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Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: **Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform; Proposed Rules [CMS-1599-P].**

Dear Administrator Tavenner:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to provide our views 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 and Proposed Fiscal Year 2014 Rates* [CMS-1599-P]. Our detailed comments on the proposals put forward by the Centers for Medicare & Medicaid Services (CMS) are set forth below, and our views are as follows:

- **We do not support CMS' proposal of a new hospital inpatient admission medical review benchmark of one Medicare utilization day, or two midnight stays.**

- **We are concerned that CMS' new inpatient admission policy will result in added administrative burden for physicians, and ask that CMS consider the downstream effects of its proposal on physician time and patient access to care.**

- **We strongly urge CMS to require that Medicare Recovery Auditors (RACs) be: 1) required to have audits conducted by a physician of the same specialty and/or subspecialty and licensed in the same jurisdiction as the admitting physician; 2) required to limit the scope of hospital admission audits to the information in the medical record that was known to the physician at the time of admission; and 3) subject to a financial penalty when found to have made an erroneous overpayment determination.**

- **We suggest that CMS explore whether the use of a short stay outlier payment adjustment might be a vehicle to remedy the trend of increased observation care and the related issues that this trend has caused for physicians and patients.**

- **We have concerns with CMS' proposal to implement separate cost centers for computed tomography (CT) and magnetic resonance imaging (MRI), and ask that CMS produce an analysis regarding the accuracy of its data for these services and the effect that this change will have on patient access to care in non-hospital settings prior to implementation.**

- **We support CMS' decision not to add categories of Hospital Acquired Conditions (HACs) at this time; we strongly oppose non-payment for HACs in the inpatient or in any payment setting that are not reasonably preventable through the application of evidence-based guidelines developed by appropriate medical specialty organizations based on non-biased, well-designed, prospective, randomized studies.**

- **We urge CMS to withdraw the two proposed stroke outcome measures in the Hospital Inpatient Quality Reporting (IQR) Program for fiscal year 2016 until they can be properly constructed, tested, and risk-adjusted.**

- **We do not support the inclusion of the Medicare spending per beneficiary measure in the Hospital Value-Based Purchasing (VBP) program.**

- **We do not support CMS' proposal to decrease Graduate Medical Education (GME) payments by including labor and delivery inpatient days in the Medicare utilization calculation.**

Hospital Admissions

We appreciate CMS' recent efforts to address the issue of the rise of patient placement in outpatient observation care. The AMA has communicated its concerns regarding this issue to CMS several times over the past year.[1] To best address this issue, we again urge CMS to adopt our recommendations as follows:

- CMS should rescind its three-day inpatient stay requirement for coverage of SNF care per its clear statutory authority to do so in Section 1812(f) of the Social Security Act, or should allow outpatient observation care days to count toward the three-day stay requirement.

[1] May 16, 2013 letter from James L. Madara, MD to Administrator Marilyn B. Tavenner regarding *Medicare Program; Part B Inpatient Billing in Hospitals* [CMS-1455-P], available at http://www.ama-assn.org/resources/doc/washington/2013-05-16-ama-cms-patient-admission-status.pdf ; August 31, 2012 letter from James L. Madara, MD to Administrator Marilyn B. Tavenner regarding *Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs* [CMS–1589–P], available at http://www.ama-assn.org/resources/doc/washington/2012-08-31-hopd-proposed-rule-comment.pdf.

- CMS should convene a workshop with all affected stakeholders, including representatives of physicians, patients, and hospitals, to discuss common-sense, comprehensive solutions to the issues outlined in our prior comments.

- CMS should revise its current policy regarding changes in a patient admission status to require the concurrence of the admitting or treating physician.

- CMS should preclude Medicare contractor recoupments from physicians associated with inappropriate admissions or discrepancies between the hospital and physician's site of service.

- CMS should require that claims edit software be developed with meaningful physician input and be transparent, and should preclude claim denials that do not have the concurrence of a practicing physician in the same specialty as the admitting or treating physician.

We look forward to continued engagement with CMS on the above recommendations.

Definition of Inpatient

We do not support CMS' proposal of a new hospital inpatient admission medical review benchmark of one Medicare utilization day, or two midnight stays. Under CMS' proposal, Medicare contractors would presume that hospital inpatient admissions are reasonable and necessary for beneficiaries who exceed the benchmark, and would presume that hospital services spanning less than two midnight stays should have been provided on an outpatient basis, unless there is clear documentation in the medical record supporting the physician's inpatient stay order (or patients are being seen for an inpatient-only service or procedure).

While we understand CMS' desire to provide greater clarity regarding what constitutes an inpatient stay, we think that the proposed two midnight stay threshold would prove overly complicated, and would unduly extend beyond the current benchmark of 24 hours. For example, under CMS' proposal, the visit of a patient who comes to the hospital at 1:00 am on a Monday, and stays through 11:00 pm on Tuesday—a total of 46 hours—would be presumed by Medicare review contractors to have been properly categorized as an outpatient stay. Incongruously, the visit of a patient who comes to the hospital at 11:00 pm on a Monday, and stays through 1:00 am on a Wednesday—a total of 26 hours—would be presumed by a Medicare review contractor to have been properly categorized as an inpatient stay.

Consistent with the current benchmark, we believe that if the physician's intent and expectation is for a hospital stay of greater than 24 hours, then the stay should be considered inpatient. The patient should be designated as under observation care if the physician's intent for the hospital stay is less than 24 hours. The use of 24 hours as a threshold for observation should be a guideline; it is not unusual for patients to be admitted to inpatient status before 24 hours. We do support CMS' stipulation that the physician or practitioner ordering the hospital inpatient admission must have admitting privileges at the hospital and be responsible for the inpatient care of the patient.

We do not support CMS' proposed starting point for the two midnight stay benchmark, namely, the time at which a patient is moved from any outpatient area in the hospital to the bed where inpatient services are provided. This policy is likely to create confusion because a hospital may not distinguish between an inpatient bed/area and an outpatient bed/area, and because a patient may be admitted as an inpatient and remain in the same bed/area that they were in prior to that admission. Should CMS proceed with its proposed two midnight stay policy in spite of our concerns, we strongly urge CMS to define the starting point as the earliest time at which: (1) the physician writes the order for admission or observation; (2) the patient is treated by a physician in the emergency department; or (3) the patient is placed in a bed for observation. For example, a patient who is placed in outpatient observation care at 11:00 pm Monday, is then later admitted as an inpatient, and is then discharged at 1:00 am Wednesday, would meet the two midnight stay threshold because they received either outpatient observation care or inpatient care on Monday at midnight and on Tuesday at midnight. Further, we strongly urge CMS to use this same alternative starting point to satisfy the three-day inpatient stay requirement for SNF coverage.

Physician Documentation

We ask that CMS clarify its discussion of the requirement of physician documentation and its related proposed regulatory amendment at 42 CFR § 412.46(b). On one hand, CMS is proposing regulatory text to state that "no presumptive weight shall be assigned to a physician's order under § 412.3 or the physician's certification under Subpart B of Part 424 of this chapter in determining the medical necessity of inpatient hospital services." At the same time, however, CMS' proposal creates a situation where RACs must override a presumption that a patient was properly admitted as an inpatient or outpatient, based on the two midnight stay threshold, by looking at the physician's documentation and the medical record as a whole.

In our view, in practice this will mean that RACs will apply a more vigorous review of physician documentation—a review for which RACs possess inadequate medical expertise—when they are required to review admissions that do not comport with the two midnight stay threshold. Consequently, physicians will be under pressure from hospitals to increase and supplement their documentation to meet Medicare contractors' standard of review. **We are concerned that this policy will result in added administrative burden for physicians, and ask that CMS consider the downstream effects of its proposal on physician time and high quality care.**

Medicare RACs

To more effectively address the problems surrounding inpatient admissions, we strongly urge CMS to require that RAC medical reviews be conducted by physicians of the same specialty and/or subspecialty and licensed in the same jurisdiction. As CMS notes, "the factors that lead a physician to admit a particular patient based on the physician's clinical expectation are significant clinical considerations." We agree that physician decision-making encompasses evaluation of complex clinical factors and, therefore, have expressed repeated concern that non-physicians are tasked with medical review of physician decision-making. We are also aware of RACs' practice of employing untrained individuals, who are not always required to have a college degree, let alone medical training, to conduct reviews of Medicare claims on services questioned on appeal by the provider or facility, and strongly oppose the use of such unqualified personnel to conduct audits.

RAC reviews should also be limited to the information in the medical record that was known to the physician at the time of the decision to admit, a recommendation also made by the American Hospital Association. Physicians base their clinical judgments on the body of information available to them at the time of admission, and make their admission decisions accordingly. We have serious concerns regarding CMS' policy that RACs auditors should be required to consider the medical record in its entirety, which is likely to include information which may not have been foreseeable by the physician at the time of admission. Such hindsight review by the RACs is inappropriate and does not reflect the reality of providing patient medical care. Further, this policy will only fuel hospital reluctance to admit inpatients for fear that RAC auditors will later disagree with the physician's admission determination based on factors which were unknown to the physician at the time of admission. CMS' proposal to include this policy in regulation is, therefore, contrary to CMS' stated objective, namely, to decrease the trend of placement of patients in extended observation care by giving hospitals some assurance regarding inpatient admissions through a clarified inpatient admission policy. For these reasons, CMS should require the RACs to rely on the information known to the physician at the time of the decision to admit.

RACs must also be subject to a financial penalty for incorrect determinations regarding inpatient stays or other reviews. While CMS currently requires RACs to repay the contingency fee for determinations overturned on appeal, that safeguard has not been effective in eliminating the high volume of erroneous overpayment determinations made by the RACs. According to CMS' most recent RAC report to Congress, provider-appealed overpayment determinations are decided in favor of the provider 43 percent of the time.[2] This number is far too high, and demonstrates that RAC overpayment determinations are often wrong. Meaningful financial penalties would be a disincentive for RAC fishing expeditions, erroneous payment determinations, and the drain that these actions have on both physician practices and the Medicare appeals process.

Short Stay Outlier

We suggest that CMS consider whether the use of a short stay outlier payment adjustment might be a vehicle to remedy the problem of increased observation care and the related issues that this trend has caused for physicians and patients. The short stay outlier is utilized by CMS as an adjustment to the payment rate for long term care hospital (LTCH) stays that are generally much shorter than the average length of stay for a Medicare severity long-term care diagnosis-related group.

Our impression is that the use of a short stay outlier affords LTCHs the flexibility to tailor patient stays for the amount of time to most appropriately address patients' clinical needs. In the same vein, we ask CMS to explore whether allowing an adjustment for inpatient care could better foster appropriate patient lengths of stay. The current "either /or" dynamic of either classifying a patient as an inpatient, or as an outpatient, and the resulting trend of hospital placement of patients in outpatient observation care to avoid denials and audits, might be alleviated by a short stay outlier that could serve to remove the pressure of making such bright line determinations.

[2] Centers for Medicare & Medicaid Services report entitled *Recovery Auditing in the Medicare and Medicaid Programs for Fiscal Year 2011*, available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Recovery-Audit-Program/Downloads/FY2011-Report-To-Congress.pdf.

Pneumococcal Vaccines

We support CMS' proposal to amend the Conditions of Participation (CoPs) for Hospitals to allow for the administration of U.S. Food and Drug Administration (FDA)-approved pneumococcal vaccines. We understand CMS' view that the current CoPs only allow for the administration of polysaccharide pneumococcal vaccines. We agree that the proposed change would increase patient access to pneumococcal vaccines, which can prevent deadly pneumonia, especially in the elderly.

Imaging Cost Centers

We have concerns with CMS' proposal to implement separate cost centers for CT and MRI. Some stakeholders have pointed out that the proposed cost centers would not appropriately reflect the cost of performing these imaging services, which have different equipment costs and employ different technologies. Specifically, for hospitals that report CT and MRI separately, stakeholders have estimated that, using CMS' cost center methodology, the cost of a skull x-ray would be $82 and the cost of a head or brain CT scan would be $84. These costs lack validity on their face. We are also concerned that CMS does not appear to have done a thorough analysis of the effect of this policy on settings outside of the hospital. **We urge CMS to thoroughly evaluate this policy, including an in-depth study to produce verifiable data regarding the effect that this change would have on patient access to care for CT and MRI outside the hospital setting.**

Medicare Hospital Acquired Conditions (HACs)

The AMA supports the agency's decision not to add categories of HACs at this time. For the past several years, CMS has proposed and adopted a number of HACs for which hospitals will not receive an increased payment unless they are properly coded as present on admission (POA). **The AMA reiterates our previous comments that we strongly oppose non-payment for HACs in the inpatient or in any payment setting that are not reasonably preventable through the application of evidence-based guidelines developed by appropriate medical specialty organizations based on non-biased, well-designed, prospective, randomized studies.** Because the current inpatient HACs do not meet these criteria, we continue to have significant concerns about this policy. To be reasonably preventable, there should be solid evidence, published in peer-reviewed literature, that by following certain evidence-based guidelines, the occurrence of an event can be reduced to zero, or near zero, among a typically broad and diverse patient population, including high-risk patients. There is strong, unequivocal disagreement with CMS throughout the medical community, however, that many inpatient HACs are reasonably preventable. Some patients, particularly high-risk, co-morbid individuals, may still develop the conditions on the HAC list.

Further, CMS' decision to apply the HAC-POA policy to medical conditions that often are not "reasonably preventable" can create a "catch 22" situation for hospitals, physicians, and other health care professionals involved in patient care. For example, antibiotics used prophylactically to reduce post-operative infections may sometimes unpredictably increase the incidence of other infections, e.g., clostridium difficile. The AMA is also concerned that the HAC-POA policy arbitrarily exposes hospitals, physicians, and other health care professionals to increased risk of liability suits. This arbitrary risk is even more egregious since the HAC-POA policy applies to conditions that often are not "reasonably preventable."

The AMA promotes efforts to enhance and strengthen the patient-physician relationship, as well as efforts aimed at the education of patients and families so that they can engage in the safe management of their care as they are treated in a variety of care settings. For these reasons, and others mentioned above, we continue to urge CMS to choose a more effective approach to balancing risk and improving quality and patient safety by encouraging physician adoption of quality improvement tools.

Proposed Implementation of HAC Reduction Program for FY 2015

CMS proposes a methodology for implementing section 3008 of the Affordable Care Act (ACA), which requires the Secretary to implement a HAC payment adjustment beginning in FY 2015. In presenting background on this section, CMS reviews how various other policies address concerns regarding HACs, including the adjustment to the Medicare Severity Diagnosis Related Group (MS-DRG) payment that is made when specified preventable HACs are present as a secondary diagnosis (discussed above), the National Coverage Decisions regarding never events issued in 2009, and the public reporting of data on certain HACs on the Hospital Compare website.

For reasons discussed above in this comment letter, we do not support implementation of the HAC payment adjustment beginning in FY 2015. To implement this program, CMS proposes to adopt eight measures, grouped into two domains, for the FY 2015 HAC Payment Reduction Program. While the AMA opposes the overall implementation of this program, we urge the agency to consider comments submitted by the American College of Surgeons related to the proposed domains.

Hospital Inpatient Quality Reporting (IQR) Program

In the proposed rule, CMS states that it plans to include the following two stroke outcome measures in the IQR Program for FY 2016:

- Hospital 30-day, All-Cause Risk-Standardized Rate of Mortality Following an Admission for Acute Ischemic Stroke (Stroke Mortality) Measure; and

- Hospital 30-day, All-Cause Risk-Standardized Rate of Readmission Following Acute Ischemic Stroke (Stroke Readmission) Measure.

CMS states in this rule that it plans to adopt both measures even though the measures are not endorsed by the National Quality Forum (NQF) and are not recommended by the Measures Application Partnership (MAP). **We urge CMS to withdraw its proposal to include the two measures in the IQR until they can be properly constructed, tested, and risk-adjusted.**

In terms of the *30-day stroke mortality measure*, there is compelling scientific evidence that stroke severity, as measured by the National Institutes of Health Stroke Scale (NIHSS), is the single most important determinate of 30-day outcomes for acute ischemic stroke having more discriminatory power than all other variables combined. A recently published *Journal of the American Medical*

Association (JAMA) article also demonstrates the importance of including the NIHSS.[3] It has been established that risk models based on administrative data or clinical data that do not include stroke severity have inferior discrimination, substantial unaccounted for variance, and result in marked misclassification of hospital performance for 30-day mortality. In addition, Yale CORE/CMS (measure steward) voluntarily withdrew this measure from NQF consideration. **Therefore, we urge CMS to begin collecting stroke severity in the form of the NIHSS score and work to revise this measure to include adjustment for stroke severity, prior to implementation in the IQR.**

With regard to the proposed *30-day stroke readmission measure*, there is a growing body of evidence which suggests the primary drivers of variation in 30-day readmission rates involve variables which are neither included in this model nor captured in administrative claims data, including poor social supports, poverty, and inadequate community resources, which are all factors that are beyond the control of hospitals and physicians. The measure also does not include exclusions for those patients who die post discharge. This measure will not be identifying higher or lower quality of care, but will instead reflect unaccounted variability in case mix and other unmeasured factors.

The NQF technical advisory panel declined to endorse the stroke readmission measure due to the lack of information regarding the extent to which hospital level factors influence readmission rates, and noted concerns related to the risk-adjustment strategy, the importance of readmissions, and the potential for unintended consequences.

Medicare Spending per Beneficiary

CMS added a *Medicare Spending per Beneficiary measure* to the Hospital VBP program for FY 2015. The proposed measure is inclusive of all Part A and Part B payments from three days prior to a hospital admission through 30 days post-discharge, with some exclusions. This measure is not currently NQF-endorsed. The AMA reiterates our previous comments that we do not support the inclusion of this measure in the Hospital VBP. As is the case for the physician office setting, the AMA believes that the ability to measure hospital efficiency is in a nascent stage. Perhaps in the future, once the measure specifications have been developed and the measure is risk-adjusted, has coding and claims normalization improvements, and there is a demonstrated linkage of spending to outcomes or some other quality metric, this measure could be appropriate for inclusion in the Hospital VBP. **Until that time, we continue to have concerns with the inclusion of this measure in the Hospital VBP program. We also recommend that the measure include clearly stated reporting requirements, and an analysis of unintended consequences.**

GME Payments

We are concerned about CMS' proposal to include labor and delivery days in the GME Medicare utilization calculation. Including labor and delivery inpatient days in the Medicare utilization calculation invariably would reduce direct GME payments because direct GME payments are based, in part, on a hospital's Medicare utilization ratio and the denominator of that ratio, which includes the hospital's total inpatient days, would necessarily increase at a higher rate than the numerator, which

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

includes only the hospital's Medicare inpatient days. CMS predicts that by including these days, GME payments will decrease by $15 million in FY 2014 alone. The Association of American Medical Colleges (AAMC) and others project a shortage of 91,500 physicians by 2020; by 2025 the shortage will grow to 130,600 physicians. New and existing medical schools have taken the first step in addressing physician shortages by expanding the number of medical students enrolled in their respective institutions. The next critical step is to ensure that our nation has adequate GME training opportunities through federal funding. **Therefore, we urge CMS not to implement its proposal to decrease GME payments. Cutting federal funds jeopardizes the ability of GME programs to address physician shortages and ensure access to care.**

Conclusion

Thank you for the opportunity to share the views of the AMA regarding CMS' proposals in *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Longer Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates* [CMS-1599-P]. Should you have any questions regarding this letter, please contact Sharon McIlrath, Assistant Director, Federal Affairs at sharon.mcilrath@ama-assn.org or 202-789-7417.

Sincerely,

James L. Madara, MD