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Marilyn Tavenner, Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1588-P P.O. Box 8011 Baltimore, MD 21244-1850

June 30, 2014

Dear Administrator Tavenner:

The Society of Hospital Medicine (SHM) is pleased to offer comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule entitled, *Medicare Program;* Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program (CMS 1607-P) published May 15, 2014 in the Federal Register.

SHM represents the nation's 44,000 hospitalist physicians whose primary professional focus is the general medical care of hospitalized patients. SHM is an organization dedicated to promoting the highest quality care for all hospitalized patients, and we commend CMS's efforts to encourage continued improvement in the quality and efficiency of health care delivered to our nation's Medicare beneficiaries. We share your commitment to improving performance and coordination of care, and welcome the opportunity to continue to work with you on initiatives that create incentives and reward providers for efficient use of resources.

SHM shares CMS's commitment to the delivery of the highest quality cost-conscious and evidence-based care to all hospitalized patients, including Medicare beneficiaries. We appreciate the opportunity to review and provide comments on various quality programs as outlined within the FY 2015 Hospital Inpatient Prospective Payment System Proposed Rule as detailed below.

Hospital Readmissions Reduction Program: Proposed Changes

SHM continues to be strongly committed to reducing unnecessary hospital readmissions and recognizes this goal as a vital component of improving patient care and reducing overall health expenditures in the United States. We support most of the proposed refinements of the planned readmissions algorithm; however, we have a few concerns as follows:

Changes to the Planned Readmissions Algorithm

SHM understands that there are differences between unplanned readmissions to initiate chemotherapy and radiation therapy, and planned admissions for maintenance treatment. However, there are clinical circumstances in which a patient might have planned admissions for both of these. For example, a planned admission for a first cycle of chemotherapy or radiation therapy following a hospitalization during which a new malignancy is diagnosed would penalize a hospital under the modifications to the readmissions algorithm that excludes CCS 211 Therapeutic Radiation and CCS 224 Cancer Chemotherapy. SHM suggests these remain in the "planned readmissions" category or that appropriate exclusion criteria are applied.

Proposed Addition of CABG Surgery Measure in FY 2017

CMS is proposing to add coronary artery bypass graft (CABG) surgery to the list of applicable conditions for the Hospital Readmissions Reduction Program. SHM broadly supports the addition of appropriate conditions to the program to encourage the reduction in unplanned and preventable readmissions. However, we note our concern about the ability for measures to accurately reflect readmissions that are both preventable and within the scope of the index hospitals' control. We are wary of adding additional conditions to the program without further refinements to ensure hospitals are not being penalized inappropriately.

SHM recently commented on the National Quality Forum's draft report on *Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors*. As noted in our comments on that draft report, we maintain that adjusting measures for socioeconomic status and other demographic factors would account for a broader range of factors impacting the quality and efficiency of care provided. SHM has been consistently in support of adjusting measures, like those for readmissions, to account for situations beyond the providers' scope of control. By acknowledging the impact of these social determinants of health, measures will be better able to capture meaningful differences in care between providers and drive quality improvement efforts within healthcare systems. SHM has also endorsed legislation (H.R. 4188, the *Establishing Beneficiary Equity in the Hospital Readmission Program Act*) that would start to address some of these concerns.

Further, SHM understands the implications of crediting the index hospital performing the CABG with the readmission, but notes that there should be areas for accountability on both the index and discharge hospitals. For example, if the discharge hospital does not perform accurate medication reconciliation, an error resulting in readmission should not reasonably be attributed to the index hospital.

Hospital Value-Based Purchasing (HVBP) Program

SHM supports the proposed removal of six measures from the 2017 HVBP Program, due to being topped out. These measures include PN-6, SCIP-Card-2, SCIP-Inf-2, SCIP-Inf-3, SCIP-Inf-9, and SCIP-VTE-2.

SHM supports the intent of the three new measures being proposed for inclusion in 2017 HVBP: MRSA Bacteremia, *C. difficile* infection, and PC-01: Elective Delivery Prior to 39 Completed Weeks Gestation These measures address conditions with high prevalence and impact. With respect to MRSA Bacteremia and *C. difficile* infection, we note our concern that a clear methodology be designed to ensure that community-acquired infections versus hospital-acquired infections are appropriately captured. Though we note Standardized Infection Ratios are used, reassurance that such ratios are valid tools to exclude cases of community-acquired infections, which are not uncommon and could inappropriately impact a hospital's performance score, would be favorable.

SHM supports CMS' proposal to include the Care Transition Measure from HCAHPS in the HVBP Patient Experience of Care domain for 2018. Managing safe and effective transitions of care are a critical competency of the healthcare system and merits inclusion in a pay-for-performance system. Hospitalists are key components to ensuring patients safely transition from hospital to home, and SHM has taken a leading role in providing mentorship for safe transitions through Project BOOST.

Project BOOST (Better Outcomes by Optimizing Safe Transitions) is a key patient-centered program that helps ensure patients have a clear understanding of their hospital stay and after-care plan. The tools and approach are based on principles of quality improvement (QI), evidence-based medicine, and incorporates personal and institutional experiences. BOOST helps providers identify key questions to ask, whom should be conducting calls, and streamlining and tracking the process. Project BOOST is a national initiative led by the Society of Hospital Medicine to improve the care of patients as they transition from hospital to home.

Proposed Technical Updates Policy for Performance Standards

SHM appreciates the needs of CMS to have the ability to incorporate 'nonsubstantive' technical updates for performance standards in HVBP Program measures. There is a significant lag between the time that the measures are adopted for a particular program year and the time that the measures are actually used. However, SHM believes that the definition of a substantive update should have a set parameter for degree of change. Clarification of what constitutes a 'substantive' versus a 'non substantive' update is necessary.

Furthermore, the process for CMS communicating any changes to hospitals would be critical, regardless if the changes yield more or less stringent requirements. SHM believes that there should be a transparent and consistent notification process, with opportunity for comment and revision, especially as related to changes that fall outside a defined threshold. This would be particularly salient when the updates "[supersede] the performance standards that we [CMS] establish prior to the start of the

performance period for the affected measures," as indicated in the proposed rule. These sorts of midstream changes could have profound implications for an individual hospital's expectations and performance in the HVBP.

Hospital-Acquired Condition (HAC) Reduction Program

SHM encourages CMS' continued efforts to define high-cost, high-volume DRG-related conditions that occur in the inpatient setting, particularly those that result in a higher payment secondary DRG diagnosis and could have otherwise been averted through adherence to evidence—based practices. As mandated by Section 5001(c) of the 2005 Deficit Reduction Act and Section 3008 of the Affordable Care Act, the implementation of the Hospital-Acquired Condition Reduction (HAC) Reduction Program for FY 2015 aligns with the national strategy to improve health care quality by promoting the prevention of HACs, such as "serious reportable events" and Hospital-Acquired Infections (HAIs). SHM continues to be supportive of the HAC Reduction Program as a mechanism to identify hospitals that underperform in preventing well-identified, measurable, and preventable adverse events.

SHM supports the inclusion of established AHRQ Patient Safety Indicators (PSIs) and the CDC HAIs measures in the HAC Reduction Program. SHM also agrees with the creation of two domains of measures that will capture adverse events among Medicare FFS discharges and non-Medicare patients, use Medicare FFS claims and National Healthcare Safety Network (NHSN) chart-abstracted data, and are risk-adjusted at the patient, unit and hospital levels.

SHM continues to endorse the eight established AHRQ Patient Safety Indicator (PSI) component indicators that compose the AHRQ PSI-90 composite measure, representing the weighted Domain 1 of the Total HAC Score for FY 2015. Composite measures PSI-6, PSI-7, PSI-8, PSI-12, PSI-13, PSI-14 and PSI-15 are related to high cost post procedural and surgical events in the Medicare beneficiary population while PSI-3 (prevention of Stage III/IV pressure ulcers in patients hospitalized longer than 5 days) focuses on a preventable event in this vulnerable population. SHM strongly supports the CDC NHSN catheter-associated urinary tract infection (CAUTI) and central line-associated blood stream infection (CLABSI) representing the weighted Domain 2 of the Total HAC Score for FY 2015.

SHM looks forward to current NQF maintenance review of AHRQ PSI-90 composite measure and CDC NHSN CAUTI and CLABSI measures. SHM agrees with the addition of CDC NHSN Surgical Site Infection (SSI) measure for FY 2016 and CDC NHSN *Methicillin-Resistant Staphylococcus aureus* (MRSA) Bacteremia to Domain 2 of the Total HAC Score. SHM continues to be wary of including *C. difficile* infection as an HAC measure. The main risk factors for *C. difficile* infection include exposure to antibiotics, hospitalization and advanced age, which aptly characterize our Medicare beneficiary population. SHM appreciates the Association for Healthcare Professionals in Infection Control and Epidemiology (APIC) "Guide to Preventing *Clostridium difficile* infections" but despite this work, there continues to be a dearth of evidence-based preventative therapies and strategies to effectively mitigate this epidemic. As noted in our comments for the HVBP Program, we continue to have concerns regarding the distinction between community-acquired and hospital-acquired, in particular for both MRSA and *C. difficile* infections.

SHM supports the addition of PSI-9 (peri-operative hemorrhage rate), PSI-10 (peri-operative physiologic metabolic derangement rate) and PSI-11 (post-operative respiratory failure rate) or a combination of these measures to the PSI-90 composite measure and looks forward to future commenting processes when appropriate.

SHM agrees with the two year applicable time periods for the collection of Domain 1 and 2 measures for FY15 and the methodology for determination of the weighted contributions of Domain 1 and Domain 2 measures to the Total HAC score for each institution. SHM supports the point assignment schedule for each Domain to identify the twenty-five percent of hospitals with the highest Total HAC Scores who will be subjected to payment reductions.

Medicare Payment for Short Inpatient Hospital Stays

Inpatient admissions and observation status has been the subject of great concern and interest for hospitalists, who are frequently the front-line providers making these decisions and/or providing the care to patients in the hospital. Current policies are difficult to navigate, particularly with the introduction of the 2-midnight benchmark.

SHM appreciates that CMS has taken this opportunity to explore alternatives. We believe that a system that accounts for short inpatient hospital stays would help alleviate some of the confusion observation status is causing for hospitalists and their patients. We caution, however, that this does not ameliorate many of the broader and inherent problems with observation status.

In defining a short or low cost inpatient stay, SHM believes that the system should be responsive enough to account for differences in condition severity and co-morbidities that impact the length of stay in the hospital. As noted in the proposed rule, there are some diagnosis-related groups (DRGs) that typically have shorter mean lengths of stay; based on the figures supplied in Table 5, anywhere from 2.66% - 7.71% of DRGs have mean lengths of stay less than 2.0 days. These are DRGs wherein the expected length of stay is already relatively low, so they would seem to preclude any sort of adjustment by a new short inpatient stay system. However, with the 2-midnight rule, these cases may now be potentially considered outpatient "observation" care. The new short or low-cost inpatient stay payment system should ensure that these cases are appropriately reimbursed as inpatient care.

At the same time, the system also needs to account for cases where a patient spends less time or requires fewer resources than would otherwise be expected for a given DRG. These would be cases that could fall into the 2-midnight rule time benchmark, but should also have the flexibility to account for stays longer than two midnights or requiring greater resources. The current payment system, including the 2-midnight rule, may serve as a disincentive to discharging patients as soon as clinically appropriate; rather it encourages the provision of care that conforms to arbitrary timelines.

It is critical to relieve the counter-intuitive pressures of the 2-midnight rule, particularly as it impacts those DRGs that already have short average lengths of stays, and to have a payment system that reflects the actual care provided to patients – the care patients need. SHM greatly encourages CMS to pursue both of these priorities as functional first steps towards broader reforms in the payment system.

SHM has been considering two different options for short inpatient stays: a "lower acuity modifier" for DRGs and short inpatient stay DRGs. These are detailed further below.

A "lower acuity modifier" would have the benefit of allowing providers to use currently existing DRGs, but will require them to indicate when a patients' condition does not necessitate the full complement and extent of services normally provided under that DRG. Based on clinically-appropriate rules, providers would indicate when a particular patient requires lower-acuity services during their stay in the hospital. (For example, simple pneumonia & pleurisy DRG 089 vs. simple pneumonia & pleurisy DRG 089 low-acuity, depending on the patient's clinical acuity). This would be denoted in the billing claims and a payment adjustment would be applied to that DRG claim. Such a program would be comprehensive of most DRGs and would account for most conditions in the hospital. Certain DRGs, such as acute STEMI, would not be eligible for the adjustment based on the intensity of services required. Providers could even apply this modifier retrospectively once a patient's condition and clinical needs are fully known.

This option recognizes the general lack in clinical distinction between patient populations in the inpatient and observation settings. It could also virtually eliminate the myriad patient-level issues associated with observation status and enable observation status to return to its original intent. At the same time, the use of audits would still be prevalent to ensure proper application of the low-acuity modifier, necessitating complementary RAC reform.

The second option would be to create short-stay DRGs that would account for many of the services that require hospital services, but may not require the requisite 2-midnights in order to be considered inpatient. Many stakeholders have expressed interest in creating a methodology for a short-stay inpatient DRG system. This would enable providers to bill Part A services for a select group of short-stay DRGs, thus granting those patients access to the Part A cost-sharing structure and access to SNF coverage. However, the ability to identify even a fraction of the DRGs which might be applicable may be unduly burdensome. As noted below, the top three diagnoses in observation status at the University of Wisconsin, Madison accounted for less than one-fifth of total observation encounters. This reality adds greatly to the complexity and difficulty of establishing this option. Also, it would still leave observation status intact for many cases and leave a system in place where subjectivity and RAC auditing would continue in a similar fashion to what currently exists.

In order to create a list of short-stay DRGs, CMS would need to work with providers to identify the conditions that would be appropriate candidates for such a payment scheme. These short-stay DRGs may replicate some of the already existing DRGs, but reflect the lower acuity and intensity of the case. SHM notes the following conditions as potential candidates for a short-stay DRG:

- Chest pain without evidence of coronary ischemia
- Syncope, without malignant cause
- Abdominal pain without apparent significant pathology
- Dehydration without severe renal dysfunction

¹ Sheehy, A., Graf, B., Gangireddy, S., Hoffman, R., Ehlenbach, M., Heidke, C., Fields, S., & Liegel, B. (2013). Hospitalized but not admitted: characteristics of patients with "observation status" at an academic center. *JAMA Internal Med*, 1-8. doi: 10 1001

- Minor electrolyte disturbances
- Transient ischemic attack
- Ataxia without intracranial pathology
- Headache without intracranial pathology
- Fever, self-limited
- Nausea and vomiting, self-limited
- Dizziness and vertigo, without intracranial pathology

A list of short stay DRGs would create a different set of pressures within the healthcare system, akin to that of observation status. Recovery Audit Contractors will still be incentivized to aggressively pursue the appropriateness of DRG claims and observation status claims. Observation status itself will not be fixed by a short-stay DRG system. Indeed, all short-stay inpatient admissions for conditions that fall outside of the short-stay DRG list would likely be subject to intense scrutiny by payers and auditors. That means that exceptions to the list, or conditions not previously contemplated in the list, would likely be presumed to be outpatient-only. This would create a whole new array of issues for hospitalists, hospitals and patients and an entirely new set of standards with which auditors can penalize providers.

We note that any policy change would benefit from a pilot at one or more hospitals that could identify and work out any unanticipated problems or unintended consequences, while helping to create the education tools to properly implement the program. The provider experience of the roll-out of the 2-midnight rule was fraught with confusion and could have been improved by fine-tuned guidance and support developed before a national implementation. Furthermore, any policy change would also be more successful with concomitant reform and improved transparency of the RAC program.

General Comments about Observation Status and Inpatient Admissions

SHM cautions against viewing a system to account for short inpatient stays as a complete solution for the structural issues with observation status and inpatient admission policies that negatively impact patients and providers alike. The use of observation status today has clearly gone well beyond its original intent- both in duration, frequency, and severity of conditions seen. The clinical capabilities of hospitals today have yielded an average length of stay of 4.8 days in 2010.² The reduction in length of stay has been fairly consistent throughout Medicare's inception, when length of stay averaged around 9.1 days.³ This decreasing trend couples with increases in observation stays. The Office of the Inspector General of the Department of Health and Human Services reported that in 2012, 11% of all observation

² National Hospital Discharge Survey: 2010 Table, Number and rate of Hospital Discharges. Centers for Disease Control and Prevention. Accessed via http://www.cdc.gov/nchs/fastats/hospital.htm.

³ Reed, L.S., and Carr, W. Utilization and Cost of General Hospital Care: Canada and the United States, 1948-1966. Social Security Bulletin, November 1968. Accessed via http://socialsecurity.gov/policy/docs/ssb/v31n11/v31n11p12.pdf.

stays lasted for three nights or more.⁴ The prevalence of outpatient observation claims rose from an average of 28 per 1,000 Part B beneficiaries per year to 53 in 2012.⁵

The current form of observation care is often indistinguishable from inpatient services; in practice, it is not a "well-defined set of specific, clinically appropriate services" as indicated in Medicare's observation status policy. A recent study at the University of Wisconsin Hospital and Clinics identified a total of 1141 distinct ICD-9 condition codes associated with observation status billing claims during the 18-month study period. The top 3 observation diagnoses were chest pain, abdominal pain, and syncope & collapse, which accounted for only 18.8% of total observation encounters. The large number of diagnosis codes, combined with the fact that the top 3 codes accounted for less than one-fifth of all observation encounters, demonstrate that observation status is not "well-defined," and suggests that observation policy is markedly different from what is occurring in real clinical practice.

SHM studied the impacts of observation status on hospitalists and their patients. SHM suggests that broader, systemic changes may be the best long-term solution to the observation/inpatient issue. We recommend exploring the development of a viable replacement that meets the needs of patients, providers, and the Medicare program while simplifying the Medicare payment system. Under this option, all patients admitted to the hospital would be considered inpatients and therefore share the same financial liabilities. Hospitals and Medicare would save on costs related to RAC oversight and the use of costly external services (electronic health records, external review organizations, Milliman, InterQual, etc.) to make status designations.

SHM recognizes the difficulty with implementing broader structural reforms and that any changes would need to be enacted in a budget-neutral manner. Concerns could be minimized through the careful development of a formula to account for these changes. Patients could be admitted to the hospital as inpatients without acuity determination, or difference in reimbursement. This could be coupled with the initiation of a data monitoring program with the end results being shared utilization goals between the Medicare program and providers. SHM acknowledges that this option would require major restructuring, but would ultimately provide more clarity and consistency for providers and patients.

Suggested Exceptions to the 2-Midnight Benchmark

Echoing previous comments about a short inpatient stay DRG list, SHM has concerns that a list of exceptions to the 2-midnight rule could have an effect quite opposite of the original intent. Such a list could become the default expectation for what conditions or circumstances are acceptable exceptions to the 2-midnight rule and any other situation would face that much more scrutiny and threat of audit

⁴ Department of Health and Human Services Office of Inspector General. Hospitals' use of observation stays and short inpatient stays for Medicare beneficiaries (OEI-02-12-00040). Available at: http://oig.hhs.gov/oei/reports/oei-02-12-00040.pdf (accessed June 4, 2014).

⁵ MedPAC 2014 Report to Congress. Chapter 3: Hospital inpatient and observation services. Available at: http://www.medpac.gov/documents/Mar14 entirereport.pdf (accessed June 26, 2014).

⁶ Sheehy, A., Graf, B., Gangireddy, S., Hoffman, R., Ehlenbach, M., Heidke, C., Fields, S., & Liegel, B. (2013). Hospitalized but not admitted: characteristics of patients with "observation status" at an academic center. *JAMA Internal Med*, 1-8. doi: 10 1001

as a result. Ultimately, SHM suggests CMS pursue broader solutions to observation status instead of making minor adjustments to the 2-midnight rule.

However SHM does recognize that in the interim, the 2-midnight policy needs to be refined in order to reflect the realities of patient care. Some situations may not be appropriate for classification as outpatient, regardless of the length of stay. For example, the 2-midnight rule could categorize short stays in the intensive care unit (ICU) as "outpatient"—this is completely counter-intuitive and fails to account for the amount and intensity of services required to be available in that setting.

Hospital Inpatient Quality (IQR) Reporting Program (formerly RHQDAPU)

In general, SHM supports most of the changes outlined in the IQR Program. We understand and appreciate CMS' proposal to report a 30-day risk-standardized episode of care payment measure for pneumonia and heart failure, as a way to tighten networks of care to optimally measure for these patients. As such, SHM believes we need to consider innovative ways in which to identify these patients early in the inpatient admission, implement evidence-based clinical pathways to assure the patient moves efficiently through their stay with optimal outcomes, develop a tight network of post-acute providers, and implement an enhanced communication system to identify where the patient is at any point in timed during the 30-day window.

In terms of the proposal to align the EHR Incentive Program reporting and submission timelines for clinical quality measures with those of the Hospital IQR Program, SHM fully supports and embraces this goal of harmonization across quality programs.

Final Remarks

In conclusion, SHM greatly appreciates the opportunity to review and offer comments on the FY 2015 CMS Proposed IPPS Rule. Hospitalists have a unique understanding of the practical application and implementation of performance measures in the hospital setting. We recognize that there are huge resources being used to both develop metrics and utilize data appropriately. However, we are concerned that rapidly dropping or adding measures to quality programs will have the unintended consequence of being both disruptive and discouraging to clinicians. We remain eager for future opportunities to consider more detailed information as current and impending quality programs are further developed and refined. If you have any questions regarding our comments, please contact Jill Epstein, Senior Advisor, Performance Measurement & Reporting, at jepstein@hospitalmedicine.org.

Sincerely,

Burke T. Kealey, MD, SFHM

President

Society of Hospital Medicine