

June 16, 2016

Andrew Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1655-F
P.O. Box 8011
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 Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports (CMS-1655-P)* published by the Centers for Medicare & Medicaid Services (CMS) on June 16, 2016 in the Federal Register.

SHM represents the nation's nearly 50,000 hospitalists whose primary professional focus is the general medical care of hospitalized patients. SHM shares CMS' vision of promoting high quality care, improving outcomes, and streamlining care coordination for Medicare beneficiaries. We appreciate the opportunity to review and provide comments on the new and updated measures in the Hospital Value-Based Purchasing and Inpatient Quality Reporting programs as well as the notification requirements for observation services as part of implementation of the *NOTICE Act*.

SHM offers the following comments on the proposals:

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

Proposed New Measure for the FY 2021 Program Year: Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI) (NQF #2431)

CMS proposes to include the AMI Payment measure in HVBP beginning with the FY 2021 program year. The measure is currently in use in the Hospital Inpatient Quality Reporting Program. CMS indicates it views this measure as addressing an area of critical

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importance for quality improvement, namely a clinical area with high resource expenditures and variation between providers. As CMS acknowledges, the Measures Application Partnership (MAP) did not support (58% of MAP votes) inclusion of this measure in the HVBP program. SHM opposes finalizing this measure into the HVBP program at this time.

SHM notes that episode-based payment measures overlap with broader spending measures, such as the Medicare Spending Per Beneficiary Measure (MSPB). Therefore, when CMS uses these measures, hospitals are scored, and potentially penalized, twice for the same patients and services. As CMS indicates in their rationale for proposing the measure, “we believe that even if some services were double counted, hospitals that offer quality service and maintain better results on the MSPB and condition-specific payment measures relative to other hospitals in the Hospital VBP Program could receive an increased benefit by performing well on both quality measures and payment measures.” The reverse would also be true, that hospitals with poor performance could receive an increased penalty due to the double counting of services.

As CMS notes, AMI is a high volume condition that contributes greatly to costs for the Medicare program. Given this fact, it stands to reason that poor performance on this episode-based measure would be a controlling factor in performance on the broader Medicare Spending Per Beneficiary Measure, much more so than other lower volume clinical conditions. Therefore, performance in the Efficiency and Cost Reduction Domain would be disproportionately controlled by costs of certain clinical conditions, such as AMI, and performance around other conditions would be masked. While SHM supports episode-based payment measures, we recommend CMS explore a methodology to ensure fairer measurement, such as excluding costs associated with episode-based payment measures from broader payment measures.

Proposed New Measure for the FY 2021 Program Year: Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Heart Failure (HF) (NQF #2436)

CMS proposes to include the HF Payment measure in HVBP beginning with the FY2021 program year. The measure is currently in use in the IQR Program. As CMS acknowledges, the Measures Application Partnership (MAP) did not support (65% of MAP votes) inclusion of this measure in the HVBP program. SHM opposes finalizing this measure into the HVBP program at this time citing our same rationale in opposing the AMI Payment measure.

Proposed Update to an Existing Measure for the FY2021 Program Year: Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate (RSMR) Following Pneumonia Hospitalization (NQF #0468)

CMS proposes to update the measure cohort for the Pneumonia Mortality Rate measure to include patients who are hospitalized with a principal diagnosis of aspiration pneumonia or a principal diagnosis of sepsis with a secondary diagnosis of pneumonia.

SHM recommends against finalizing the expansion. 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 at higher risk for complications, readmissions and death, despite evidence-based treatment and prevention strategies. In addition, the measure will be capturing relatively different cohorts of patients with different baseline factors that influence morbidity

and mortality rates, all of which will impact performance on the measure. Of particular interest would be those patients with psychiatric and substance abuse comorbidities as penalizing hospitals that provide these services may further hinder ability to expand the much needed services required to support them. 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.

Proposed Hospital and CAH Notification Procedures for Outpatients Receiving Observation Services

CMS proposes several reforms in notifying patients of their outpatient status regarding observation care as part of the implementation of the *NOTICE Act*. Although transparency about observation status and its financial implications is worthwhile, SHM does not believe that the notification process, as proposed, will provide clarity for patients or improve patient care, but will likely increase patient confusion.

More broadly, many of our concerns with the MOON and the notification process stem from larger structural issues associated with observation status. Observation status in its current form makes little, if any, clinical sense and as a payment policy confounds patients and providers alike. SHM strongly encourages CMS to consider structural reforms to observation status as part of a more comprehensive approach to improving patient care and patient experience and increasing transparency of healthcare costs.

Proposed Requirements for Written Notice

CMS is proposing that hospitals and CAHs would be required to use a standardized written notice, the Medicare Observation Outpatient Notification (MOON), to notify an individual who receives outpatient observation services. The MOON would explain to individuals that they are receiving observation services and as such are not considered admitted inpatients. It would also include the reason for their status, as well as the implications of receiving observation services, such as transparency about cost-sharing requirements and post-hospitalization eligibility for Medicare-covered SNF care. The MOON is meant to be written in standardized, plain language to ensure that all Medicare eligible individuals receive accurate and easy to understand information.

SHM believes that the MOON, as currently drafted, will increase misunderstanding for patients who are generally unfamiliar with hospital and Medicare terminology. We strongly recommend CMS restructure and revise the draft MOON to more clearly and better address patient understanding and provider concerns.

As proposed, the draft MOON is complicated, is difficult to understand, uses technical terms, and is unnecessarily lengthy. We believe that the expected reading and comprehension level it requires is too high for the average patient. For example, the MOON is written in such a way as to expect that patients have a baseline understanding of the difference between inpatient and outpatient status. The introductory paragraph, which states "You are a hospital outpatient receiving observation services, also called an observation stay. You are not an inpatient," assumes that the patient reading the form is fully aware of the definitions and differences of these terms. Based on our experience as hospitalists, we have found a large number of patients do not fully understand the difference between inpatient and outpatient.

In addition, many elderly patients or patients with cognitive impairments may not be able to truly appreciate their billing status, and often, even highly medically literate patients may not understand the full implications of these terms as they apply to clinical and billing outcomes.

We also have concerns about CMS including language to direct quality of care complaints to the Quality Improvement Organizations (QIOs). Inclusion of this statement is beyond the scope of the original NOTICE Act requirements, which was only to inform the patient of their billing status and its financial implications. The statement, “if you have a complaint about the quality of care that you are getting during your outpatient stay,” implies that observation/outpatient status is a quality of care issue, when it is in reality a billing distinction. We are concerned that inclusion of this element on the MOON will conflate issues around observation as a billing status with issues around care quality. The section has the very real potential of encouraging patients to contact the QIO instead of first attempting to alleviate any confusion around observation status by contacting their hospital billing, case management, or patient relations departments.

We are also concerned about the ability for QIOs to respond to inquiries from patients who are frustrated by their status determination and its consequences. QIOs are overwhelmed, as evidenced by the recent suspensions for retraining on application of the 2 midnight rule and are not in a position to meaningfully address billing questions or complaints from individual patients. Without restructuring, this section of the MOON will likely increase confusion and frustration for both patients and providers. SHM recommends CMS more clearly differentiate between status determination and quality of care concerns. We also strongly recommend CMS encourage patients to work with their physicians and hospital around quality of care concerns as a first response. In addition to clinical staff, many hospitals have patient navigators, case workers, billing staff and other providers who are all trained to be front-line responders to patient issues and concerns.

SHM also requests clarification about what CMS intends could be contained in the “Additional Information” section. The proposed rule and the draft MOON do not contain enough information to determine whether this section is necessary.

Proposed Signature Requirements

CMS proposes that the written notification must be signed by the individual receiving observation services, or a person acting on the individual’s behalf to acknowledge receipt of the notification. If a signature is refused, the hospital staff that presented the notification must sign the MOON in their stead. Requiring a signature of the hospital staff raises ethical concerns for physicians and other hospital providers, who may not feel they have the right to sign a document when they are not financially responsible for or legally acting on the patients’ behalf. An alternative would be to have a check or initial box to indicate that a patient or caregiver refused to sign. It is also unclear how providers will determine when it is appropriate to seek alternative signatures and who, patient family member or other caregiver, should be engaged to sign the MOON.

No Appeal Rights under the NOTICE Act

It is not clearly stated on the MOON that the patient has no right to appeal their status determination. Their lack of direct Medicare appeal rights for status determinations (as decided by Medicare, not the provider) as well as for the MOON itself, should be addressed in the MOON. One of the first questions

patients or their caregivers have upon learning they are under observation status is “how do I change this?” or “how will you, as my physician, change this.” More clarifying language is needed to ensure patients understand their lack of appeal rights, as well as the fact that their physician does not have the authority to change their status. A lack of clarity only heightens the risk of harm to the relationship between patient and physician. Of even greater concern is the potential for an increase of patients leaving the hospital or otherwise foregoing treatment against medical advice if they are unhappy with the financial implications. Neither result will rectify patient’s billing classification and its financial implications or serve to improve patient health.

Hospital Inpatient Quality Reporting (IQR) Program

Proposed Expansion of the Cohort for the PN Payment Measure: Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (NQF #2579)

CMS proposes to update the measure cohort for the Pneumonia Payment measure to include patients who are hospitalized with a principal diagnosis of aspiration pneumonia or a principal diagnosis of sepsis with a secondary diagnosis of pneumonia.

SHM recommends against finalizing the expansion. 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 at distinctly higher risk for complications, readmissions and death, despite evidence-based treatment and prevention strategies. In addition, the measure will be capturing relatively different cohorts of patients with different baseline factors that influence in-hospital and recovery times, all of which will impact performance on the measure. 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.

Proposed Adoption of Excess Days in Acute Care after Hospitalization for Pneumonia (PN Excess Days) Measure

CMS is proposing to adopt the PN Excess Days measure as a new measure for the IQR. The measure would count the number of excess days spent in acute care, spanning inpatient readmissions, observation status and emergency department visits.

SHM advises against inclusion of the PN Excess Days measure at this time. Similar to the episode-based payment measures, we view the PN Excess Days measure as placing providers in “double jeopardy” as a significant proportion of excess days are already measured – and penalized – under existing readmission measures. In addition, and contrary to CMS’ rationale for proposing the measure, recent research from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) suggests that hospitals are not using observation status as a way to avoid triggering a readmission or to decrease readmission rates.¹ We request CMS provide more information about the impact of the measure and model how performance may differ from the existing readmission measure before moving forward with implementation.

¹ RB Zuckerman, SH Sheingold, EJ Orav, J Ruhter, and AM Epstein. Readmissions, Observation and the Hospital Readmissions Reduction Program. *NEJM*. 2016; 374: 1543-1551.

General Comments Surrounding HCAHPS in Value Based Purchasing

SHM supports the intentions of the HCAHPS survey, but has raised concerns in the past about its focus in value based purchasing programs. We believe it has questionable ability to form a valid assessment of patient experience in the hospital, particularly due to its low response rate. SHM also has concerns that some of the questions asked in the survey can be counterproductive, particularly regarding the management of pain.

With the ever-growing opioid crisis, the three questions regarding proper pain management in the hospital (i.e. During this hospital stay, did you need medicine for pain? How often was your pain well controlled? How often did the hospital staff do everything they could to help with your pain?) are of particular concern to hospitalists. These questions have the very real potential of leading the patient to believe not only that pain medicine was the best course of treatment, but also that the hospital staff should have managed their pain by all means available, including opioid prescribing. The fear of a negative patient response on these questions risks inappropriately penalizing hospitals and physicians who, in the exercise of medical judgment, opt to limit the use of opioid pain relievers when their use is not appropriate and instead potentially reward those who prescribe opioids more frequently. SHM recommends excluding these three questions from the HCAHPS Survey until their impact on inappropriate opioid prescribing can be determined.

Conclusion

SHM appreciates the opportunity to provide comments on the 2017 Inpatient Prospective Payment System proposed rule. If you require any additional information, please contact Josh Boswell, Director of Government Relations at jboswell@hospitalmedicine.org or 267-702-2632.

Sincerely,



Brian Harte, MD, SFHM
President, Society of Hospital Medicine