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June 15, 2015

Andrew Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
Attention: CMS-1632-P
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 Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program; Proposed Rule

Dear Mr. Slavitt:

On behalf of the over 80,000 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 Policy Changes and Fiscal Year 2016 Rates; Revisions of Quality Reporting Requirements for Specific Providers, Including Changes Related to the Electronic Health Record Incentive Program* (Proposed Rule) published in the *Federal Register* on April 30, 2015.

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 related hospital quality improvement efforts, and can offer insight to CMS' proposed modifications to these programs.

In this letter, we provide comments to specific CMS incentive programs addressed in the Proposed Rule; however, across all programs discussed in this letter, the **ACS strongly supports measures based on clinical data because clinical data typically provide more accurate and relevant information compared to claims-based data for the purposes of quality measurement.** Claims-based data do not accurately address the nuances of comorbidities,



severity, conditions present on admission, complications, and patient experience, and do not enable adequate risk adjustment. Additionally, it is important to stress that factors such as social support, community resources, literacy, homelessness, and income level, all of which have been shown to have direct effects on patient outcomes, cannot be accounted for given that claims-based data do not have the capability to capture this vital information. Therefore, it is very likely that measures that rely on claims-based data alone could have the unintended consequence of disproportionately affecting rural and/or “safety-net” hospitals that care for larger numbers of patients with low sociodemographic status (SDS). To this end, we encourage the use of clinical data for accountability purposes such as public reporting or in pay-for-performance programs.

In addition, across all programs discussed in this letter, the ACS suggests that CMS follow the work of the National Quality Forum (NQF) two-year pilot project titled *Risk Adjustment for Sociodemographic Factors*,¹ which aims to provide recommendations on the appropriate application of risk adjustments to performance measures data. ACS will closely track the NQF findings, but **we currently support considering SDS adjustment for measures used in accountability applications (e.g., public reporting and pay-for-performance) on a case-by-case basis. ACS also encourages development of SDS stratification measures used to drive improvements for the benefit of the patient.** Closely evaluating the appropriate measures for SDS confounding variables will lead to a deeper understanding of the relationship between these variables and clinical outcomes. However, only measures where the provider does not have control over the outcome should be considered for SDS. Without the use of appropriate risk adjustment for certain measures, results will be less reliable due to SDS confounding variables. Until there are further findings on the appropriate application of risk adjustment, ACS supports the following methodology, when appropriate:

- For purposes of **accountability** (e.g., public reporting, pay-for-performance), SDS factors should be included in risk **adjustment** of the performance score unless there are conceptual reasons or empirical evidence indicating that adjustment is unnecessary or inappropriate; and
- For purposes of **identifying and reducing disparities**, performance measures should be **stratified** on the basis of relevant SDS factors

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¹ National Quality Forum. Risk Adjustment for Socioeconomic Status (SES) and Other Demographic Factors. Available at http://www.qualityforum.org/Risk_Adjustment_SES.aspx.



when used in analysis by individual providers, policymakers, researchers, and the public working to reduce disparities.²

PROPOSED CHANGES TO MS-DRG CLASSIFICATIONS AND RELATIVE WEIGHTS

Proposed Changes to Specific MS-DRG Classifications

MDC 5 - Diseases and Disorders of the Circulatory System

CMS is proposing the creation of five new MS-DRGs for fiscal year (FY) 2016 that would distinguish more complex, more invasive cardiovascular procedures from less complex, less invasive procedures. Not only would this proposal increase the resource coherence of these new MS-DRGs, CMS' clinical advisors stated that it would also result in improved clinical coherence for the various cardiovascular procedures. CMS is proposing to delete MS-DRGs 237 and 238 and create the following five new MS-DRGs instead:

- Proposed new MS-DRG 268 – Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC;
- Proposed new MS-DRG 269 – Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC;
- Proposed new MS-DRG 270 – Other Major Cardiovascular Procedures with MCC;
- Proposed new MS-DRG 271 – Other Major Cardiovascular Procedures with CC; and
- Proposed new MS-DRG 272 – Other Major Cardiovascular Procedures without CC/MCC.

The ACS joins the Society for Vascular Surgery in supporting CMS' proposal to create these five new MS-DRGs and assign endovascular abdominal aorta graft implantation procedures to MS-DRGs 268 and 269.

We appreciate CMS' response to concerns from the surgical community that MS-DRGs 237 and 238 were neither resource nor clinically coherent. Procedures that are currently assigned to MS-DRGs 237 and 238 are a mix of procedures that involve thoracic vessels, major arteries and the aorta. There is also a mix of endovascular and open procedures assigned to these MS-DRGs, some of which require devices and others do not. Therefore, we appreciate CMS continuing to review this issue and proposing this solution for FY 2016,

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² National Quality Forum. Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors Draft Report. March 18, 2014. Available at http://www.qualityforum.org/Risk_Adjustment_SES.aspx.



which will serve to accommodate new and ever evolving endovascular abdominal aortic aneurysm repair (EVAR) treatments. Since introduction in October 2000, endovascular abdominal aortic aneurysm repair (EVAR) has continued to advance with new research and discovery being performed.

Solicitation of Public Comments on Expanding the Bundled Payment for Care Improvement Initiative

CMS, through its Center for Medicare and Medicaid Innovation (CMMI), is currently testing four models of bundled payments as part of the Bundled Payments for Care Improvement (BPCI) initiative. The BPCI initiative must be evaluated, as required by statute, before implementation can be expanded. CMS seeks public input on a list of issues affecting possible expansion.

Below we provide feedback on some of the issues that CMS raised; however, **we strongly urge CMS to thoroughly evaluate the program prior to making an expansion.** Any expansion should not proceed until the current models produce useful data that can be analyzed. It is difficult to provide cogent feedback without such data. It is important for CMS to anticipate and avoid unintended incentives and consequences prior to expansion, rather than remedying such errors later. It is also crucial to examine lessons about the feasibility of all four models and CMS should compare shared characteristics among organizations that succeed with these models.

- ***Breadth and scope of an expansion:*** CMS is soliciting feedback on the breadth and scope of an expansion, in particular whether the BPCI initiative should be expanded with voluntary or required participation. In the event of expansion, we urge CMS to maintain voluntary participation and we oppose any expansion under which participation would be compulsory. We believe the BPCI initiative should continue to be voluntary because it still requires more refinements in attribution, measurement, and business practices across all the involved parties sharing the risks. Moreover, we do not believe that CMS has statutory authority to require participation in this initiative. Nothing in the language of the Affordable Care Act (ACA) or its legislative history supports concluding that Congress intended to delegate this type of policymaking authority to CMS. CMS may not rely on waiver authority under a demonstration program to mandate fundamental changes on beneficiaries and on all the relevant Medicare participating providers outside the demonstration.
- ***Episode definitions:*** CMS is seeking comment on the current list of BPCI episode definitions, other bundled services, and the duration of

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episodes. We consider the current list of 48 MS-DRGs that are part of the BPCI program Models 2, 3, and 4 to be generally sufficient. We suggest adding the following MS-DRGs, which general surgeons might be able to utilize:

- 332 Rectal resection w MCC
- 333 Rectal resection w CC
- 334 Rectal resection w/o CC/MCC
- 344 Minor small & large bowel procedures w MCC
- 345 Minor small & large bowel procedures w CC
- 346 Minor small & large bowel procedures w/o CC/MCC

Regarding types of bundled services, the ACS has examined episodes that are triggered by surgical procedures. In particular, we focused on procedures that are provided in order to treat a specific condition. We limited our work to such “condition-specific procedural bundles” in order to focus on particular MS-DRGs. As part of this work, we developed the following list of criteria for selecting surgical procedures for bundled payment:

1. Availability of adequate and relevant data for analysis
2. Elective, non-emergent procedures
3. High volume, high expenditure procedures
4. Procedures performed across the country and not isolated to only certain areas or institutions
5. Existence of evidence-based or appropriateness criteria
6. Established measurable process of care or performance measures
7. Ability of the surgical patient or outcomes to be risk-adjusted
8. Measureable variation in resource use
9. Opportunity for cost savings
10. Reasonable predictability of costs
11. Low vulnerability to CPT/ICD/DRG upcoding or miscoding
12. Includes involvement of multiple providers in the delivery of care

The ACS asks CMS to carefully consider these criteria when developing bundled services, as we believe these criteria will be beneficial both to the Medicare patient’s care and to CMS in defining functional bundled services.

CMS also seeks comment on the length of the episodes under the various models, indicating that the duration could be 30, 60, or 90 days. We urge CMS not to specify one episode length for all episodes, rather, to make a case-by-case determination on each MS-DRG. Some MS-

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DRGs can capture an adequate amount of variation in a 30-day episode, but others would require a 60 or 90-day length of time to include the ideal variation, provider types, and settings of care for that particular episode. As such, we also urge CMS to use caution when expanding episode length given the heterogeneous nature of some MS-DRGs.

As CMS considers expansion of the BPCI programs, we urge the agency to coordinate with the episode grouper/resource use measurement activities required by the Medicare Access and CHIP Reauthorization Act (MACRA). Section 101(f) of the statute, titled “Collaborating with the Physician, Practitioner, and Other Stakeholder Communities to Improve Resource Use Management” requires, in part, the development of patient care episodes to be included with physicians’ claims submitted to Medicare on or after January 1, 2018, to be used in evaluating the resources used to treat patients. The BPCI approach should be developed in step with these statutory requirements.

- **Models for expansion:** CMS is seeking comment on whether to consider one or more of the current BPCI initiatives as the first candidates for expansion. One of the primary opportunities that bundled payment presents is to encourage providers to deliver care more efficiently and improve quality and outcomes. Bundles with greater variation present a greater opportunity for cost savings. Where the variation is found, however, depends on the procedure or the condition included in the bundle. Because acute care delivery and post-acute care delivery are currently siloed sites of service and demonstrate variation in care, we believe models that include both the acute and post-acute delivery settings present ideal first steps for expansion. This will encourage coordination of care between the two sites of service.
- **Administering bundled payments:** CMS seeks comments on the feasibility of different payment approaches under the various models, including the administrative capacity and feasibility for some organizations to pay others for care during episodes or to share payments at reconciliation. In the event of an expansion, we urge CMS to require agreements between the organizations and CMS that set forth various aspects of the bundled payment arrangement, including attribution, responsibilities of the parties, payment, and dispute resolution.

With respect to attribution, although it might be primarily the individual organization’s responsibility to make attribution decisions, we urge

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CMS to articulate general guidelines or parameters, given that this is a confusing and underdeveloped aspect of bundled payment models. Assignment of responsibility for care provided is important not only for payment purposes, but also for assessing the quality of care delivered in the context of the bundle. We believe that this determination will be more straightforward for some conditions. For example, it could be easier to determine the relative involvement of hospitals, post-acute care facilities, specialists, and other physicians for a hip replacement compared to a heart attack because hip replacements have more predictable care assignments. It is best for organizations to have the flexibility to determine how to handle attribution in a way that is most appropriate, given potential differences between surgical and medical bundles, but we recommend that CMS provide some guidelines that would protect bundle participants and, at the very least, require transparency on what attribution methodology is used.

In addition, given the MACRA requirement that the Secretary develop patient relationship categories and codes (in order to facilitate the attribution of patients and episodes, in whole or in part, to one or more physicians or applicable practitioners), we urge CMS to coordinate any BPCI guidance on attribution with the MACRA requirements.

- **Data needs:** CMS is seeking comment on the types of data and functionality needed in the marketplace in order to expand the BPCI. The organizations participating in the BPCI must have access to enough historical data and actuarial expertise to accurately assess the risk that will be assumed by entering into the bundled payment agreement. Unless the participants have access to detailed and timely utilization and payment information, it is difficult to accurately predict the appropriate costs and payment for a bundled service. These data should come from sources across the continuum of care (i.e. including post-acute care data sources) not just physician and hospital data sources. We also stress the need to have real time data derived from electronic health records (EHRs), registries, cost data and other elements of interoperability for the time window applied to the bundle. This will be important for surgeons and other providers who are not in the hospital or the post-acute care setting to be kept informed of the care that is being provided as part of the episode.
- **Quality Measurement and Payment for Value:** CMS is seeking comment on quality measures that could be applied to episodes and approaches to incorporating value-based payment in the BPCI initiative. As CMS considers the types of quality measures to apply to

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episodes, we urge CMS to select measures that are meaningful and actionable. Generally speaking, risk adjusted surgical outcomes and key processes related to the five phases of surgical care (pre-op, peri-op, intra-op, post-op and post discharge) that are properly risk-adjusted are preferable to claims-based measures.

CMS should also ensure that the selection of measures/instruments is closely tied to the scope of the bundle selected for the expansion. For example, ACS has long supported the use of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey (S-CAHPS) to measure the care delivered by surgeons because S-CAHPS more closely assesses the patient experience during an episode of surgical care compared to other CAHPS surveys. Also, ACS recognizes the CAHPS landscape involves CG CAHPS, hospital CAHPS, S-CAHPS and more. We suspect that the CAHPS instrument as deployed is overly burdensome to patients and alternatives such as patient reported outcomes may be more useful. ACS remains supportive of the S-CAHPS for surgical patients and continues to seek patient reported outcomes solutions that would further the patient experience of care.

- **Other issues:** Often bundled payment arrangements include the concept of gainsharing, which is an arrangement where a hospital gives a physician a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physician's efforts (i.e. if the costs of care during the episode or agreed timeframe are less than the bundled payment amount, the providers keep and share the difference). Currently, Federal laws prohibit certain gainsharing arrangements. Given that the ACA granted CMS the authority to allow gainsharing for the BPCI initiative, CMS should make clear that gainsharing under an expanded BPCI initiative will continue to be allowed if CMS moves forward with an expansion.

OTHER DECISIONS AND PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS

Hospital Readmissions Reduction Program

Effective FY 2013, section 3025 of the ACA reduces payments to applicable hospitals with readmissions exceeding an expected level. The payment reductions are based on a formula that compares each hospital's payments for actual readmissions (risk-adjusted) to payments based on an estimate of that hospital's expected readmissions (also risk-adjusted).

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While we understand that excess readmissions can be an indicator of poor quality of care and wasteful spending, we urge CMS to carefully consider the risk adjustment methodology used for measures in this program. Hospital readmissions can be related to many factors, such as pre-existing chronic conditions, SDS, and patient non-compliance with discharge plans. Providers should not be held accountable for these factors, which are largely (if not entirely) outside of their control. Inadequate risk adjustments that do not account for these factors could result in unfair penalties for hospitals that care for the highest acuity Medicare patients. This could create a perverse incentive for hospitals to avoid these patients, thereby posing a serious threat to patient access to care. As such, **the ACS urges CMS to apply more comprehensive risk adjustments that account for these and other potential drivers of readmission.**

Proposed Refinement of Hospital 30-Day, All Cause, Risk-Standardized Readmission Rate (RSSR) Following Pneumonia Hospitalization Measure Cohort (NQF #0506) for FY 2017 Payment Determination and Subsequent Years

CMS proposes to expand the cohort of patients that are included in CMS Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization measure, believing that a broader cohort would better represent the population of patients receiving clinical management and treatment for pneumonia. The ACS remains concerned about the use of all-cause readmission measures. Readmission risk prediction remains a complex and poorly understood endeavor. This is largely due to the fact that multiple factors affect readmission rates, including the complexity of the medical condition, the effectiveness of inpatient treatment and care transitions, patient understanding and adherence to treatment plans, patient health literacy and language barriers, and the availability and quality of post-acute and community-based services, particularly for low-income patients. While we support efforts to enhance care coordination throughout the healthcare system, many of these factors are outside of the clinical delivery system's direct control. This is particularly true for regional referral hospitals that accept patients from diverse and distant areas not under the control or influence of the regional referral hospital. **If CMS is going to hold clinical delivery systems responsible for the multiple factors that may influence a patient's likelihood of being readmitted, it is critical that adequate risk adjustments are applied to the measures.** A risk adjustment strategy for all-cause readmission measures should focus on patient subgroups and their specific factors and outcomes, and should account for sociodemographic factors, as mentioned earlier.

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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. Under this program, CMS calculates a VBP incentive payment percentage for a hospital based on a hospital's Total Performance Score for a specified performance period. The total amount available for value-based incentive payments for a fiscal year is equal to the total amount of the payment reductions for all participating hospitals for such fiscal year, as established by the Secretary. For FY 2016, the funding pool will be 1.75 percent, and it will increase to 2.0 percent for FY 2017 and beyond. Measures available for inclusion in the VBP are those that are included in the Inpatient Quality Reporting (IQR) Program and have been included on the Hospital Compare website for at least one year prior to the start of the relevant VBP Program performance period.

Proposed Retention, Removal, Expansion, and Updating of Quality Measures for the FY 2018 Program Year

AHRQ PSI-90: The ACS is concerned with the inclusion of the AHRQ PSI-90 composite measure in the Hospital VBP Program, in part because it relies on administrative or claims-based data. Limited clinical information is included in claims data, which makes it difficult for a claims-based measure to address the nuances of comorbidities, severity, and complications. This also affects the ability to perform adequate risk adjustment. As such, **ACS strongly supports measures based on clinical data**, which by contrast allow for more detailed and accurate information. We also have a number of specific concerns about the PSI-90 composite and measures within PSI-90, which follow.

AHRQ PSI-90 is undergoing NQF maintenance review and as part of that process, AHRQ is considering the addition of three PSI measures to the PSI-90 composite measure: PSI-9 (perioperative hemorrhage or hematoma rate), PSI-10 (postoperative physiologic and metabolic derangement rate), and PSI-11 (postoperative respiratory failure rate). If AHRQ adds these three measures to the composite, the expanded version of PSI-90 must be included in the hospital IQR program and included on Hospital Compare for at least a year before the VBP performance period, as required by the ACA.

AHRQ PSI-10 (Postoperative Physiologic and Metabolic Derangement Rate): With respect to PSI-10, this measure's denominator, which includes all elective surgical discharges for patients 18 and older, is broad and includes a heterogeneous surgical population. A better patient safety indicator may require more than one measure to get meaningful, actionable results. In

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addition, the ACS is concerned that patients with postoperative sepsis are more likely to experience renal failure, which is of particular concern in the elderly population.

AHRQ PSI-12 (Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate): The ACS also has concerns with PSI-12, a measure included in the PSI-90 composite. We urge AHRQ to consider the exclusion of trauma patients for “hospital acquired” PE/DVT. Due to the nature of traumatic injury, trauma patients are at high risk for PE/DVT even when aggressive preventive measures are taken.³ Because of this, trauma centers have been vigilant in the detection of PE/DVT by routinely screening trauma patients with duplex ultrasound scans of the legs.⁴ It is common that PE/DVT is not present on admission because it could take days for the thrombosis to develop following trauma. Consequently, there appear to be high rates of PE/DVT in trauma patients due to early identification of calf vein thrombosis,⁵ which has resulted in surveillance bias (frequency of testing leading to more detection).⁶ Given this heightened risk for PE/DVT in trauma patients, trauma centers are unfairly penalized when PSI-12 is included in pay-for-performance programs such as the hospital VBP program. This unintended consequence is well documented and there is currently a national multi-center study on DVT in PE in trauma patients with 17 Level 1 trauma centers.

The importance of trauma centers cannot be overstated. According to the CDC, receiving care for a severe injury at a designated/verified trauma center can lower risk of death by 25 percent,⁷ yet more and more trauma centers are closing due to costs.⁸ This is especially problematic as PSI-12 is weighted

³ Haut, Elliott R., Eric B. Schneider, Amar Patel, Michael B. Streiff, Adil H. Haider, Kent A. Stevens, David C. Chang, Melanie L. Neal, Christopher Hoefft, Avery B. Nathens, Edward E. Cornwell, Peter J. Pronovost, and David T. Efron. "Duplex Ultrasound Screening for Deep Vein Thrombosis in Asymptomatic Trauma Patients: A Survey of Individual Trauma Surgeon Opinions and Current Trauma Center Practices." *The Journal of Trauma: Injury, Infection, and Critical Care* 70.1 (2011): 27-34.

⁴ Bandle, Jesse, Steven R. Shackford, Jessica E. Kahl, C. Beth Sise, Richard Y. Calvo, Meghan C. Shackford, and Michael J. Sise. "The Value of Lower-extremity Duplex Surveillance to Detect Deep Vein Thrombosis in Trauma Patients." *Journal of Trauma and Acute Care Surgery* 74.2 (2013): 575-80.

⁵ Olson, Erik J., Ashley L. Zander, Jan-Michael Van Gent, Steven R. Shackford, Jayraan Badiee, C. Beth Sise, and Michael J. Sise. "Below-knee Deep Vein Thrombosis." *Journal of Trauma and Acute Care Surgery* 77.3 (2014): 459-63.

⁶ Haut, Elliott R., Eric B. Schneider, Amar Patel, Michael B. Streiff, Adil H. Haider, Kent A. Stevens, David C. Chang, Melanie L. Neal, Christopher Hoefft, Avery B. Nathens, Edward E. Cornwell, Peter J. Pronovost, and David T. Efron. "Duplex Ultrasound Screening for Deep Vein Thrombosis in Asymptomatic Trauma Patients: A Survey of Individual Trauma Surgeon Opinions and Current Trauma Center Practices." *The Journal of Trauma: Injury, Infection, and Critical Care* 70.1 (2011): 27-34.

⁷ U.S Department of Health and Human Services. Centers for Disease Control and Prevention. *Access to Trauma Centers in the United States*. N.p.: n.p., 2009. Available at <http://www.cdc.gov/traumacare/pdfs/traumacentersfactsheet20090921-a.pdf>.

⁸ Shen, Yu-Chu, Renee Y. Hsia, and Kristen Kuzma. "Understanding the Risk Factors of Trauma Center Closures." *Medical Care* 47.9 (2009): 968-78. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3121699/>.

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heavily within the PSI-90 composite measure.⁹ **The ACS recommends that trauma patients be excluded from PSI-12. Instead, we strongly recommend that AHRQ and CMS track PE/DVT in the trauma population by way of two discrete measures: (1) PE/DVT for trauma patients who have surgery and (2) PE/DVT in trauma patients who do not have surgery. These measures for tracking PE/DVT in the trauma population should be separate from the PSI-12 measure/PSI-90 composite.**

AHRQ PSI-15 (Accidental Puncture or Laceration): The ACS also has concerns with PSI-15, a measure included in the PSI-90 composite. We continue to receive questions from ACS members expressing confusion regarding coding for PSI-15, which is a highly weighted component of the AHRQ PSI-90 composite. We appreciate CMS' reference to the American Hospital Association Coding Clinic guidance on PSI-15 in the FY 2014 IPPS final rule,¹⁰ but we believe that coding for accidental puncture is still non-uniform due to lack of clarity as to what constitutes an "accident." Often punctures or lacerations are incorrectly coded as "accidental" when the puncture or laceration was part of the surgery.¹¹ Measures that have questionable reliability and validity should not be weighted so heavily. **We request that CMS provide more precise guidance regarding the correct coding of PSI-15. Improving the guidance is critical given the weight of PSI-15 in the PSI-90 composite.**

CDC NHSN CLABSI versus AHRQ PSI-7 (Central Venous Catheter-Related Blood Stream Infections Rate): The ACS also has concerns with PSI-7, a measure included in the PSI-90 composite. The inclusion of PSI-7 and NHSN CLABSI in both the Hospital VBP and the Hospital Acquired Conditions (HAC) Reduction Program results in the inclusion of different measures addressing the same condition, central line infections, within the same program and across programs. As a result, central line infections at hospitals are quadruple counted, as a component of both PSI-90 and as a separate NHSN CLABSI outcome measure, based on different data sources.¹²

⁹ U.S. Department of Health and Human Services. Agency for Healthcare Research and Quality. *Patient Safety Indicators (PSI) Parameter Estimates*. Truven Health Analytics, Mar. 2015. Available at http://www.qualityindicators.ahrq.gov/Downloads/Modules/PSI/V50/Parameter_Estimates_PSI_50.pdf.

¹⁰ Centers for Medicare & Medicaid Services. Medicare program; Hospital inpatient prospective payment systems for acute care hospitals and the long term care; Hospital prospective payment system and fiscal year 2014 rates; Quality reporting requirements for specific providers; Hospital conditions of participation; Payment policies related to patient status; Final rule. Available at: <http://www.gpo.gov/fdsys/pkg/FR-2013-08-19/pdf/2013-18956.pdf>.

¹¹ Barney, et. al. "Reporting patient safety indicator-15." 1 May 2014. Available at <http://bulletin.facs.org/2014/05/reporting-patient-safety-indicator-15/>.

¹² Rajaram, Ravi, Cynthia Barnard, and Karl Y. Bilimoria. "Concerns About Pay-for-Performance Programs." 313.9 (2015): 897-98. *The JAMA Network*. 3 Mar. 2015. Web. 15 May 2015. Available at <http://jama.jamanetwork.com/article.aspx?articleid=2109967>.

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Given that the NHSN CLABSI measure draws from clinical data, whereas PSI-7 is limited to Medicare claims, the ACS supports the use of the NHSN CLABSI measure and continues to have concerns with the PSI-90 measure.

CDC SSI Outcome Measure: The ACS has identified an unintended consequence of the CDC Surgical Site Infection (SSI) measure (NQF #0753), which tracks SSI rates in colon surgeries and abdominal hysterectomies. General and colorectal surgeons have brought it to our attention that this measure is disproportionately skewing and penalizing SSI rates in large tertiary centers that perform exenterations, especially for recurrent cancers. Exenterations are rare, complex multi-organ system resections and are performed for one of three reasons: colorectal cancer, a genitourinary (GU) cancer, or a gynecologic cancer. The few institutions that perform these rare operations may be disproportionately affected by misclassification of SSIs in cases or recurrent cancer when the colon has previously been removed and only small bowel is included as the GI component of the exenteration. The unintended consequence could be remedied by a new CPT code for exenteration for recurrent cancer including small bowel sans colon, or as we propose, exclusion of exenteration from NQF #0753. This would only have a small impact on SSI reporting in general, but avoid unintended consequences to high-end institutions performing exenterations. **Therefore, in order to most accurately and reliably report meaningful SSI rates, ACS recommends that exenterations be excluded from the CDC SSI.**

Previously Adopted and Newly Proposed Measures for the FY 2019, FY 2021, and Subsequent Program Years

National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) and Central Line Associated Blood Stream

Infection (CLABSI) Outcome Measures: CMS invites public comment on its intent to propose to include select ward data, or non-intensive care unit (ICU) locations (defined as adult or pediatric medical, surgical, and medical/surgical wards), in the Catheter-Associated Urinary Tract Infection (CAUTI) and Central Line Associated Blood Stream Infection (CLABSI) measures, beginning with the FY 2019 program year. The ACS supports this proposal and agrees that this will allow hospitals without ICU locations to have a greater opportunity to participate in public reporting and quality improvement and help hospitals with these settings further drive improvements in care. These measures were broadened in January 2015 to include patient care areas outside ICUs and the broadened measures were approved by NQF. However, this expansion must be tested for unintended consequences and the proper identification of exclusions. **Therefore, we strongly recommend that CMS**

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and the NHCN closely track the implementation of these newly revised measures.

Possible Measure Topics for Future Years

CMS again seeks comments on measures that could potentially be used to expand the Efficiency and Cost Reduction domain in the future, as currently the Payment-Standardized Medicare Spending Per Beneficiary (MSPB) is the only measure in this domain. Specifically, CMS is considering adding more condition and/or treatment-specific episode measures. Generally speaking, Medicare spending measures that are episode-focused are more reliable, meaningful and actionable. These measures could improve coordination and transitions of care and thereby increase the efficiency of care across the full continuum. Additionally, public reporting of episode-based measures could assist patients with medical decision-making by providing more precise and contextual data versus broad-based spending measures, such as the MSPB, which fail to provide data related to specific procedures or treatments.

If CMS were to include episode-based measures of Medicare spending in the hospital VBP in the future, we urge that they be used in place of, rather than in addition to, the MSPB measure. Because episode-based measures have the potential for more accurate and actionable data reporting and because we continue to have concerns with the lack of a demonstrated linkage between spending and outcomes in regards to current cost measures, we consider episode-based measures a possible alternative and improvement to the MSPB measure.

We also urge CMS to consider the methodology for developing episode-based measures. The methodology should be just as rigorous as the standards applied to quality measures, including multi-stakeholder expert consensus, evidence-based medicine, and the use of clinical guidelines, where applicable. It is also critical that unintended consequences are closely monitored. In addition, the development of these measures should take into account that each episode could have different parameters that should be specific to the relevant condition or procedure. **As such, we urge CMS to move forward slowly to learn from the initial episode measures and other programs that rely on episode-based measures, such as the BPCI initiative.**

Hospital Acquired Condition Reduction Program

Section 3008 of the Affordable Care Act required CMS to implement a hospital-acquired conditions (HAC) payment adjustment beginning in FY 2015. This requires CMS to reduce hospital payments by one percent for

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hospitals that rank among the lowest performing 25 percent with regard to HACs specified under this program. The payment adjustment will result in the applicable hospitals receiving 99 percent of the payment that would otherwise apply (i.e., a 1 percent payment reduction).

Proposed Domain 1 and 2 Weights for FY 2017

CMS proposes to decrease the weight of the HAC Reduction Program's Domain 1, which is comprised of PSI-90, from 25 percent to 15 percent, in FY 2017. CMS notes that MedPAC and other stakeholders recommended that Domain 2, comprised of CDC healthcare-associated infections measures, be weighted more than Domain 1 because they believed the CDC chart-abstracted measures are more reliable and actionable than claims-based measures. **The ACS supports the decrease in weight of Domain 1** in FY 2017 and thanks CMS for prioritizing measures based on clinical data, for the reasons outlined above.

Proposed Measure Refinements for FY 2018

CMS proposes that, beginning in FY 2018, the NHSN CLABSI and CAUTI measures used in the HAC Reduction Program would be refined to reflect select ward (non-ICU) locations. The ACS supports this proposal and agrees that this will allow hospitals without ICU locations to have a greater opportunity to participate in public reporting and quality improvement and help hospitals with these settings further drive improvements in care. These measures were recently broadened to include patient care areas outside ICUs and approved by NQF. However, we strongly recommend that CMS and the NQF track the implementation of these newly revised measures to monitor any unintended consequences.

Implementation of the HAC Reduction Program for FY 2016

Below we reiterate several comments on measures that are currently included in the HAC program, and for which we have provided more details in the hospital VBP program, above.

AHRQ PSI-90: The ACS is concerned with the inclusion of the AHRQ PSI-90 composite measure in the HAC Reduction Program. Our concerns are similar to those articulated above regarding the inclusion of this measure in the hospital VBP program. In brief, PSI-90 relies on claims-based data, but we prefer measures based on clinical data, which, by contrast, allow for more detailed and accurate information.

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AHRO PSI-10 (Postoperative Physiologic and Metabolic Derangement

Rate): As we noted above in our VBP comments, this measure's denominator is broad and includes a heterogeneous surgical population. A better patient safety indicator may require more than one measure to get meaningful, actionable results.

AHRO PSI-12 (Perioperative Pulmonary Embolism (PE) or Deep Vein

Thrombosis (DVT) Rate): The ACS also has concerns with PSI-12, a measure included in the PSI-90 composite. As we noted above in our VBP comments, the ACS recommends that trauma patients be excluded from PSI-12. Instead, we strongly recommend that AHRQ and CMS track PE/DVT in the trauma population by way of two discrete measures: (1) PE/DVT for trauma patients who have surgery and (2) PE/DVT in trauma patients who do not have surgery. These measures for tracking PE/DVT in the trauma population should be separate from the PSI-12 measure/PSI-90 composite.

AHRO PSI-15 (Accidental Puncture or Laceration): We also reiterate our concerns expressed in our VBP comments regarding PSI-15, a measure included in the PSI-90 composite. We continue to receive questions from ACS members expressing confusion regarding coding for PSI-15, which is a highly weighted component of the PSI-90 composite. Often punctures or lacerations are incorrectly coded as "accidental" when the puncture or laceration was part of the surgery.¹³ As such, we request that CMS provide more precise guidance regarding the correct coding of PSI-15, especially given the weight of PSI-15 in the PSI-90 composite.

CDC NHSN CLABSI versus AHRO PSI-7 (Central Venous Catheter-Related Blood Stream Infections Rate)

Rate): The ACS also has concerns with PSI-7, a measure included in the PSI-90 composite. The inclusion of both PSI-7 and NHSN CLABSI in both the Hospital VBP and the HAC Reduction Program results in the inclusion of different measures addressing the same condition, central line infection, within the same program and across programs. As a result, central line infections at hospitals are quadruple counted, as a component of both PSI-90 and as a separate NHSN CLABSI outcome measure, based on different data sources.¹⁴ Given that the NHSN CLABSI measure draws from clinical data, whereas PSI-7 is limited to codes from

¹³ Barney, et. al. "Reporting patient safety indicator-15." 1 May 2014. Available at <http://bulletin.facs.org/2014/05/reporting-patient-safety-indicator-15/>.

¹⁴ Rajaram, Ravi, Cynthia Barnard, and Karl Y. Bilimoria. "Concerns About Pay-for-Performance Programs." 313.9 (2015): 897-98. *The JAMA Network*. 3 Mar. 2015. Web. 15 May 2015. Available at <http://jama.jamanetwork.com/article.aspx?articleid=2109967>.

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Medicare claims, the ACS supports the use of the NHSN CLABSI measure in these two programs and continues to have concerns with the PSI-90 measure.

CDC SSI Outcome Measure: For purposes of the HAC program, we reiterate our more detailed comments regarding the CDC SSI measure in the VBP program, namely, that in order to most accurately and reliably report meaningful SSI rates, ACS recommends that exenterations be excluded from the CDC SSI.

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.

Removal of Measures for the FY 2018 Payment Determination and Subsequent Years

CMS proposes to remove four measures from the IQR Program beginning with the FY 2018 payment determination. For five additional measures, only the chart-abstracted versions would be removed and the EHR-based versions would be retained. All but three of the nine measures affected are proposed for removal because CMS has identified them as meeting the statistical test as "topped out."

We remain concerned with the premature removal of "topped out" measures and urge CMS to continue to track the clinical action previously measured to identify any subsequent gaps in care. **ACS supports CMS' proposal to retain the electronic versions of specific topped out measures.** We support this proposal not only because it would allow hospitals to continue to use these measures for both the IQR Program and the Medicare EHR Incentive Program, but because it provides a mechanism by which CMS can continue to track performance on these measures into the future. Alternatively, CMS could consider including topped out measures as part of a composite to continue to monitor care and provide meaningful and actionable data.

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New Measures for the FY 2018 Payment Determination and Subsequent Years

CMS proposes to create a series of condition-specific clinical episode-based payment measures that are clinically-related to the triggering episode during an episode window that begins three days prior to the initial inpatient stay and ends 30 days after discharge. CMS describes the criteria it used to select the proposed clinical episodes: (1) the condition constitutes a significant share of Medicare payments and potential savings; (2) a high degree of agreement among clinical experts that Medicare payments for services provided during the episode can be linked to the care provided during the hospitalization; (3) a substantial proportion of episode payments and potential savings for post-acute care; (4) high variation in post-discharge payments; and (5) the medical condition is managed by general medicine physicians or hospitalists and the surgical conditions are managed by surgical subspecialists, enabling comparison between similar practitioners. The proposed clinical episode-based payment measures include:

- Kidney/UTI Clinical Episode-Based Payment,
- Cellulitis Clinical Episode-Based Payment,
- Gastrointestinal Hemorrhage Clinical Episode-Based Payment; and
- Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment.

While ACS supports CMS's efforts to incorporate more specific episode-based payment measures into this program, we have concerns with the construction of the cellulitis and gastrointestinal (GI) hemorrhage measures because these conditions, themselves, are extremely broad with varying levels of severity. Due to the broad nature of these conditions, these measures lack reliability because it is difficult to define the extent of cellulitis or GI hemorrhage in enough detail. For example, cellulitis is inherently difficult to identify and varies across comorbid conditions. Patients with diabetes further confound cases of cellulitis since these patients are immunocompromised. Because of the variation, a severe case of cellulitis can result in a long hospital stay, whereas a limited case may be treated at home. This is especially relevant to the clinical episode-based payment measure because the episode is defined as 30 days after discharge. In other words, the cost of mild cellulitis treated at home should not be compared to a more severe case in an immunocompromised patient with a long hospital stay.

GI hemorrhage is similar to cellulitis in that it is extremely broad with varying levels of severity. In an example of a minor GI hemorrhage case, a patient may have a nasogastric tube that is decompressing their stomach post-op that begins to show traces of blood. However, the patient may suddenly experience severe gastritis with hemorrhage requiring transfusion, in which case GI hemorrhage

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becomes severe. Furthermore, lower GI bleed does not include conditions such as hemorrhoids or inflammatory bowel diseases, which bleed a lot compared to diagnoses with minimal bleeding.

In summary, ACS believes these measures include varying patient and clinical circumstances that are not homogeneous and therefore difficult to risk adjust and therefore should not be used for accountability purposes. We also we believe variation across both GI hemorrhage and cellulitis could be warranted and should be rewarded not penalized.

During the NQF Measure Applications Partnership (MAP) review of these measures, the MAP “conditionally supported” these measures pending NQF endorsement. These measures have not been reviewed by NQF and therefore should not be implemented until the measures are fully endorsed. ACS will plan to follow the NQF review of these measures as part of the upcoming Cost and Resource Use Project.

PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In FY 2013, CMS established a quality reporting program beginning in FY 2014 for PPS-exempt cancer hospitals, as required under section 1866(k) of the Act, as added by section 3005 of the ACA. **We urge CMS to consider adding the following three measures to the PCHQR program**, all of which the NQF Measures Application Partnership have “conditionally supported”:

- **E0219: Post breast conservation surgery irradiation and E0225: At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer.** Since 2007, the National Cancer Data Base has reported facility-level compliance with these measures to approximately 1500 Commission on Cancer (CoC) accredited programs. If it would improve the expediency of providing this valuable information to the public, we recommend progressing inclusion of these measures in the PPS-Exempt Cancer Hospital Quality Reporting program and the IQR program independently. Though compliance with these measures is generally high, they are clinically significant enough to remain an important benchmark for public reporting among all types of hospitals providing cancer care as they are critical to impacting the outcome of care. These measures are also currently being reported publicly through the voluntary Pennsylvania Health Care Quality Alliance (PHCQA), <http://www.phcqa.org/>.

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- **E0221- Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection.** Measure E0221 was initially reported by the ACS CoC in 2013. It has wide applicability for public reporting for all hospitals that care for cancer patients.

We appreciate the opportunity to comment on this proposed rule. The ACS looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Vinita Ollapally, Regulatory Affairs Manager, in our Division of Advocacy and Health Policy. She may be reached at vollapally@facs.org or at (202) 672-1510.

Sincerely,

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