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Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1632-P
P.O. Box 8013
Baltimore, MD 21244-1850

Dear Acting Administrator Slavitt:

The Society of Hospital Medicine (SHM) is pleased to offer the following comments on the proposed rule entitled *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 (CMS-1632-P)*, published by the Centers for Medicare & Medicaid Services (CMS) on May 5, 2015 in the Federal Register.

SHM represents the nation's 44,000 hospitalists whose primary professional focus is the general medical care of hospitalized patients. We commend CMS' efforts to promote the highest quality care for our nation's Medicare beneficiaries. SHM shares your commitment to improving performance and coordination of care, and welcomes the opportunity to continue working with you on initiatives that create incentives and reward providers for efficient use of resources.

SHM shares CMS' vision of high-quality care rooted in the best available evidence for improving outcomes. We appreciate the opportunity to review and provide comments on various hospital quality programs detailed in the FY 2016 Inpatient Prospective Payment System proposed rule.

Solicitation of Public Comments on Expanding the Bundled Payments for Care Improvement (BPCI) Initiative

Breadth and scope of expansion

We suggest two models as additions to current BPCI models. Since these models are very similar to existing models, but with minor changes, both could be considered sub-models. The first model, which we call Model 2A, would include acute care, but would not start accounting until after discharge. In essence, the difference between Model 2 and Model 2A is that 2A would exclude the hospital DRG payment and would base the

target price and anchor event on discharge. Since the hospital DRG payment makes up a significant portion within this bundle and is a relatively set amount, there is little that can be done by providers to influence DRG cost. A Model 2A would shift the accounting structure away from DRGs to areas where providers can exert a higher level of cost control and influence.

Model 3 focuses on post-acute care services and the episode is triggered by an acute care hospital stay and begins at the initiation of post-acute care services in a skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), long-term care hospital (LTCH), or home health agency (HHA). The episode includes post-acute care services, physicians' services, and related services provided during an inpatient hospital readmission, but does not include services provided during the episode-initiating acute care hospital stay. Currently, a Physician Group Practice (PGP) cannot initiate in Model 3 unless they cared for the patient in the acute anchor setting. A Model 3A would allow providers to initiate in the PAC setting without being present in the hospital. This would further promote opportunities for clinicians to demonstrate their leadership in driving value under the Bundle Program.

We support nationwide voluntary expansion by the Center for Medicare & Medicaid Innovation (CMMI) of the existing BPCI models. If any BPCI bundles are made mandatory, we suggest a phased-in approach and only within clinical areas/conditions that have clearly demonstrated wide ranging implementation feasibility during the testing phase.

Episode Definitions

CMS should consider adding a bundle option to include Part D costs to encourage the use of lower cost, yet equivalent drugs, and incentivize more cost-conscious prescribing patterns. Additionally, this option could be used to align the BPCI with other national efforts to reduce the use of over-utilized drugs such as antipsychotics and antibiotics. However, to make such an option feasible, risk adjustment or some kind of outlier pool would need to be developed to account for high-cost yet necessary prescriptions or unavoidable brand-name drugs.

We also suggest that CMS consider adding bundles specific to post-acute care. An example of such a bundle could be for wound care.

Roles of organizations & relationships necessary or beneficial to care transformation

New types of relationships should definitely be allowed in furtherance of assisting participants with care transformation in an expanded model. For hospitalists in particular, allowing a PGP to be members of multiple BPCI programs by using separate TINs, would greatly assist participation. Currently, individual NPIs can only participate in a single BPCI program even if they work under several different TINs. This not only discourages hospitalist participation but also likely hampers the participation of any practitioners working under several TINs or within a multi-site group practice.

Under current regulations, the relationships encouraged under an expansion could certainly result in unintended consequences. Most notable, is a strong incentive to dump sicker patients from the bundle. To address this problem, some kind of risk adjustment or accounting for outliers would be helpful. Alternatively or even coupled with risk adjustment, an additional incentive could be made available for bundles made up of higher risk (sicker) patients – similar in concept to the enhanced incentive available under the current Physician Value Based Payment Modifier for groups treating high-risk patients.

Setting bundled payment amounts

In considering approaches to setting bundled payments under model expansion, we strongly support the creation of prospective rates and basing rates on regional experience. When seeking to rebase bundled payment rates, an annual cost of living adjustment would be beneficial, but any further rebasing should not, at a minimum, be done any sooner than within a 5 year period. This time frame is needed to afford predictability to participants whose efforts stand to be rewarded for efficient, high-quality health care delivery. Setting the basic target prices for 5 years with cost of living increases would also encourage wider participation .

Another methodology worth considering in setting target payments would be to simply allow participants propose a customized approach that is based on their unique circumstances. While such proposals would clearly be subject to CMS approval, this added flexibility would give providers the ability to adjust based on regional and even local conditions.

Mitigating risk of high-cost cases

We appreciate the CMS recognition of the potential negative financial impact that high -cost episode cases could have on some providers. To address this risk, we strongly support the concept of establishing an outlier pool similar to what is done in IPPS and OPSS.

Further, and in keeping with a flexible approach, CMS should consider analyzing risk thresholds separately based on participating provider, hospital, and patient characteristics (i.e., major teaching vs. community hospitals; high DSH vs. low DSH hospitals, prevalence of dual eligible population, etc.). To the extent that thresholds are materially different, CMS could institute separate thresholds for different peer groups that emerge from this methodology.

Administering bundled payments

We believe Awardees, Awardee Facilitators or Awardee Conveners should be eligible to perform the administration and adjudication function as warranted by individual contract negotiations and as a particular situation may necessitate. At the same time, standards required for CMS approval of an administrator/adjudicator function should include a certain level of credibility, a demonstrated ability to pay claims, and sufficient financial resources to handle any shortfalls that may arise.

Data Needs

Lack of a specific EMR, most notably among hospitalists and post-acute providers, with which to store and access data, coupled with issues of data transparency and access to facility data is a major impediment for small physician group practices to enter the BPCI program. To assist with initiator-specific EMR needs, CMS should consider pooling participating providers within some kind of convener organization similar to an exchange as a means to spread the cost of much-needed EMR technology.

We urge CMS to require hospitals and PAC facilities participating in the Medicare program to deliver comprehensive data feeds from their EMRs, including clinical and administrative details, to any Episode Initiator (or their Convener/Facilitator) participating in the BPCI program. Data feeds should include, but not be limited to federal quality data, benchmarking information, compliance with care plan information, and a MDS. Broadly shared data would better enable the gathering and dissemination of critical clinical, functional, and administrative data for care teams serving patients in BPCI episodes.

Health IT

To promote EMR use among PAC facilities, we suggest making EMR use part of facility assessment under the Star Rating program. This would encourage facilities to further their level of connectivity by seeking creative alliances with other groups and institutions. This structure would encourage voluntary EMR adoption without adding to financial pressures created by mandatory penalty/incentive programs such as Meaningful Use.

Quality Measurement and Payment for Value

In considering the quality measures that could be applied to episodes and approaches to incorporating value-based payment in the BPCI initiative, we recommend retaining a minimum set of standard metrics coupled with the ability to add custom metrics on a regional basis. We support incorporating value-based payment under model expansion by reducing the discount percentage for high quality care or increasing the discount percentage for low quality care.

Transition from Medicare FFS payments to bundled payments

We recommend a five year transition period from Medicare FFS payment to bundled payment under an expanded model. A transition period of this length is necessary to fully accommodate the care redesign process and to fully operationalize other factors that are necessary to successfully implement a bundled payment.

Other Issues

Due to evolving capabilities to initiate a bundled payment, CMS should consider adding additional flexibility to how often a new bundle can be added to the program. We suggest structuring the program to allow for the initiation of a new bundle once or twice a year.

We also suggest adding more flexibility on the use of Net Payment Reconciliation Amount (NPRA) funds and gainsharing to providers. For example, under current guidelines providers cannot participate in gainsharing above limitations that are based on what they are actually billing Medicare. This puts heavy restrictions on gainsharing for providers such as group practice leaders, who may be contributing heavily in the care redesign process or other aspects of a successful bundle, but aren't doing significant amounts of direct billing and therefore cannot participate in a level of gainsharing that corresponds with their effort. This same dynamic is experienced by many front-line hospitalists who are often called upon to do much within a bundled payment, but receive very little return. They are charged with improving care processes, care coordination, quality improvement and in some circumstances co-manage patients within existing surgical bundles. These are efforts that weigh heavily on cost reduction within a bundle – however, their level of direct billing and resulting gainsharing allowance does not reflect this effort.

Hospital Readmissions Reduction Program: Proposed Changes for FY 2016 through FY 2017

CMS proposes to expand the measure cohort for the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506) measure starting in 2017. This expansion would include patients who are hospitalized with a principal discharge diagnosis of aspiration pneumonia or have a principal discharge diagnosis of sepsis or respiratory failure with a secondary diagnosis of pneumonia present on admission.

Although SHM agrees with CMS' conceptual rationale for this expansion, we recommend that CMS continue developing the measure to address the concerns outlined below. We concur that it is important to ensure that the measure is accurately capturing a hospital's complete set of patients with pneumonia. Pneumonia cases can be coded slightly differently, which may have consequences on cases identified by the measure and on the facility's performance within the Readmissions Reduction Program.

We have two concerns about the scope of the expansion. First, we do not recommend including aspiration pneumonia in the definition of the measure. The majority of patients with aspiration pneumonia are medically frail patients with comorbidities that predispose them to recurrent aspiration events; as such, these patients represent a cohort that is distinctly higher risk for readmissions despite evidence-based treatment and prevention strategies. Second, the expanded cohort may artificially increase the rate of readmissions for given hospitals unless the data from the benchmarking period are appropriately adjusted to include the cohort of patients with aspiration pneumonia. Such a change could create short-term performance issues when compared to readmission benchmarks. We request further clarification from CMS on how these measures may impact hospitals' performance and caution against proceeding with the expansion until these concerns are addressed. Additionally, SHM strongly recommends that after these concerns are addressed, CMS develop a communication strategy around the changes to the measure, as well as how it will impact publicly reported mortality and readmission rates.

Hospital Value-Based Purchasing Program: Proposed Policy Changes for the FY 2018 Program Year and Subsequent Years

Proposed New Measure for the FY 2018 Program Year: 3-Item Care Transition Measure (CTM-3) (NQF #0228)

CMS proposes to include the 3-Item Care Transition Measure (CTM-3), contained in the HCAHPS patient experience survey, as part of the facility performance assessment for FY 2018 HVBP. As with many of the HVBP metrics, the CTM-3 would emphasize improvement of the healthcare team, made up of a mix of providers in the hospital. The measure continues the trend of moving healthcare towards shared decision-making with patients and their caregivers and aims to improve patient-centeredness in hospitals. SHM broadly supports measure concepts and processes centered on these laudable goals. However, SHM has a few technical concerns with the CTM-3, which may have implications on whether the measure should be included in the HVBP program.

The language of the CTM-3 questions and responses may be difficult for patients to understand, particularly for those with limited English proficiency. For example, it is not immediately clear what "my health care needs" means, and may elicit variable responses based on a patient's relative understanding of the phrase. The response option "I was not given any medication when I left the hospital" may also present a confusing choice for patients. It is unusual for patients to be discharged with medications in hand; more commonly, patients are given prescriptions to be filled within the community. Finally, questions 2 and 3 do not include reference to the role of a surrogate. Many frail elderly patients have a surrogate to help provide their medical care, and as such, questions on care transitions should inquire whether "I or my caregiver" understood key issues in management of health or medications.

Generally, SHM has concerns about the validity of the HCAHPS tool overall, and the CTM-3, as a scale for assessing patient experience of hospital care. The HCAHPS is a voluntary survey with a low response rate and is

meant to be completed by the patient themselves. SHM strongly recommends future development of questions and assessment tools designed to provide meaningful information for quality improvement and reflective of the realities of patient relationships to family and other caregivers.

Hospital Inpatient Quality Reporting (IQR) Program

Proposed Removal of Hospital IQR Program Measures for the FY 2018 Payment Determination and Subsequent Years

CMS proposes to remove nine measures from the Inpatient Quality Reporting (IQR) program. Although SHM agrees that it is appropriate to remove topped out measures and measures that are not widely utilized, we have some concerns about the retention of certain measures only in their electronic forms.

Six of the measures (STK-01, STK-06, STK-08, VTE-1, VTE-2, and VTE-3) will have their chart-abstracted versions removed, but will be retained as electronic clinical quality measures. SHM has some concern about the validity of electronic submission of these measures. While chart abstraction can be resource-intensive for providers, it is seen as a more accurate method for performance assessment. These topped-out measures may present an opportunity for further substantiation of the use of electronic data in the future. We recommend CMS continue work on validating electronic clinical quality data.

CMS proposes to remove the chart abstraction version of AMI-7a Fibrinolytic Therapy Received within 30 Minutes of Hospital Arrival Measure (NQF #0164), but retain the measure as an electronic clinical quality measure. SHM has concerns about retaining a measure in any form that is not widely reportable by many hospitals and does not meet a threshold of minimum cases for public reporting. Because of the prevalence of percutaneous coronary intervention (PCI), CMS cannot reasonably expect improved electronic reporting abilities to increase reporting rates nationwide.

Proposed Refinements to Existing Measures in the Hospital IQR Program

CMS proposes to expand the measure cohort of the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468) and the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506) measures. Similar to our comments on the expansion of the measure cohort for the pneumonia measure in the Hospital Readmissions Reduction Program, SHM has concerns about the implementation of expanded measures. As CMS' calculations show, the expanded cohort comprises a forty percent increase in the number of cases included in the measure and adds 86 hospitals to the public reporting rolls.

SHM has two issues with the scope of expansion for both measures. First, we do not recommend including aspiration pneumonia in the definition of the measures. The majority of patients with aspiration pneumonia are medically frail patients with comorbidities that predispose them to recurrent aspiration events; as such, these patients represent a cohort that is distinctly higher risk for readmissions despite evidence-based treatment and prevention strategies. Second, the expanded cohort may artificially increase the rate of readmissions for given hospitals unless the data from the benchmarking period are appropriately adjusted to include the cohort of patients with aspiration pneumonia. Such a change would create short-term performance issues when

compared to readmission and mortality benchmarks. We request further clarification from CMS on how these measures may impact hospitals' performance and caution against proceeding with the expansion until these concerns are addressed. Additionally, SHM strongly recommends that after these concerns are addressed, CMS develop a communication strategy around the changes to the measure, as well as how it will impact publicly reported mortality and readmission rates.

Proposed Additional Hospital IQR Program Measures for the FY 2018 Payment Determination and Subsequent Years

CMS proposes adding eight measures to the IQR program in FY 2018. SHM offers comments on the following measures:

- Hospital Survey on Patient Safety Culture

SHM agrees with the importance of targeting hospital patient safety culture for quality and process improvement. However, SHM has some concerns about the implementation of a structural measure on administering a patient safety culture survey. We believe this structural measure will in effect mandate the use of patient safety surveys as part of public reporting. Although the measure is centered on a worthwhile quality improvement area, it will add burden to hospitals as they increase administrative costs for survey implementation and evaluation, even as the impact the measure will have on improving patient safety culture in hospitals remains unclear.

- Clinical Episode-Based Payment Measures

CMS proposes to add four clinical episode-based payment measures: Kidney/Urinary Tract Infection, Cellulitis, Gastrointestinal Hemorrhage and Lumbar Spine Fusion/Refusion. The three medical measures (Kidney/UTI, Cellulitis and GI Hemorrhage) are of particular interest to hospitalists. These measures were submitted to the National Quality Forum (NQF) Measures Application Partnership (MAP). SHM has concerns about the use of these measures in performance assessment programs without further development and recommends CMS not finalize their inclusion at this time.

The measures are meant to reflect the total costs associated with caring for patients with the respective condition. However, without complementary quality measures, the measures offer no tools or resources for how to improve, or in this case, decrease costs. SHM is also concerned these measures are not appropriately adjusting for variations in disease presentation and severity and variations in the sociodemographic status of patients, which can have significant impacts on the course and costs associated with treatment. Before implementing these measures for widespread use, we urge the development of a full set of complementary quality measures to be associated with the cost measures to facilitate quality and performance improvement.

SHM also has specific concerns about the ability of providers to determine, with accuracy, when a kidney urinary tract infection begins exactly, which has bearing on whether an index admission is triggered for the Kidney/UTI measure.

Patients with cellulitis often have a wide variability in clinical presentation. The Cellulitis episode-based payment measure does not account for differences in acute and chronic cellulitis, nor explain how the billing code, which includes abscess, adjusts for the variability in severity of diagnosis.

The GI Hemorrhage episode-based payment measure does not appear to account for differentiation between upper and lower GI hemorrhages. The etiology of the bleed has direct bearing on a patient's length of stay and, therefore, costs to the healthcare system. SHM is concerned that the risk adjustment/comorbidity adjustment does not adequately account for these differences.

Future Consideration for Electronically Specified Measures: Consideration to Implement a New Type of Measure that Utilizes Core Clinical Data Elements

SHM strongly supports the use of clinical data to improve risk adjustment of quality and outcome measures. The consideration of new core clinical data elements presents a step towards more nuanced quality measures that could have immense implications for quality improvement in hospitals nationwide and more accurate assessments of provider performance. However, upon reviewing this list of core clinical data elements, SHM would like CMS to clarify what their expectations are for collecting these measures. If this is to become a list of required elements for all patients, SHM cautions CMS about the potential for overutilization of healthcare resources in pursuit of collecting data for compliance purposes. If this is not the intention, SHM requests that CMS develop a clear strategy to ensure that providers are not collecting information irrelevant to the patient's condition.

Although SHM generally agrees with the list of core clinical data elements, and suggests that albumin could be added as a lab result that has association with morbidity and mortality in some patient populations, we recommend that CMS clarify their approach to core clinical data elements before moving forward.

Conclusion

SHM appreciates the opportunity to provide comments on the 2016 Inpatient Prospective Payment System proposed rule. If you require any additional information or clarification, please contact Joshua Lapps, Government Relations Manager at jlapps@hospitalmedicine.org or 267-702-2635.

Sincerely,



Robert Harrington, Jr, MD, SFHM
President, Society of Hospital Medicine