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June 14, 2013

Ms. Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1599-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) 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital CoPs

Dear Ms. Tavenner:

On behalf of the over 79,000 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) 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation* that was published in the *Federal Register* on May 10, 2013.

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 (IPPS) and hospital quality improvement efforts and can offer insight to CMS' proposed modifications to these programs.

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

Indirect Medical Education Payment 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.

Hospital Readmissions Reduction Program

Effective October 1, 2012, section 3025 of the Affordable Care Act (ACA) requires the reduction of payments to Medicare Prospective Payment System 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. CMS proposes to expand the applicable conditions and procedures for this program to include patients admitted for an acute exacerbation of chronic obstructive pulmonary disease and elective total hip arthroplasty and total knee arthroplasty.

While we understand that excess readmissions can be an indicator of poor quality of care and wasteful spending, we urge CMS not to further expand the Hospital Readmissions Reduction Program beyond the current and proposed 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 determinants of outcome. Outcomes for chronic illnesses can vary widely, resulting in potentially unfairly penalizing hospitals and physicians for readmissions that are not under their control. Another unintended consequence would be penalizing hospitals that care for the highest acuity Medicare patients and the potential that these hospitals will decrease their care for such patients, thereby creating an access issue. 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.

Hospital Value-Based Purchasing Program

FY 2013 was the first year of payment adjustments under the Hospital Valued-Based Purchasing (VBP) program, which was established by the ACA. CMS will base each hospital's VBP percentage on its Total Performance Score for a

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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 2014, the funding pool increases to 1.25 percent of the hospital's base-operating Diagnosis Related Group (DRG) payments.

FY 2015 Hospital VBP Program Measures

In the FY 2013 IPPS final rule, CMS finalized the addition of three new measures to the Hospital VBP program. We commented on these measures last year, and we reiterate some specific comments on these finalized measures below.

AHRQ PSI-90: CMS added AHRQ PSI-90, a patient safety composite, to the Hospital VBP program for FY 2015. While we support the use of the AHRQ PSI-90 composite measure in the Hospital Inpatient Quality Reporting (IQR) program, we do not believe that it should be included in the Hospital VBP program. First, for the Hospital VBP, we do not support the use of PSI-15: Accidental puncture or laceration, which is included in the AHRQ PSI-90 composite. Due to 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 AHRQ PSI-90 composite makes it difficult to drill down to identify specific cases where one of these events occurs, which makes the measure less action-oriented and more difficult for use in driving improvement. Finally, the Measure Applications Partnership (MAP) recommended in its 2012 report 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.

CLABSI: CMS added the CLABSI: Central Line-Associated Blood Stream Infection measure to the Hospital VBP program for FY 2015. We remain concerned that confusion as to the definition of CLABSI results in significant variation in coding for this condition. The use of uniform diagnosis guidelines would greatly improve the reliability of this measure, and we recommend that CMS adopt the Centers for Disease Control/National Healthcare Safety Network (CDC/NHSN) CLABSI guidelines for identifying and reporting the

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CLABSI measure. In addition, we continue to question the need for including CLABSI as both a Hospital Acquired Condition (HAC) and as a measure in the Hospital VBP, which would penalize hospitals twice for the same event. As such, we urge CMS to either account for CLABSI as a HAC or as a Hospital VBP measure, but not both.

Medicare Spending per Beneficiary: CMS added a Medicare Spending per Beneficiary measure to the Hospital VBP program for FY 2015. 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 National Quality Forum (NQF)-endorsed. We do not support the inclusion of this measure in the Hospital VBP. Perhaps in the future once the measure specifications have been developed and the measure is risk adjusted, has coding and claims normalization improvements, and there is a demonstrated linkage of spending to outcomes or some other quality metric, this measure could be appropriate for inclusion in the Hospital VBP. We also recommend that the measure include clearly stated reporting requirements, an analysis of unintended consequences, and be endorsed by the NQF or other third party.

FY 2016 Hospital VBP Program Measures

CAUTI: CMS proposes to include Catheter-Associated Urinary Tract Infection (CAUTI) for the Hospital VBP program in FY 2016. This measure has already been finalized for the Hospital IQR program and the MAP has recommended it for inclusion in the Hospital VBP program. We generally support the inclusion of the CAUTI measure in the Hospital VBP program, but we restate our belief that 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. 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 urinate. In addition, certain patients should be excluded, such as bedridden elderly patients whose urine output cannot be monitored otherwise, those who have had complex pelvic surgery, and those with a history of urinary retention. The measure should also include a data capture point for catheter reinsertion to monitor the rate of repeat instrumentation and infection risk for those with early catheter removal.

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CLABSI: The CLABSI measure is currently finalized for the FY 2015 Hospital VBP program, but not for subsequent years. In this proposed rule, CMS proposes to continue the inclusion of this measure in the Hospital VBP for FY 2016. CMS did not automatically propose continuation of this measure last year because the CDC was planning to submit a revised version of the measure for NQF endorsement that would involve a reliability adjustment. CMS states that a reliability-adjusted measure would better account for differences in patient case mix, exposures to medical devices or procedures, and unmeasured factors that cause variation in outcomes among hospitals. First, we urge CMS to provide the measure specifications for the revised version of this CLABSI measure. It is difficult to provide cogent feedback without a clear understanding of the measure at issue. In addition, if an improved version of this measure will be available, we urge CMS to not continue the use of the version approved for FY 2015. We also continue to stress the need for uniform diagnosis guidelines, which would greatly improve the use of this measure, and we recommend that CMS adopt the CDC/NHSN CLABSI guidelines for identifying and reporting the CLABSI measure.

SSI: CMS proposes to include the NHSN Surgical Site Infection (SSI) measure in the Hospital VBP for FY 2016. Reporting on this measure is currently limited to colon and abdominal hysterectomy procedures. We support the inclusion of this measure that was developed by the ACS in partnership with the CDC because it is an NQF-endorsed measure that provides critical information for tracking and reducing infections that affect surgical patients' quality of care in the hospital setting.

FY 2017 Hospital VBP Program Measures

MRSA and *C. difficile*: CMS intends to adopt the Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia and the *Clostridium difficile* (*C. difficile*) standardized infection ratio measures in the Hospital VBP for FY 2017. We urge CMS to provide the measure specifications for these measures. Without more information on the measure description, numerator, denominator, and exclusions, it is extremely difficult to provide constructive feedback on whether these measures are appropriate for inclusion in the Hospital VBP. Given that there is a certain percentage of the general population who have these infections or are carriers, an appropriate approach to calculating the numerator and denominator and identifying exclusions is critical.

If the MRSA and *C. difficile* measures are adopted, it will be important to control for known regional variation in the infection rates. To compare a

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hospital in an endemic area to one in a non-endemic area is a flawed approach and the rates will not be reflective of practice. This could result in hospitals that care for high-risk populations being inadvertently targeted or incentivized to limit access to care to such high-risk patients. Also, it should be noted that the expense of screening all patients in the ICU, ER, and pre-op areas for MRSA and *C. difficile* in order to document whether these infections are present on admission (POA) will be a significant additional cost to the hospital. Rather than using measures that track the MRSA and *C. difficile* infection rates, it might be more appropriate to include measures that focus on best practices and guidelines for patients who contract MRSA or *C. difficile* as inpatients.

For MRSA, specifically, it will be important to differentiate community-acquired from healthcare-associated strains, even if only based on antibiograms. For *C. difficile*, specifically, some patients will contract *C. difficile* after receiving a single dose of appropriate pre-operative antibiotic, and such infections are typically not preventable. Also for *C. difficile*, data should be carefully stratified by number of surgical patients in the hospital, as well as kinds of operations. This might be challenging, but the rates of *C. difficile* are higher in surgical versus non-surgical patients and are particularly high in GI surgery patients. It is unlikely that these rates are affected by infection control practices. As such, if a hospital performs a greater number of colorectal procedures compared to other hospitals, the *C. difficile* rates would overall be higher, even if the hospital were perfectly compliant with all applicable guidelines and practices. Again, we urge CMS to provide the measure specifications for these measures to allow stakeholders to provide constructive feedback.

HAC Reduction Program

The ACA requires CMS to implement a HAC payment adjustment beginning in FY 2015. Hospitals that, relative to the national average, are in the worst performing quartile of all hospitals for HACs specified under this program would receive a one percent payment reduction.

CMS proposes to adopt eight measures, grouped into two domains, for the FY 2015 HAC Payment Reduction Program. We provide comments on proposed Domain 1, proposed Alternate Domain 1 that CMS is proposing to possibly use instead of Domain 1, and proposed Domain 2.

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Proposed Domain 1

AHRO PSI-3 (Pressure ulcer rate): If this measure is included in the HAC Reduction Program, the measure should incorporate an exclusion for nascent pressure ulcers that are undetectable at admission, but present soon afterwards. In many cases, patients (who are typically elderly and coming from their home or from a skilled nursing facility) present to the hospital after being sick for several days. These patients may not have been moving and have developed a pressure-related injury to their back or extremity. Because the death of the tissue takes several days, a patient can develop a decubitus ulcer two or three days after being admitted from an injury that was actually POA. As a result, if this measure is included in the HAC Reduction Program, the specifications should exclude patients with occult injury that is detectable within a few days of admission.

AHRO PSI-5 (Foreign object left in body): It is reasonable to include this measure in the HAC Reduction Program. However, the measure definition should clearly exclude hardware placed in the body, or other devices intentionally left, even temporarily, in the body.

AHRO PSI-6 (Iatrogenic pneumothorax rate): We have concerns regarding the underlying assumptions for the proposed use of this measure as a HAC. Although iatrogenic pneumothorax might be greatly reduced through application of evidence-based guidelines, there are circumstances, such as trauma, where a surgeon may not be able to 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 patients with lack of intravenous access and acuity (including emergency cases, patients with hypotension, and those who are coding), high risk patients, and the morbidly obese be excluded from this measure. Also, the measure should not apply if clinicians have used all available means of avoiding iatrogenic pneumothorax such as ultrasound guidance and use of the Trendelenberg position.

AHRO PSI-10 (Postoperative physiologic and metabolic derangement rate): We do not support the inclusion of this measure in the HAC Reduction Program because the measure specifications do not provide clear criteria for determining “metabolic derangement.” In addition, we do not support the inclusion of this measure in the HAC Reduction Program because it is not NQF-endorsed.

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AHRQ PSI-12 (Postoperative PE/DVT rate): We are also concerned about the inclusion of PSI-12 in the HAC Reduction Program because of the limited exclusion criteria and potential unintended consequences of the use of this measure. Patients with a diagnosis of cancer or trauma should be excluded because these patients represent a very high-risk group due to their underlying medical condition. Emergent cases and patients with a prior history of PE or DVT should also be excluded. In addition, this measure could discourage the early diagnosis of PE or DVT. The measure could also encourage the use of overly aggressive anticoagulation immediately after surgery to reduce the risk of PE and DVT, possibly resulting in more bleeding events, which is a non-tracked adverse outcome. Tracking post-operative hemorrhage in conjunction with this measure could be helpful.

PSI-15 (Accidental puncture and laceration rate): We are concerned about the inclusion of PSI-15 in the HAC Reduction Program because adequate coding guidelines for accidental puncture do not currently exist. As we describe above in the Hospital VBP section, due to 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. For example, expected enterotomies should be excluded from this measure. This could occur 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. In such cases, it is common and even expected that enterotomies will occur. To include such expected enterotomies in this measure could result in a decrease in care of patients with small bowel obstruction. In addition, because this measure is fraught with coder inaccuracies due to the lack of specificity as to what has been punctured or lacerated, we do not support CMS’ proposal to include PSI-15 in this program.

Proposed Alternate Domain 1

AHRQ PSI-90: CMS proposed AHRQ PSI-90, a patient safety composite, for the HAC Reduction Program. While we support the use of the AHRQ PSI-90 composite measure in the Hospital Inpatient Quality Reporting (IQR) program, we do not believe that it should be included in the HAC Reduction Program. For the reasons discussed above, we do not support the use of PSI-15: Accidental puncture or laceration, which is included in the AHRQ PSI-90 composite. Second, the AHRQ PSI-90 composite makes it difficult to drill down to identify specific cases where one of these events occurs, which makes the measure less action-oriented and more difficult for use in driving

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improvement. Finally, although the MAP “supported direction” of this measure in its 2013 report, several hospitals and hospital associations did not recommend the measure’s inclusion, highlighting that both facilities and surgeons are in agreement that AHRQ PSI-90 should not be included in the HAC Reduction Program.

Proposed Domain 2

CAUTI: CMS proposes to include Catheter-Associated Urinary Tract Infection (CAUTI) for the HAC Reduction Program. The measure has already been approved for the Hospital IQR program and the MAP has approved it for inclusion in the Hospital VBP program. We restate some of our suggested 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. 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. In addition, certain patients should be excluded, such as bedridden elderly patients whose urine output cannot be monitored otherwise, those who have had 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.

CLABSI: CMS proposes to add the CLABSI: Central Line-Associated Blood Stream Infection measure to the HAC Reduction Program. We are concerned about the inclusion of CLABSI in this program because CLABSI is never fully preventable. The incidence can be decreased, but it cannot be fully eradicated unless surgeons avoid placement of Central Lines, which is impractical. In addition, as stated above, we continue to be concerned that confusion as to the definition of CLABSI results in significant variation in coding for this condition. The use of uniform diagnosis guidelines would greatly improve the reliability of this measure, and we recommend that CMS adopt the CDC/NHSN CLABSI guidelines for identifying and reporting the CLABSI measure.

SSI: CMS proposes to include the NHSN Surgical Site Infection (SSI) measure in the HAC Reduction Program. Reporting on this measure is currently limited to colon and abdominal hysterectomy procedures. As previously stated, we support the inclusion of this measure that was developed by the ACS in partnership with the CDC because it is an NQF-endorsed

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measure that provides critical information for tracking and reducing infections that affect surgical patients' quality of care in the hospital setting.

MRSA and C. difficile: CMS intends to adopt the Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia and the *Clostridium difficile* (*C. difficile*) standardized infection ratio measures in the HAC Reduction Program. As we noted in our comments above, we urge CMS to provide the measure specifications for these measures. Without more information on the measure description, numerator, denominator, and exclusions, it is extremely difficult to provide constructive feedback on whether these measures are appropriate for inclusion in this program. Given that there is a certain percentage of the general population who have these infections or are carriers, an appropriate approach to calculating the numerator and denominator and identifying exclusions is critical.

Also as we commented above, if the MRSA and *C. difficile* measures are adopted, it will be important to control for known regional variation in the infection rates. To compare a hospital in an endemic area to one in a non-endemic area is a flawed approach and the rates will not be reflective of practice. This could result in hospitals that care for high-risk populations being inadvertently targeted or incentivized to limit access to care to such high-risk patients. Also, it should be noted that the expense of screening all patients in the ICU, ER, and pre-op areas for MRSA and *C. difficile* in order to document whether these infections are present on admission will be a significant additional cost to the hospital. Rather than using measures that track the MRSA and *C. difficile* infection rates, it might be more appropriate to include measures that focus on best practices and guidelines for patients who contract MRSA or *C. difficile* as inpatients.

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practices. Again, we urge CMS to provide the measure specifications for these measures to allow stakeholders to provide constructive feedback.

Payment for Direct Graduate Medical Education Costs

CMS proposes that patient days associated with maternity patients admitted as inpatients who receive ancillary labor and delivery services when the inpatient routine census is taken shall be included in the Medicare utilization calculation. Therefore, CMS would include Medicare labor and delivery inpatient days in the numerator and all labor and delivery inpatient days in the denominator of the Medicare utilization ratio. CMS acknowledges that this would likely reduce direct Graduate Medical Education (GME) payments because the denominator of the ratio, which includes the hospital's total inpatient days, would increase at a higher rate than the numerator of the ratio.

We ask that CMS consider delaying action on this proposal. We note that in the FY 2010 IPPS rule, CMS made a change to include labor and delivery days in the Disproportionate Share Hospital (DSH) ratios. Subsequently in the FY 2013 IPPS rule, CMS finalized a proposal to count labor and delivery days in the calculation of IME payments. As noted previously by the Medicare Payment Advisory Commission (MedPAC), DSH, IME, and GME are significantly interconnected, and changes to these payments have large impacts upon many IPPS hospitals. Prior to implementing additional changes to this interrelated set of IPPS payments, we urge CMS to undertake a comprehensive and unified impact analysis of including labor and delivery days in payment calculations for all three payments rather than making changes in a piecemeal fashion. The comprehensive review that we suggest is the best protection against unintended consequences that sometimes arise when changes to parts of systems are made without consideration of the whole system effects.

Avoiding unintended consequences to our Nation's GME system is particularly important when that GME system is being transformed to meet the 21st century needs of Medicare beneficiaries and of our rapidly changing healthcare delivery system. It would be particularly unfortunate if well-intentioned sequential but uncoordinated changes to DSH, IME and GME funding resulted in disproportionately negatively affecting the production of the generalist practitioners of medicine and surgery that are critical to our aging population.

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Policy Proposal on Admission and Medical Review Criteria for Hospital Inpatient Services

CMS' Proposal on Hospital Inpatient Services

In the CY 2013 Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) rule, CMS expressed concern about the recent increases in length of time that patients spend as hospital outpatients receiving observation services. CMS also solicited comments on potential policy changes to improve clarity regarding when a patient is appropriately admitted to the hospital as an inpatient.

Under this proposed IPPS rule, CMS proposes inpatient hospital admission guidance under which physicians should order an inpatient admission. CMS proposes that Medicare review contractors would be instructed to:

1. presume that the inpatient admission is reasonable and necessary for a beneficiary who requires:
 - a. more than one Medicare utilization day (meaning an encounter that crosses two midnights) in the hospital receiving medically necessary services); or
 - b. a procedure specified on the inpatient only list; and
2. presume generally that services spanning less than two midnights should have been provided on an outpatient basis, absent clear physician documentation in the medical record specifying the relevant factors that support the physician's order and expectation that the beneficiary required an inpatient level of care.

ACS Comments on CMS' Proposal on Hospital Inpatient Services

Overall we are supportive of CMS' "two midnights" proposal as it applies to criteria for Medicare review contractors, but we believe there are other aspects of the issue of patient status that remain unclear, as described in more detail below. Most importantly, CMS should provide patients with assurance that their care and financial obligations will not be adversely affected, also discussed in greater detail below. We agree that it is fair for Medicare review contractors to presume an inpatient admission is reasonable and necessary for a patient who has been in the hospital receiving medically necessary services for two midnights or for a procedure on the inpatient only list. We also agree that it is fair to presume that services spanning less than two midnights could possibly be provided on an outpatient basis, absent clear physician documentation in the medical record that the patient required an inpatient level of care. If the medical record documents the need for an inpatient admission

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and the patient remains in the hospital for two midnights, the need for the inpatient admission should not be questioned by Medicare review contractors. In the case that a patient is admitted as an inpatient, but does not remain in the hospital for two midnights, we agree with CMS' view that clear and complete documentation of the clinical facts supporting the expectation of a stay crossing two midnights would justify the medical necessity of the inpatient admission, regardless of the actual duration of the hospital stay and whether it ultimately crosses two midnights.

We are concerned, however, about CMS' proposed starting point for this time-based instruction, namely, when the patient is moved from any outpatient area to a bed in the hospital in which the additional hospital services will be provided. In many hospitals, outpatient beds and inpatient beds are virtually identical and the services a patient might receive are indistinguishable. If a patient were initially considered on observation but was then admitted to inpatient, the patient may not necessarily be moved to a different bed or area. Accordingly, we recommend that the starting point for the two midnights clock start at the time the patient is determined to be either an inpatient or an outpatient, not some other time. For example, if a patient were put on observation status for 36 hours, then admitted as an inpatient for 24 hours, that patient should be considered in the hospital for 60 hours and meeting the two midnights threshold. In addition, we strongly urge CMS to consider time spent as an outpatient to count toward the three-day qualifying stay requirement for Medicare Part A coverage for skilled nursing facility (SNF) services. Under this recommendation, in the example above, a patient would need to spend an additional 12 hours in the hospital, rather than 48 to meet the three-day SNF requirement.

Additional ACS Comments Related to Patient Status Designation: Difficulty with Prospectively Determining Patient Status

While we generally agree with CMS' two presumptions, and we believe these presumptions will be helpful for Medicare review contractors by providing them with more defined guidelines for retroactively reviewing whether admissions were reasonable and necessary, the problem for physicians of prospectively determining a patient's status still exists. It is not always clear from the time a patient comes to the hospital whether or not the patient should be admitted as an inpatient. A common example is when a patient who recently had surgery comes to the emergency room with a complaint. The on-call doctor decides the patient is not doing well enough to go home. At this point the patient is in the hospital, but it is often not clear whether the patient should be admitted as an inpatient or to observation status. The patient could

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require lab tests or CT scans, which could take several days. If seen prospectively from the point of view of the admitting physician, the physician often cannot even make an educated guess at the time of “admission” as to the correct patient status. Even if the physician includes clear and comprehensive documentation in the medical record, the required information to justify an inpatient admission simply may not yet be available.

A partial solution to this problem of lack of adequate information to make a decision is Condition Code 44, which can be used to change a patient’s status from inpatient to observation while the patient is still in the hospital, based on specified criteria. We ask CMS to create a similar code along with policy guidelines to change a patient’s status from observation to inpatient while the patient is still in the hospital. This would make it easier for physicians to make the best clinical decision they can at the time the patient comes to the hospital, but still allow the physician to change that decision as more information about the patient’s status is obtained. We strongly urge CMS to consider this recommendation.

Additional ACS Comments on Patient Status Designation: Financial Consequences for Patients

We also agree with the points that CMS raised in the CY 2013 OP/ASC rule that keeping patients on observation status for long periods of time can have adverse financial consequences for patients. From the patient perspective, we view the designation of inpatient versus observation as largely arbitrary. This distinction does not improve the quality or the value of patient care. Not only does maintaining two status designations for provision of often identical services hold no benefit for the patient, this policy could be a serious detriment. Patients often do not know whether they are considered an inpatient or on observation status because the setting and services they receive could be similar. Even if patients do know their status, it is not uncommon for it to be changed.

Although the care patients receive in the inpatient and outpatient setting could often be the same, the difference in the financial impact could be drastic. In the CY 2013 OP/ASC rule, CMS recognized that patients must pay separate copays for each outpatient service, and that in the case of a long stay as an outpatient, the sum of the various copays could far exceed the inpatient deductible. Patients could also be required to pay for self-administered drugs in the outpatient setting, despite the fact that such drugs are covered by Medicare Part A in the inpatient setting. In addition, time spent in the hospital as an outpatient does not count toward the three-day qualifying inpatient stay

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required for Medicare Part A coverage in a SNF. As such, the existence of the two designations does not improve the care a patient receives, and in fact significantly increases the risk of financial harm to the patient in cases where the patient receives observation services for long periods of time.

Additional ACS Comments on Patient Status Designation: Consequences for Healthcare System

From the standpoint of the healthcare system and its providers, the patient status designation does not facilitate improved delivery of care or more efficient use of physician resources. Physicians provide care to their patients that the physicians deem medically necessary, regardless of the patient's status. CMS' longstanding guidance states that the need for admission is a complex *medical* judgment dependent on multiple factors.¹ In addition, in order for a hospital to change a patient's status from inpatient to observation using condition code 44, both the practitioner responsible for the care of the patient and the hospital's utilization review committee must concur with the change.² Nevertheless, physicians themselves are often unclear as to the admission status otherwise given to their patients by the facility. We have received repeated feedback from our members that the status can be determined by the hospital, often with no input from the physicians. Or worse, a treating physician will make a decision whether to admit, and the hospital sometimes changes the status without appropriately notifying the physician.

We also disagree with CMS' view that the acuity level of the typical patient receiving outpatient observation services is lower than that of the inpatient level given how place of service designations are currently used by facilities. We also disagree with CMS' reduction of the value of some codes that are performed more than 50 percent of the time in the outpatient setting. In previous comment letters, the ACS has strongly opposed the agency's belief that there would be a difference in physician work based on status of inpatient versus observation. For example, the Current Procedural Terminology (CPT) code descriptors for 99224-99226 (subsequent observation care) are identical

¹ CMS has issued longstanding instructions that the need for admission is a complex medical judgment that depends upon multiple factors, including an expectation that the beneficiary will require an overnight stay in the hospital or need more than 24 hours of care, the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's policies, the relative appropriateness of outpatient and inpatient treatment, and other factors. See Section 10, Chapter 1 of the Medicare Benefit Policy Manual (Pub. 100-02).

² Medicare allows hospitals to change a patient's status from inpatient to outpatient using condition code 44 on an outpatient claim. The Medicare rules require both the practitioner responsible for the care of the patient and the utilization review committee to concur with the decision. See Section 50.3, Chapter 1 of the Medicare Claims Processing Manual (Pub. 100-04); MLN Matters article SE0622.

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to 99231-99233 (subsequent hospital care) and the pre-, intra-, and post-service times are also identical between the two sets of codes. Any differences in patient acuity and necessary physician work would be accounted for in terms of different levels of visits, not reduction of time and relative value units (RVUs).

Although the requirements for assignment of status found in medical necessity screening tools such as InterQual are based on criteria of facility resource utilization, these often do not take into account physician resource use. For example, if a patient came into the hospital with a diagnosis of acute renal failure with a creatinine level of 6, used a vein light for intravenous access and was placed on intravenous fluids at 75cc/hour, the patient would not qualify for inpatient status. According to InterQual criteria, the fluids must run at 100cc/hour or greater to qualify for inpatient status. However, the physician work to order 75cc/hour versus 100cc/hour of fluids is the same, but the resources used by the facility would be different and result in different payments to the facility. As such, the process of assigning a status using software such as InterQual does not include criteria related to separately billable *physician* work. The physician work to perform a problem-focused exam, for example, is the same for patients who are designated inpatient versus observation care. Consequently, the patient status designations neither improve care delivery nor inform physician resource use; rather these designations unnecessarily complicate an already complex health care system.

Additional ACS Recommendations on Patient Status Designation

In light of the adverse impacts on both patients and the health care system as a result of lack of clarity surrounding a patient's status, we make the recommendations below. To address the discordant financial effects of being admitted as an inpatient versus on observation status, the sum of the co-payments for patients who receive observation services should be capped at the inpatient deductible. In addition, hospitals should not bill Medicare beneficiaries for self-administered drugs they received while receiving observation services; instead Medicare coverage should be provided for such drugs. Also, the qualifying criteria for SNF coverage should also be revised so that CMS counts the time a patient spends in a hospital outpatient department receiving observation services toward the three-day hospital inpatient stay that is required for coverage of SNF care. These changes would ensure that patients are held harmless financially for the shortcomings of Medicare's current billing processes.

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From the health system perspective, payment rates should be aligned so that the payment is the same for equivalent services, even if provided in different settings. In the MedPAC March 2012 Report to the Congress, MedPAC made a recommendation to reduce payment rates for evaluation and management (E/M) office visits provided in hospital outpatient departments so that total payment rates for these visits are the same whether the service is provided in an outpatient department or a physician office.³ Although this recommendation is focused on E/M services in the hospital outpatient department compared to a physician office, MedPAC is clear that “[t]his effort is the start of a broader effort by the Commission to move toward having the same payment for the same service provided to similar patients across sites of care.”⁴ Therefore, if a patient is receiving medically necessary services, it is irrelevant whether the services are provided in the inpatient or outpatient setting, and the payment differentials for these settings should be eliminated.

In addition, the hospital’s designation of a patient should be disconnected from the site-of-service required for billing of a physician’s claim. Because proprietary software such as InterQual or decisions made by the hospital often determine a patient’s status based on hospital, not physician, resource use, it is inequitable to deny a physician’s payments because the site-of-service on the physician’s Medicare Part B claim does not match the hospital’s designation of a patient’s status. CMS has approved this type of denial, and at least one Recovery Audit Contractor (RAC) has notified surgeons that the RAC will deny surgeons’ Part B claim if the RAC determines that inpatient stay should be denied due to lack of medical necessity.⁵

Finally, we recommend that CMS coordinate comments received in response to the FY 2014 IPPS rule and comments received in response to the CY 2013 OPPI/ASC rule with comment received in response to the recent proposed rule: *Medicare Program; Part B Inpatient Billing in Hospitals* published in the *Federal Register* on March 18, 2013. The inpatient criteria described in the IPPS rule could have a pronounced impact on the Part B Inpatient Billing in Hospitals proposed rule, so we request that CMS coordinate both final rules and release them simultaneously.

³ Medicare Payment Advisory Commission, Report to the Congress Medicare Payment Policy at 74 (March 2012).

⁴ Medicare Payment Advisory Commission, Report to the Congress Medicare Payment Policy at 71 (March 2012).

⁵ First Coast Service Options began issuing notification letters on August 31, 2012 advising Part B surgeons of the intent to recoup payment if the corresponding inpatient DRG claim were denied as medically unnecessary. See http://medicare.fcso.com/Inpatient_DRG/243403.asp.

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PROPOSED QUALITY DATA REPORTING REQUIREMENTS FOR SPECIFIC PROVIDERS

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.

Refinements to CAUTI and CLABSI

CMS proposes to expand the CLABSI and CAUTI measures to select non-ICU locations, namely medical wards, surgical wards, and medical/surgical wards. CMS believes this expansion is consistent with the NQF update of these measures allowing for their application beyond ICUs. We generally agree that this expansion is reasonable, although we urge CMS to provide updated versions of the measure specifications for these measures. We support the concept of infection reduction, however, the definition, calculation of numerator and denominator, and the exclusions are all critical information, without which it is not possible to provide sound feedback.

FY 2015 Hospital IQR Program Measures

Hospital-Wide All-Cause Unplanned Readmission

CMS finalized the Hospital-wide All-cause Unplanned Readmission Measure (HWR) (NQF #1789) to the Hospital IQR program for fiscal year 2015. The ACS did not support the inclusion of this measure in our comments to CMS last year. We explained that 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 for the reasons listed below.

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

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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 (JAMA) 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 some models, but the utility of such factors has not been widely studied.”⁶ 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.”⁷

Furthermore, in the MAP Pre-rulemaking Report for 2013, MAP noted that their recommendation to support this measure is contingent on NQF endorsement. We understand that this measure is still being updated and therefore pending NQF endorsement. We will follow its progress closely to be sure that there is consensus that it meets the state of the art modeling for risk factors and is appropriate for inclusion in the Hospital IQR.

FY 2016 Hospital IQR Program Measures

30-day Stroke Readmission Measure

CMS proposes to include the Hospital 30-day, All-Cause Risk-Standardized Rate of Readmission Following Acute Ischemic Stroke in the Hospital Inpatient Quality Reporting (IQR) Program for Fiscal Year 2016. CMS states that it plans to adopt this measure even though it is not endorsed by the NQF. The primary drivers of variation in 30-day readmission rates involve variables that are not included in this model nor captured in administrative claims data, including poor social supports, poverty, and inadequate community resources. Additionally, readmission after an acute ischemic stroke are often caused by exacerbation of other non-related medical conditions that frequently co-exist in these patients, or by compounding problems resulting from socioeconomic

⁶ Kansagara at al., Risk Prediction Models for Hospital Readmission, 306(15) JAMA 1688, 1695 (2011)

⁷ Id. at 1697.

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issues in individual patients. CMS currently has no mechanism to risk-adjust for lack of education or financial resources, both major drivers of poor outcomes. As a result, this measure may have the unintended consequence of disproportionately affecting “safety-net” hospitals that care for disproportionately larger numbers of patients with low socioeconomic status. We are concerned that there is no way to substantiate that the measure model will provide adequate discrimination and prevent unintended consequences if implemented. In conclusion, we urge CMS to not adopt these measures for inclusion in the fiscal year 2016 IQR, and instead work to ensure that any stroke outcome measures used by the program are properly developed, tested, and risk-adjusted.

30-day Stroke Mortality Measure

CMS proposes to include the Hospital 30-day, All-Cause Risk-Standardized Rate of Mortality Following an Admission for Acute Ischemic Stroke (Stroke Mortality) Measure in the Hospital Inpatient Quality Reporting (IQR) Program for fiscal year 2016. CMS states that it plans to adopt this measure even though it is not endorsed by the NQF, was not recommended by the MAP, and was withdrawn for NQF consideration by YALE CORE/CMS (the measure steward). There is compelling evidence that stroke severity, as measured by the National Institutes of Health Stroke Scale (NIHSS), is the most important determinate of 30-day outcomes for acute ischemic stroke. It has also been established that statistical risk models that do not account for stroke severity result in inferior discrimination, unaccounted for variance, and misclassification of 30-day mortality in the hospital setting. A recently published JAMA⁸ article also demonstrates the importance of including the NIHSS. Therefore, we urge CMS to begin collecting stroke severity in the form of the NIHSS score and work to revise this measure to include adjustment for stroke severity, prior to implementation in the IQR.

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

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⁸ Fonarow et al. Comparison of 30-Day Mortality Models for Profiling Hospital Performance in Acute Ischemic Stroke With versus Without Adjustment for Stroke Severity. JAMA. 2012;308(3):257-264. Available at: <http://jama.jamanetwork.com/article.aspx?articleid=1217240>. Last accessed: August 13, 2012.



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 recognized by CMS 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. We suggest that in addition to the current exclusion criteria for hospice category patients, that CMS recognize the use of ICD-9 code V66.7 *Encounter for palliative care*.

Other unintended consequences could be that a hospital would divert these patients to other hospitals, keep the patient in observations status for prolonged periods of time, 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 specifically urge CMS to incorporate the palliative care diagnosis code (V66.7 Encounter for palliative care) into the exclusion criteria for mortality measures related to all major surgical procedures.

PPS Exempt Cancer Hospital Quality Reporting Program

In the FY 2013 IPPS rule, CMS established a quality reporting program beginning in FY 2014 for PPS-exempt cancer hospitals as required under section 3005 of the ACA. CMS has contracted with the ACS to plan and implement the reporting of cancer care measures to CMS on behalf of the 11 PPS-exempt cancer hospitals.

Last year CMS proposed five measures for the new cancer hospital quality reporting program, 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)

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3. Adjuvant hormonal therapy (Tamoxifen or third generation aromatase inhibitor is considered or administered within 1 year of diagnosis to women > 18 with AJCC T1cN0M0, or Stage II or III hormone receptor positive breast cancer (NQF #0220)

CMS has proposed several measures for addition to this program starting in FY 2015 and FY 2016, including an SSI measure, several SCIP measures, Clinical Process measures, and a Patient Experience of Care measure. We do not believe these measures are ideal given that this program applies to high level cancer centers. Rather, the ACS continues to support the inclusion of the three process of clinical care measures for breast and colon cancer patients described above 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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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, Deputy Director for Regulatory and Quality Affairs in our Division of Advocacy and Health Policy. He may be reached at bjasak@facs.org or at (202) 672-1508.

Sincerely,

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