We urge CMS to reassign procedure code 39.78 to MS-DRG 237 and 238. Branched and fenestrated aortic endografts represent a markedly more complicated and intense procedure than the typical infra renal endograft placement. In assigning branched and fenestrated aortic endografts to the peripheral intervention family DRG 252-254, CMS is grossly undercompensating payment to hospitals for the resources involved in this procedure. We strongly support the request for reassignment to MS-DRG 237 and 238 as a more fair assignment.

Chronic Total Occlusion of Artery of the Extremities

CMS received a request to change the severity level for diagnosis code 440.4 (Chronic total occlusion of artery of the extremities) from a non-CC to a CC. Based on analysis of data from the FY 2011 Medicare Provider Analysis and Review file and clinical review, CMS is proposing to change the severity level for diagnosis code 440.4 from a non-CC to a CC.

We support this recommendation. Reopening chronic total occlusions requires far more time and resource utilization compared to arteries that are not completely occluded. We believe this is an appropriate recommendation.

Code Freeze

At the September 15-16, 2010, and September 13, 2011, ICD-9-CM Coordination and Maintenance Committee meetings, CMS announced that it would implement a partial freeze of both ICD-9-CM and ICD-10 codes. 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 proposed limited code freeze.

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OTHER PROPOSED DECISIONS AND CHANGES TO THE IPPS FOR OPERATING COSTS AND GME COSTS

Hospital Readmissions Reduction Program

Effective October 1, 2012, section 3025 of the Affordable Care Act (ACA) reduces payments to Medicare Prospective Payment System (PPS) hospitals with readmissions exceeding an expected level. Currently, the Hospital Readmissions Reduction program is limited to three conditions: acute myocardial infarction, heart failure, and pneumonia, but CMS plans to expand the list of applicable conditions in future years' rulemaking.

While we understand that excess readmissions is often an indicator of poor quality of care and wasteful spending, we urge CMS not to expand the Hospital Readmissions Reduction Program beyond the current three conditions unless adequate guidelines exist for future conditions and the associated measures can be properly risk adjusted. Hospital readmissions for chronic illnesses are related to both pre-existing chronic conditions as well as to the education level and socioeconomic status of patients, all of which are major drivers of poor outcomes. Outcomes for chronic illnesses can vary widely, resulting in potentially unfairly penalizing hospitals and physicians for readmissions that are not under their control. As such, these other drivers of readmission and mortality should be taken into consideration in the risk adjustment process. In addition, readmission measures should exclude readmissions for conditions that are unrelated to the original admission, such as "readmission" due to traumatic injury.

Indirect Medical Education Adjustment

CMS proposes to continue the Indirect Medical Education (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.

In addition, we are concerned with CMS' proposals to count labor and delivery days in the denominator of the intern and resident to bed ratio, which results in

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cuts to Medicare's IME payments. As such, we urge CMS not to finalize this proposal.

In addition, we are generally concerned about matching the available number of residency slots to the medical school graduate volumes. New and existing medical schools have taken the first step in addressing physician shortages by expanding the number of medical students enrolled in their respective institutions. The next critical step is to ensure that our nation has adequate GME training opportunities through federal funding. Cutting federal funds jeopardizes the ability of GME programs to address physician shortages and ensure access to care.

Payment for Graduate Medical Education and Indirect Medical Education Costs

New Teaching Hospitals: Proposed Change in New Program Growth Period from 3 to 5 Years

With respect to hospitals that begin training residents in a new program for the first time on or after October 1, 2012, CMS proposes to extend by two years the current three-year window in which the hospital may establish and grow new programs. Under this proposal, the new teaching hospital's resident cap would be determined at the end of the fifth year and set permanently effective with the beginning of the sixth program year.

We support this extension and believe that it is generally an improvement that will give teaching institutions more time to reach a steady state of resident numbers and enables the teaching hospital to evaluate and select residents that are a better fit for the program. In addition, we believe that this five-year window is likely sufficient as most new programs will fill at least some of their higher post-graduate year (PGY) level positions (PGY-2 through PGY-4) by accepting residents transferring from other programs rather than starting by filling only a PGY-1 group during the first new program year and filling subsequent positions thereafter from the bottom up.

Clarification Related to 5-Year Period Following Implementation of ACA Section 5503 GME FTE Resident Cap Reductions and Increases

In order for a hospital to receive an increase to its FTE resident cap pursuant to redistribution rules enacted in section 5503 of the ACA, the hospital must, among other requirements: 1) maintain the number of primary care residents at

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or above its average level during the three most recent cost reporting periods ending before enactment of section 5503; and 2) ensure that at least 75 percent of the positions attributable to the redistribution are in primary care or general surgery residencies (i.e. the 75-percent threshold).

CMS now proposes to remove section 5503 slots from a hospital that fails to fill at least half of those slots in the first, second, and/or third cost reporting period of the 5-year period. We do not believe the first cost reporting period should be used for this calculation. This would exert undue pressure on the teaching hospital to simply fill the slots rather than encourage appropriate selectivity of high quality applicants. Instead, we recommend that CMS assess the second and third cost reporting periods to determine how many 5503 slots have been filled.

CMS further proposes that failure to fill slots awarded under section 5503 in a timely manner will also be deemed a failure to meet the 75-percent threshold. (CMS clarifies that the 75-percent threshold applies throughout the 5-year period as long as the hospital uses some amount of its section 5503 slots in the cost reporting period involved.) We request clarification from CMS regarding the definition of the term “in a timely manner” as it relates to this proposal.

CMS further proposes that any hospital receiving section 5503 slots will lose all those slots unless all of them are filled in its final cost reporting period of the 5-year period. We are concerned that this provision would hurt longer residencies, including General Surgery. We request that CMS revise this proposal to require that 80 percent, rather than 100 percent, of the slots are filled at five years. This modification would encourage the evaluation, selection, and retention of the most appropriate residents rather than simply filling slots with residents who are not the best fit for the program.

ACA Section 5506: Preservation of Resident Cap Positions from Closed Hospitals

Section 5506 of the ACA permits the redistribution of residency positions of teaching hospitals that close to other teaching hospitals. The redistribution is to be done in the following priority order: first to hospitals in the same, or contiguous, core-based statistical area; second to hospitals in the same state; third to hospitals in the same region of the country; and fourth, if necessary, based on redistribution rules under ACA section 5503.

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CMS proposes to reduce the deadline by which a hospital must apply for an increase in its full-time equivalent (FTE) cap based on slots from a closed teaching hospital from four months following the CMS public notice of the hospital's closing to 60 days after that notice. We do not support this shortening of the deadline for hospitals. Tight lead times incentivize less thoughtful decision-making and could disproportionately hurt smaller, non-university sponsored programs.

Regarding effective dates for slots awarded under section 5506, we encourage CMS to award section 5506 slots under all ranking criteria prospectively. We also believe that the regulatory cap adjustment for FTE residents displaced from closed hospitals is still necessary and appropriate and that the exception from the rolling average for those residents should not be eliminated. Residency closing is very stressful for residents and disruptive to their education, so regulations that add to their stress and instability should be minimized. It is also important to note that residency closures often adversely impact the care of the most vulnerable populations that the residency programs serve.

PROPOSED QUALITY DATA REPORTING REQUIREMENTS FOR SPECIFIC PROVIDERS AND SUPPLIERS

Hospital Inpatient Quality Reporting Program

Under the Hospital Inpatient Quality Reporting (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. We discuss specific proposals related to the Hospital IQR program below.

Proposed Removal of One Chart-Abstracted Measure

Beginning with the FY 2015 payment determination, CMS proposes to remove "SCIP-VTE-1: Surgery patients with recommended VTE prophylaxis ordered" because another measure currently used in the program, "SCIP-VTE-2: Surgery patients who received appropriate VTE prophylaxis within 24 hours of pre/post surgery" assesses practices that are more proximal in time to better surgical outcomes resulting from the use of VTE prophylaxis. CMS also notes that SCIP-VTE-1 was not recommended for continued National Quality Forum (NQF) endorsement. We support CMS' proposal to remove SCIP-VTE-1, and we agree that SCIP-VTE-2 is a better measure for tracking use of VTE

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prophylaxis and that it is not necessary to include both SCIP-VTE-2 and SCIP-VTE-1.

Proposed Removal of 16 Claims-Based Measures

HAC Measures: Beginning with FY 2015 payment determination, CMS proposes to remove eight HAC measures from the Hospital IQR measure set: Foreign Object Retained After Surgery, Air Embolism, Blood Incompatibility, Pressure Ulcer Stages III and IV, Falls and Trauma, Vascular Catheter-Associated Infection, Catheter-Associated Urinary Tract Infection, and Manifestations of Poor Glycemic Control. We support CMS' proposal to remove these measures from the Hospital IQR program, and we agree that more broadly applicable NQF-endorsed measures are available that address the same HACs. We restate our previously noted concerns regarding the inclusion of HACs in the Hospital IQR program that are not appropriately risk adjusted, do not have comprehensive exclusion criteria, and are not NQF endorsed. In addition, it is unnecessary to penalize hospitals twice for the same conditions: once under the HAC nonpayment policy, and then a second time under the Hospital IQR program. As such, we support CMS' proposal to remove these HACs from the Hospital IQR program.

AHRQ IQI Measures: Also beginning in FY 2015, CMS proposes to remove the following three Agency for Healthcare and Research and Quality (AHRQ) Inpatient Quality Indicator (IQI) measures from the Hospital IQR measure set: IQI-11: Abdominal aortic aneurysm mortality rate (with or without volume); IQI-19: Hip fracture mortality rate; and IQI-91: Mortality for selected medical conditions (composite). We support the removal of these measures.

Regarding IQI-19: Hip fracture mortality rate, we agree with the American Association of Orthopaedic Surgeons' (AAOS) support for the removal of this measure from the Hospital IQR program. Although hip fractures are common among the elderly and can lead to an increased risk of death, we do not believe that assessments of hospital quality based on short-term mortality is reflective of significant improvements in patient outcomes. In addition, in-hospital mortality measures could lead to unintended consequences such as earlier than advisable discharge of patients, diversion of patients to other hospitals, or overtreatment of patients to avoid a mortality.

We have specific comments regarding IQI-11: Abdominal aortic aneurysm mortality rate (with or without volume). This measure assesses the number of deaths per 100 discharges with the procedure code for abdominal aortic

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aneurysm (AAA) repair. The measure bundles mortality from elective open AAA repair (less than five percent) and mortality from elective endovascular repair (less than two percent) with mortality from rupture AAA repair (close to 50 percent). The risk adjustment for this measure does not compensate for the ruptured AAA, so hospitals with a high frequency of ruptures are unfairly impacted. As a result, we strongly recommend removal of this measure from the Hospital IQR program.

As noted in previous years, we also have general concerns regarding mortality measures. Mortality measures that are derived from administrative or claims data do not take into account decisions made by the patient or family, along with the surgical team treating the patient, to withhold treatment for terminal or end-of-life issues. Whereas some current mortality measures exclude patients who present to the hospital from hospice, or who are placed in hospice at the time of admission, it is often not possible to make a decision to avoid futile treatment at the time of admission for certain diseases that would normally require surgery or other aggressive therapy for optimal treatment. Often those diseases manifest themselves later in the course of treatment as part of the end-of-life process and it is only then that a decision to provide the patient “comfort care” can be reasonably made. Thus, lacking any mechanism to include that type of decision into the administrative claims data, the ACS is concerned that providers of care will be unduly penalized from the perspective of a mortality measure in some instances for making what most would regard as a humane and reasonable decision in the patient’s best interests.

Other unintended consequences could be that a hospital would divert these patients to other hospitals, or physicians would be forced to over-treat patients, who are truly at the end of life, in order to avoid a mortality. The ACS urges CMS to develop a reporting mechanism, similar to the POA flag, so that providers can more accurately and properly report the care that they deliver to the patient. We also urge CMS to incorporate the palliative care diagnosis code (V66.7 Encounter for palliative care) into the exclusion criteria for mortality measures related to surgical procedures.

AHRQ PSI Measures: Also beginning in FY 2015, CMS proposes to remove the following five AHRQ Patient Safety Indicator (PSI) measures from the Hospital IQR measure set: PSI-06: Iatrogenic pneumothorax, adult; PSI-11: Post Operative Respiratory Failure; PSI-12: Post Operative PE or DVT; PSI-14: Post Operative wound dehiscence; PSI-15: Accidental puncture or laceration. We support CMS’ proposal to remove these five measures from the Hospital IQR program, and we have specific comments related to PSI-15:

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Accidental puncture or laceration. PSI-15 should be removed because adequate coding guidelines for accidental puncture do not currently exist. Because there is a lack of clarity as to what constitutes an “accident,” coding for accidental puncture is non-uniform at its best and inaccurate at its worst. Often punctures or lacerations are incorrectly coded as “accidental” when the puncture or laceration was a natural consequence or part of the surgery. An example of this situation is an enterotomy in a patient undergoing a laparotomy who requires a lysis of dense adhesions for a small bowel obstruction or in order to reach other intra-abdominal pathology. This measure is fraught with coder inaccuracies due to the lack of specificity as to what has been punctured or lacerated. As such, we support CMS’ decision to remove this measure from the Hospital IQR program.

Our concerns with PSI-15: Accidental puncture or laceration extend to the inclusion of PSI-90: Complication/patient safety for selected indicators (composite) in the Hospital IQR program due to the fact that PSI-15 is included in the PSI-90 composite. Generally speaking, we support the inclusion of PSI-90 in the Hospital IQR program, in part because of its utilization of hierarchical log regression with risk-adjusted ratio reporting of observed-to-expected events. However, because PSI-90 includes PSI-15 with its associated limitations described above, we maintain reservations about the continued use of PSI-90, and we hope that the lack of specificity for PSI-15 can be addressed in the future. We believe this limits the use of PSI-90 to the Hospital IQR program, rather than the Hospital Value-Based Purchasing program.

Proposed Addition of Hospital IQR Program Measures for FY 2015 Payment Determination and Subsequent Years

Hip/Knee Surgical Complications: CMS proposes to add a new measure, “Hip/Knee Complication: Hospital-Level Risk-Standardized Complication Rate (RSCS) Following Elective Primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)” to the Hospital IQR program. We agree with the AAOS’ position not to support the inclusion of this measure in the Hospital IQR program. While we agree that complications following primary elective THA and/or TKA are important patient outcomes that may reflect on quality of care delivered to patients undergoing these procedures, we believe that there is limited evidence linking care processes and complication outcomes from primary elective THA and/or TKA. In addition, not enough is known regarding the attribution of complications to care processes.

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Hip/Knee Readmissions: CMS proposes to add another hip/knee related measure, “Hip/Knee Readmission: Hospital-Level 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA)” to the Hospital IQR program. We agree with the AAOS’ position not to support the inclusion of this measure in the Hospital IQR based, in part, on lack of adequate risk adjustment. The measure should risk-adjust for a wide range of variation in patient characteristics and should capture as many comorbidities as possible, especially obesity. The measure should also account for socioeconomic status. Without proper risk-adjustment, this measure could create an access to care problem for certain high-risk and comorbid patients as hospitals could feel pressure to deselect such patients based on their higher risk for readmission.

Hospital-wide Readmissions: CMS proposes to add the Hospital-wide all-cause unplanned readmission measure (HWR) (NQF #1789) to the Hospital IQR program. The Hospital IQR program currently includes readmission measures for heart failure, pneumonia, and acute myocardial infarction. CMS notes that these measures account for a relatively small proportion of total readmission and states that the HWR measure could portray a broader sense of the quality of care in hospitals. While we agree that reducing preventable readmissions will bring down healthcare costs, we do not support the inclusion of the HWR measure in the Hospital IQR program.

First, the effect of case mix on this measure is currently unproven. The measure does not adequately account for socioeconomic factors and resource use of heavily burdened hospitals that care for disadvantaged populations, which may unfairly impact such institutions. Second, the HWR models are broad with respect to populations evaluated, yet constrained to one outcome of uncertain and unproven meaning. As such, the HWR measure is not aligned with current modeling considerations focused on patient subgroups and their related risk factors and outcomes. It is generally accepted in most medical disciplines that focused risk adjustment algorithms perform best when applied to focused patient populations.

A recent article in the *Journal of the American Medical Association* regarding risk prediction for hospital readmission noted that “readmission risk prediction remains a poorly understood and complex endeavor. Indeed, models of patient-level factors such as medical comorbidities, basic demographic data, and clinical variables are much better able to predict mortality than readmission risk. Broader social, environmental, and medical factors such as access to care, social support, substance abuse, and functional status contribute to readmission risk in

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some models, but the utility of such factors has not been widely studied.”² In addition, “most models created to date, whether for hospital comparison or clinical purposes, have poor predictive ability. Although in certain settings such models may prove useful, better approaches are needed to assess hospital performance in discharging patients, as well as to identify patients at greater risk of avoidable readmission.”³

Proposed Hospital IQR Program Quality Measures for the FY 2016 Payment Determination and Subsequent Years

Beginning with FY 2016 payment determination, CMS proposes to add a yes/no measure of whether the hospital uses a safe surgery checklist during three periods: prior to administration of anesthesia, prior to skin incision, and from the closure of incision prior to the patient leaving the operating room. The proposed measure has previously been adopted for use in the hospital outpatient and ambulatory surgical center quality reporting programs. The measure has not been endorsed by the NQF or the Measure Applications Partnership (MAP) because measure specifications are not yet available. CMS notes that the Council on Surgical and Perioperative Safety endorsed the use of a safe surgical checklist, specifically the World Health Organization (WHO) Surgical Safety Checklist.⁴ The WHO Surgical Safety Checklist is divided into three time periods: a sign in prior to anesthesia, one time out prior to skin incision, and a sign out before the patient leaves the operating room.

We support the use of a safe surgery checklist, but we stress the importance of hospitals’ and surgeons’ ability to adapt the checklist to fit different institutions and situations. For example, some of our members have found that the WHO Surgical Safety Checklist has proved useful, once revised to meet the specific needs of their facilities or even the specific procedure. Example adaptations include omitting the operating teams’ introductions and description of roles if all individuals already know each other or have been working together throughout the day, and adding reminders about VTE prophylaxis and beta blockers. The WHO Surgical Safety Checklist Implementation Manual itself encourages flexibility in implementation. The Implementation Manual states, “[t]he Checklist can be modified to account for differences among facilities with

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² Kansagara at al., *Risk Prediction Models for Hospital Readmission*, 306(15) JAMA 1688, 1695 (2011)

³ *Id.* at 1697.

⁴ World Health Organization Surgical Safety Checklist (First Edition), available at http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Checklist_finalJun08.pdf.



respect to their processes, the culture of their operating rooms and the degree of familiarity each team member has with each other . . . Each locale is encouraged to reformat, reorder or revise the Checklist to accommodate local practice while ensuring completion of the critical safety steps in an efficient manner.”⁵

We also emphasize the fact that the WHO Surgical Safety Checklist describes **one**, not three, time outs, or “surgical pauses.” A checklist of important steps can strengthen patient safety precautions in hospitals, but a series of three time outs can be disruptive and unworkable.

As noted in our comments to the Calendar Year 2012 *Medicare and Medicaid Programs; Hospital Outpatient Prospective Payment System; Ambulatory Surgical Center Payment* proposed rule, we urge CMS to eventually move beyond measuring only the utilization of surgical checklists as a structural measure and begin to analyze whether the surgical checklists are being used appropriately and thoroughly. The value of surgical checklists lies not simply in whether they are used, but rather in how they are used. It is possible for the use of a surgical checklist to result in a rote task that does not improve the delivery of care for which checklists are intended.

In summary, we strongly support the use of surgical checklists generally; however, until measure specifications are developed that account for the ability to modify the checklist, that provide assurance that the measure will not be interpreted as requiring three surgical time outs, and that facilitate appropriate use of the checklist, we are reluctant to support the inclusion of this measure in the Hospital IQR program. We look forward to the opportunity to provide additional clinical input, and would consider supporting the inclusion of the surgical checklist measure after further discussion regarding the issues above and other standard measure development protocols including NQF or other third party endorsement.

Proposed PPS-Exempt Cancer Hospital Quality Reporting Program

CMS establishes a quality reporting program beginning in FY 2014 for PPS-exempt cancer hospitals as required under section 3005 of the ACA. CMS proposes five measures for the new cancer hospital quality reporting program,

⁵ World Health Organization World Alliance for Patient Safety Implementation Manual Surgical Safety Checklist (First Edition), available at http://www.who.int/patientsafety/safesurgery/tools_resources/SSSL_Manual_finalJun08.pdf.



three of which were developed by the ACS Commission on Cancer (CoC) accreditation program. The three ASC CoC measures include:

1. Adjuvant chemotherapy is considered administered with 4 months (120 days) of surgery to patients < 80 with AJCC T 1 c (lymph node positive) colon cancer (NQF #0223)
2. Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis to women < 70 with AJCC T 1 c or Stage II or III hormone receptor negative breast cancer (NQF #0559)
3. Adjuvant hormonal therapy (Tamoxifen or third generation aromatase inhibitor is considered or administered within 1 year of diagnosis to women > 18 with AJCC T 1 cN0M0, or Stage II or III hormone receptor positive breast cancer (NQF #0220)

The ACS supports the inclusion of these three processes of clinical care measures for breast and colon cancer patients in the PPS-exempt Cancer Hospital Quality Reporting program.

We also strongly support the 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 cancer reporting should include rigorous clinical data collection that incorporates data audits to ensure high quality data reporting. 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.

An example of a cancer registry database that meets the above requirements is the ACS National Cancer Data Base (NCDB). The ACS NCDB is the only program that has implemented NQF endorsed measures for cancer care, reporting clinical performance using a combination of retrospective and prospective quality of care reporting tools. The NCDB and its systems already collect data to apply these measures, and have five years of experience with reporting these data to its 1,500 cancer programs. Furthermore, the system has been modified to allow real-time rapid case reporting, and can allow rapid modification to accommodate new measures when developed and approved by the NQF and CMS. The program also employs a prospective, peer controlled, validated database to quantify a number of clinical process of care measures, which allows valid comparison of clinical care among all hospitals participating in the program.

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Hospital Value-Based Purchasing Program

FY 2013 is the first year of payment adjustments under the Hospital Valued-Based Purchasing (VBP) program established by the ACA. CMS will base each hospital's VBP percentage 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.

Proposed Measures for the FY 2015 Hospital VBP Program

SCIP-VTE-1: For FY 2015, CMS is proposing to remove SCIP-VTE-1 from the FY 2015 measure set because this measure is very similar to another hospital VBP measure (SCIP-VTE-2). CMS states that SCIP-VTE-1 is not as closely linked to better surgical outcomes because it assesses the ordering of VTE prophylaxis, as opposed to the patient's actual receipt of such prophylaxis within 24 hours of surgery. We agree with CMS' rationale, and we support the removal of SCIP-VTE-1 from the Hospital VBP program.

CMS also proposes to add four measures to the Hospital VBP program. We offer specific comments on three of the proposed measures below.

PSI-90: CMS proposes to add PSI-90, AHRQ patient safety composite to the Hospital VBP program. While we support the use of the PSI-90 composite measure in the Hospital IQR program, we do not believe that it should be included in the Hospital VBP program. First, PSI-15: Accidental puncture or laceration is included in the PSI-90 composite. Due to the lack of clarity as to what constitutes an "accident," coding for accidental puncture is non-uniform. Often punctures or lacerations are incorrectly coded as "accidental" when the puncture or laceration was part of the surgery. Whereas not ideal, this lack of specificity is tolerable in the case of quality reporting under the Hospital IQR. In contrast, we have concerns with including this type of measure in the Hospital VBP program, which is focused on payment. Second, the MAP recommended that this measure not be included in the Hospital VBP program because the MAP does not believe that this measure should be tied to payment, but that it is appropriate under the Hospital IQR program. Therefore, we do not support the inclusion of PSI-90 in the Hospital VBP program.

CLABSI: CMS proposes to include the CLABSI: Central Line-Associated Blood Stream Infection measure in the Hospital VBP program. We restate our

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concerns above that significant variation in coding for this condition is a result of confusion as to the definition CLABSI. The use of uniform diagnosis guidelines would greatly improve the reliability of this measure, and we recommend that CMS adopt the NHSN CLABSI guidelines for identifying and reporting the CLABSI measure. In addition, we question the need for including CLABSI as both a HAC and as a measure in the Hospital VBP, which would penalize hospitals twice for the same event. As such, we recommend that CMS either account for CLABSI as a HAC or as a Hospital VBP measure, but not both.

Medicare Spending per Beneficiary: CMS proposes to include a Medicare Spending per Beneficiary measure for the Hospital VBP program. The proposed measure is inclusive of all Part A and Part B payments from three days prior to a hospital admission through 30 days post discharge, with some exclusions. This measure is not currently NQF-endorsed and was not recommended by the MAP for inclusion in the Hospital VBP. We do not support the inclusion of this measure in the Hospital VBP at this time. Perhaps in the future once the measure specifications have been developed and if the measure is risk adjusted, has coding and claims normalization improvements, with the inclusion of a linkage of spending to outcomes or some other quality metric, this measure could be appropriate for inclusion in the Hospital VBP. We also stress that the measure include clearly stated reporting requirements, an analysis of unintended consequences, and be endorsed by the NQF or other third party.

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".

David Hoyt, MD FACS
Executive Director

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