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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 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**

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 and recommendations regarding 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 2015 Rates* [CMS-1607-P].

IV. H. Hospital Readmissions Reduction Program (HRRP) Proposed Changes for FY 2015 through FY 2017

In the Medicare Hospital Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) final rule for fiscal year (FY) 2014, Centers for Medicare & Medicaid Services (CMS) finalized for FY 2015 two new condition-specific readmission measures: (1) Hospital-level 30-day all-cause risk-standardized readmission rate following elective total hip arthroplasty (THA) and total knee arthroplasty (TKA), National Quality Forum (NQF) #1551, and (2) Hospital-level 30-day all-cause risk standardized readmission rate following chronic obstructive pulmonary disease (COPD), NQF # 1891, respectively.

The AMA does not support the expansion of the Hospital Readmissions Reduction Program (HRRP), given that the program is adversely affecting providers who treat a large percentage of socio-disadvantaged patients. A large body of evidence demonstrates that sociodemographic factors, such as income and insurance status, affect many patient outcomes, including readmissions and costs. Sociodemographic adjustment allows for all providers to be fairly and accurately assessed on the quality of care they provide and their contribution to patient outcomes, while mitigating negative unintended consequences of measurement. Identifying appropriate sociodemographic adjustments also may help to

highlight the impact of those factors on patient outcomes, allowing them to be addressed. **Therefore, the AMA urges CMS to halt expansion of the HRRP until it can better risk-adjust measures, specifically around socioeconomic status (SES) and other demographic factors.**

The Department of Health and Human Services (HHS) recently commissioned the NQF to evaluate whether performance measures used in accountability applications, including public reporting and pay-for-performance, should be adjusted for sociodemographic factors in order to improve the accuracy of performance results. The draft report developed by a multi-stakeholder expert panel recommended the inclusion of SES and other demographic factors in risk adjustment when performance measures are to be used for accountability and in resource allocation. **The AMA strongly supports the conclusions and recommendations in the NQF draft report and urges CMS to adopt them as soon as possible in the HRRP as well as in CMS' many other quality reporting and pay-for-performance programs. Moreover, we urge CMS to place a high priority on working to address this issue and rapidly implement the change, as well as work with NQF to incorporate the recommendations into its endorsement process.**

Failing to account for SES and ignoring the recommendations of the panel will lead to inaccurate and misleading conclusions about quality and performance measurement. This could, in turn, lead to increases in disparities in health care. A simple examination of performance scores, without adjustment for patients' socioeconomic and/or sociodemographic status, ignores a number of factors that are believed to influence quality and cost of care. For example, SES and cultural status can affect health status, impede communication between the patient and the provider, and hamper the patient's desire and/or ability to follow a given treatment plan. Ignoring these factors could lead to the conclusion that physicians, hospitals, and other health care providers who serve low income patients provide lower quality care than those serving high income patients, when the differences in scores could actually be due to differences in patient mix rather than differences in quality of care provided. To hold health care providers accountable when outcomes differ for these patients, without accounting for the factors that contribute to those differences, would inappropriately penalize providers for factors outside their control. Also, performance measures that are not adjusted for demographic factors create a disincentive for physicians and other providers to treat low income patients—which could result in increased disparities of care. In addition, health care providers who treat disadvantaged patients often actually need more resources to treat these patients since they may enter the health system with more unaddressed health problems, are more likely to have multiple chronic conditions, and may require additional physician effort both at their initial visits and in follow-up care.

The AMA also agrees with the NQF expert panel's nuanced approach to using performance data in different ways depending on its purpose. Performance data should be stratified by demographic categories when the purpose is to shine a light on disparities. In addition, we appreciate that the panel calls attention to the need for valid and reliable demographic data to be used in stratification to help detect and address disparities. While stratification of performance data is appropriate for these purposes, the panel also notes substantial risk in failing to risk-adjust a limited number of health outcomes (such as readmissions) based on certain demographic characteristics (such as homelessness) when these measures are to be used to influence payment or for other accountability purposes.

We agree with the NQF panel that when unadjusted outcomes are used for accountability purposes, there can be unintended consequences. Those caring for the most challenging groups should be rewarded and

supported in their efforts; at the very least, they should not be punished for taking on the care of the most vulnerable among us.

CMS is not proposing to add any new applicable conditions to the HRRP for FY 2016. **Consequently, we urge CMS to use that time to evaluate the existing program and work with affected stakeholders to develop initiatives that would improve and make this a more reliable program for tackling the problem of hospital readmissions.** Therefore, until CMS adequately addresses risk adjustment, we do not support the proposal to expand the program to include patients readmitted following coronary artery bypass graft (CABG) surgery for FY 2017.

IV. I. Hospital Value-Based Purchasing (VBP) Program

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 certain exclusions. **The AMA reiterates our previous comments that we do not support the inclusion of this measure in the Hospital VBP program.** As is the case for the physician office setting, the AMA believes that the ability to measure hospital efficiency is in a nascent stage. While a hospital can have some influence over the spending that occurs after a patient leaves, that spending largely depends on: whether the individual has access to a primary care physician; the quality of the skilled nursing facility, home care agency, or other facility or services the patient chooses; other illnesses and conditions; and the availability of social supports. While these are all important drivers of health care costs and we need to collectively find better ways of controlling them, it is highly misleading to suggest that they reflect the "efficiency" of a hospital or to believe that "incentivizing hospitals" through reductions in hospitals' payment levels (as CMS intends to do through the Hospital VBP program) is either an appropriate or feasible way to impact those costs.

We are further concerned about the usefulness of the measure as currently designed because it does not provide truly actionable information. It tabulates the costs of all services that occurred for a Medicare beneficiary during and following a hospitalization. This occurs regardless of whether those services were related to one other in any logical way, had any relationship to the index hospitalization, or could be influenced by the hospital or physicians associated with the hospital. The measure purports to be risk-adjusted by using claims-based data for a short period of time prior to the hospitalization, despite the fact that we know that claims data, particularly in a non-managed care environment, is inadequate, incomplete, and inconsistent in its ability to measure many of the important factors that can legitimately influence costs. Moreover, there is no complementary measure of the frequency of hospitalization among the population being measured. A community that successfully reduces the frequency of avoidable hospitalizations is likely to see higher per-hospitalization costs for remaining hospitalizations and post-discharge care compared to other communities with more frequent hospitalizations.

Perhaps in the future, if the measure is risk-adjusted to account for SES and other demographic factors, 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 program. However, it should also include clearly stated reporting requirements and an analysis of unintended consequences.

Patient Experience of Care Domain

Patient experience measures for the Hospital VBP program are derived from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. HCAHPS is a national, standardized, publicly reported survey of patients' perspectives of hospital care during a recent overnight stay. The 27-question survey was developed by a broad partnership of public and private organizations and endorsed in 2005 by the NQF. HCAHPS is designed to produce comparable data on the patient's perspective on care that allows objective and meaningful comparisons between hospitals on domains that are important to patients. Patients are contacted to complete the survey after they leave the hospital. Hospitals can self-administer the survey or use an approved vendor, but CMS performs the data analysis.

The AMA has certain concerns with the current level of measurement for assessing patient experience within the Hospital VBP. Specifically, t**he current HCAHPS survey does not accurately and meaningfully assess patient satisfaction around pain control and management during hospital and emergency department visits.** This aspect of the survey does not take into account variations in treatment regimens due to physician preference, patient behavior, or health care facility practices.

HCAHPS addresses patient perspectives on eight composite topics. In addition to pain management, it measures the patient's experience regarding communication with doctors or nurses, responsiveness of hospital staff, communication about medicines, provision of discharge information, and the cleanliness and quietness of the hospital environment. The three survey questions on pain management are:

- *During this hospital stay, did you need medicine for pain? (Yes, No)*
- *During this hospital stay, how often was your pain well controlled? (Never, Sometimes, Usually, Always)*
- *During this hospital stay, how often did the hospital staff do everything they could to help you with your pain? (Never, Sometimes, Usually, Always)*

The AMA acknowledges that pain is one of the most common reasons for patients to seek medical attention and one of the most prevalent medical complaints in this country. However, the goals of pain management vary from patient to patient. When pain is acute, the overriding goal is to reduce pain intensity as quickly as possible, often in association with amelioration of its underlying cause. In those with persistent pain related to a serious medical illness, such as cancer, the goal of comfort may become linked to other concerns such as the relief of other symptoms and management of diverse problems undermining physical, psychosocial, and spiritual well-being. Although systemic pharmacotherapy is the mainstay approach in the treatment of acute and many types of persistent pain, optimal pain management involves diverse non-pharmacologic therapies. These include an array of non-invasive strategies and a large number of invasive approaches that can be administered in a multidisciplinary manner.

The HCAHPS survey primarily focuses on the effective use of pharmacotherapy. This may be consistent with the patient's wishes, but it is not always in the patient's best interest. Clinical challenges also are increased in those populations particularly vulnerable to inadequate pain assessment or management. These include newborns and young children, the elderly (including those with cognitive impairment), racial/ethnic minorities, those with English as a second language, those with relatively low socioeconomic status, and other groups that share characteristics that may increase the risk of poorly controlled pain.

These latter groups include patients with moderate to severe chronic pain due to cancer and other conditions, and patients with a history of substance abuse.

Physicians who exercise their judgment and decide to limit or not prescribe opioid analgesics to certain patients may pay the price in the form of a poor rating. Consequently, some physicians feel pressure to prescribe opioids in order to meet satisfaction metrics by which they (and their practices) are judged. HCAHPS has now created ethical tensions due to the challenges of trying to satisfy patients while refusing inappropriate requests. It also may be perversely contributing to an over-abundant supply of opioids that are being diverted and abused—which is one of the nation's major public health problems today. **Therefore, the AMA urges CMS to re-evaluate the validity of questions used on the HCAHPS survey related to pain management; whether the HCAHPS appropriately reflects patient satisfaction and whether it may encourage inappropriate treatment; and suspend the use of HCAHPS measures addressing pain management until their validity as reliable and accurate measures of quality of care in this domain has been determined.**

ICD-10-CMS/PCS Transition

The ICD-10-CMS/PCS transition is scheduled to take place on October 1, 2015. After that date, CMS will collect non-electronic health record-based quality measure data coded only in ICD-10-CMS/PCS. CMS highlights that they are concerned that the transition to a new coding system might have unintended consequences on quality measure data denominators, statistical adjustment coefficients, and measure rates. The AMA echoes these concerns. **We urge CMS to test submission of all measures with updated ICD-10 specifications prior to the deadline, and to hold providers harmless if CMS cannot accurately accept and calculate the measures. Providers should be exempted from all penalties if CMS cannot accurately calculate measures due to the transition.**

IV. J. Proposed Changes to the Hospital-Acquired Condition (HAC) Reduction Program

Section 3008 of the Affordable Care Act requires a one-percent payment reduction, beginning in FY 2015, for applicable hospitals that score within the top quartile (25 percent) for hospital-acquired conditions (HACs) that were not present on admission (POA). This policy was designed to serve the laudable goal of preventing and reducing the incidence of conditions that patients acquire during their hospital stay. However, its implementation poses serious logistical problems and can lead to unintended consequences. For example, documentation and coding issues can lead to some pre-existing conditions being incorrectly classified as HACs. Moreover, many patients will arrive at the hospital with undiagnosed and unreported conditions that only surface during the hospital stay. It is neither feasible nor a wise use of resources to subject each patient to the extensive testing that would be needed to identify every condition they may have when admitted. Yet, hospitals and physicians are legally and ethically obligated to treat all conditions within their expertise that arise during the hospital stay, regardless of when the condition is discovered or whether that treatment is fully reimbursed.

The AMA supports CMS' proposal not to add any new measures to the HAC Reduction Program for FY 2015. **As noted in prior comments, the AMA strongly opposes decreased payment for HACs in any setting unless the condition can reasonably be prevented by following evidence-based guidelines developed by appropriate medical specialty organizations**. Such guidelines must be based on non-biased, well-designed, prospective, randomized studies. Because the current HACs for inpatients 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 belief throughout the medical community that many of the inpatient HACs that CMS has identified are not reasonably preventable. Some patients, particularly high-risk, co-morbid individuals, may still develop the conditions on the HAC list despite the best efforts of physicians and hospitals.

Applying the HAC-POA policy to secondary medical conditions that are not "reasonably preventable" can unfairly penalize the hospital and health professionals for following the standard of care to treat a primary condition. For example, antibiotics used prophylactically to reduce post-operative infections often lead, unavoidably, to other infections such as 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 when the HAC-POA policy applies to conditions that are not "reasonably preventable."

CMS has specifically requested input regarding whether a standardized electronic composite measure of all-cause harm should be used in the HAC program in addition to, or in place of, claims-based measures assessing HACs, as well as suggestions regarding particular measures, their weighting, and the timeframe for adopting this method. The AMA has long supported maintaining claims-based measures as an option in quality reporting programs, as these offer the least burdensome, least costly, and most widely accessible and available reporting method. We also have general concerns about CMS moving to any mandatory requirements involving electronic measures, while the technology for electronic health records continues to evolve to address major issues and problems in key areas such as practical application, specifications, tailored design, flexibility of use, and interoperability. CMS has also invited comment on whether an exemption should apply for hospitals located in disaster areas or otherwise subject to extraordinary circumstances. We believe that such exemptions, if carefully drawn and developed with input from and in partnership with physicians and other appropriate stakeholders, would be a positive addition to the HRRP. We would be happy to work with CMS to assist in this effort.

IV. K. Graduate Medical Education (GME)

The AMA believes that CMS took a step in the right direction when it revised its regulations to increase the resident cap-building period for new teaching hospitals from three to five years. This allows new training programs additional time to grow their full-time equivalent (FTE) residency cap to meet patient demand. CMS now, however, proposes to change the effective date for the FTE cap to coincide with the three-year rolling average and intern-and-resident-to-bed (IRB) ratio cap in order to streamline these dates. While we understand the need for simplification, we are concerned that this change will reduce the number of months that new programs will have to establish their residency programs. This may actually decrease the number of resident positions in some cases. **Given growing physician shortages and the limited number of training positions available, we urge CMS to closely monitor any reductions in residency positions due to the shortened time period, and to ensure that new programs have ample time to grow before capping residency positions.**

In addition, the AMA is pleased that CMS in its proposed rule recognized that the Office of Management and Budget (OMB) labor market reclassifications may have a negative impact on certain teaching

hospitals in areas traditionally considered "rural," that are newly designated as "urban." We agree that these hospitals should still be allowed to grow their training programs for the full cap-building period and remain eligible to receive a permanent cap adjustment. This will ensure that these new training programs have an adequate number of residents to meet the needs of their patients and their communities while also providing valuable, much needed training opportunities for medical school graduates.

IV. N. Medicare Payment for Short Inpatient Hospital Stays

The AMA has written to CMS numerous times to communicate our serious concerns with CMS' two-midnight policy and the rise of observation care,[1] and most recently submitted testimony on this issue before the House Committee on Ways & Means.[2] The AMA also considered this issue at its June 2014 House of Delegates annual meeting, at which time the AMA adopted and/or reaffirmed policy related to the two-midnight rule, including:

- **CMS should repeal its August 2013 rules regarding Hospital Inpatient Admission Order and Certification, including the two-midnight rule;**

- CMS should explore payment solutions to reduce the inappropriate use of hospital observation status;

- The determination of the medical necessity for hospital admission should be made only by a doctor of medicine or a doctor of osteopathy licensed in the same jurisdiction as the treating physician;

- The AMA supports a 24-hour guideline for defining observation care, which is flexible pursuant to physician discretion, and directs the AMA to work with appropriate organizations to assure that both patients and physicians are treated fairly during the hospital admission process and to ensure that the process is transparent and administratively simple;

- The status of any observation patient who remains confined at a hospital for more than 24 hours should be changed automatically to inpatient and, if the patient spent a midnight in observation status, that midnight should be counted toward the three-day prior hospitalization requirement for Medicare coverage of skilled nursing facility (SNF) care;

- The AMA supports Medicare Part A coverage for a patient's *direct admission* to a SNF if directed by their physician and if the patient's condition meets skilled nursing criteria;

[1] AMA/AHA letter to CMS, November 8, 2013, https://download.ama-assn.org/resources/doc/washington/x-pub/two-midnight-suspension-letter-08nov2013.pdf; AMA letter to CMS, June 25, 2013, https://download.ama-assn.org/resources/doc/washington/x-pub/inpatient-prospective-payment-systems-comment-letter-25june2013.pdf; AMA letter to CMS, May 16, 2013, https://download.ama-assn.org/resources/doc/washington/x-pub/2013-05-16-ama-cms-patient-admission-status.pdf; AMA letter to CMS, August 31, 2012, https://download.ama-assn.org/resources/doc/washington/x-pub/2012-08-31-hopd-proposed-rule-comment.pdf.

[2] May 20, 2014 AMA Statement to House Ways & Means re: Medicare Two-Midnight Policy, https://download.ama-assn.org/resources/doc/washington/x-pub/two-midnights-statement-20may2014.pdf.

- All patients should be subject to the same cost-sharing requirements whether they are admitted to a hospital as inpatients or for observation services; and

- CMS should educate the public and develop tools for physicians and patients that outline the financial impact of the two-midnight policy.

The AMA opposes Medicare's two-midnight policy and believes it should be rescinded in its entirety.[3] Under the policy, Medicare contractors presume that hospital inpatient admissions are reasonable and necessary for beneficiaries who exceed the two-midnight bench mark. In addition, Medicare contractors must now presume that hospital services spanning less than two midnights should have been provided on an outpatient basis. While stays for less than two midnights may be deemed properly "inpatient" if there is clear documentation in the medical record to support the physician's inpatient stay order, such determinations necessitate contractor review and audit, so hospitals have a disincentive to permit such orders.

While we understand that CMS intended to provide greater clarity regarding what constitutes an inpatient stay by instituting this policy, the effect has been quite the opposite. The policy has led to much confusion for physicians who are now faced with estimating the length of stay for their patients and determining whether they would fit within the arbitrary rubric of a two-midnight stay. For example, under the policy, the visit of a patient who comes to the hospital at 1:00 a.m. on a Monday, and stays through 11:00 p.m. 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 p.m. on a Monday, and stays through 1:00 a.m. 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.

Adding to the complexity of the two-midnight policy is the inconsistency between when a hospital stay is considered to be inpatient for purposes of hospital reimbursement versus when a patient is considered an inpatient for purposes of coverage. The policy allows Medicare contractors to count the entire length of stay, including the time prior to the inpatient order, toward meeting the two-midnight benchmark for hospital reimbursement purposes. In contrast, the patient status does not change from "outpatient" to "inpatient" until the physician inpatient order is entered. This can alter the overall cost of the stay to the patient, and can significantly affect patient coverage for services like SNF care, for example. Physicians who are trying to both manage the overall care of their patient and respond to institutional concerns about audits are left trying to navigate multiple interests and divergent rules.

Consider the following situation, under CMS' new policy: a patient presents to the hospital at 1:00 a.m. on Monday and is placed under observation. By 2:00 a.m. on Wednesday, the patient is still in need of care, and is admitted to the hospital as an inpatient. The patient does not leave the hospital until 9:00 a.m. on Thursday, and is discharged to a SNF. Since the patient was there for more than two-midnights, she will be presumed by Medicare contractors to have been properly admitted as an inpatient for purposes of hospital reimbursement. However, because she was only an inpatient from 2:00 a.m. on Wednesday until

[3] AMA letter to CMS, June 25, 2013, https://download.ama-assn.org/resources/doc/washington/x-pub/inpatient-prospective-payment-systems-comment-letter-25june2013.pdf.

9:00 a.m. on Thursday, it is our understanding that she will not qualify for SNF care, even though she has been in the hospital for four days.

This policy is having very real and negative impact on patient safety. Emergency physicians are reporting patients coming to the emergency department often ask whether they are being admitted as inpatients. If these patients are not given assurances that they will be treated as an inpatient, they leave—even when they clearly require medical attention. There can be wide differences in cost to the patient for time spent classified as an "outpatient" under "observation." For example, self-administered drugs can cost significantly more to the patient under observation than to an inpatient. In addition, there may be repercussions related to post-acute coverage. Patients who require post-hospitalization SNF care must have a prior three-day inpatient stay to qualify for Medicare coverage. While CMS has asserted that the two-midnight bench mark addresses this issue, we think that the new two-midnight policy may have exacerbated the problem.

We continue to have serious concerns about the additional administrative burden that the two-midnight rule presents for physicians. Through sub-regulatory guidance, CMS has imposed a multitude of additional requirements on physicians who order inpatient admissions. In particular, physicians have reported significant issues concerning the completion of the order certification. Under CMS' rules, the certification must be completed, signed, dated and documented in the medical record prior to discharge, except for outlier cases. Not only does this requirement impose constraints on physicians' time and patient care schedule, but it also may negatively impact patients and Medicare expenditures by leading to delays in discharges as patients wait for hospitals to complete this paperwork. This is clearly contrary to CMS' goal of reducing unnecessary patient time spent in the hospital setting. **We strongly urge CMS to allow authentication of verbal admission orders within 30 days, rather than prior to discharge.**

While the authority to determine whether a patient requires an inpatient level of care should remain with the physician, the numerous inpatient order and certification requirements issued by CMS via sub-regulatory guidance and multiple addenda have amounted to a tremendous amount of new, confusing rules for physicians. We have advocated that, at a minimum, CMS should actively educate physicians and hospitals in regard to compliance with these requirements. Such education should go beyond CMS open door forums and national provider calls; education is needed "on the ground" to help physicians understand the litany of these requirements and their complexity.

We are pleased that CMS has adopted our recommendation in the IPPS proposed rule to explore whether the use of a short stay 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.[4] We believe that a short stay payment methodology may more appropriately reimburse services which fall below the two-midnight benchmark and lessen the pressure on hospitals to either admit or place in observation care.

We feel strongly, though, that CMS should rescind the current two-midnight policy and consider new payment methodologies for short stays as an alternative, rather than a supplement, to the flawed two-midnight policy.

[4] AMA/American Hospital Association letter to CMS, November 8, 2013, https://download.ama-assn.org/resources/doc/washington/x-pub/two-midnight-suspension-letter-08nov2013.pdf

CMS specifically asks whether a short inpatient hospital stay should be one where the average length of stay for the Medicare severity diagnosis-related group (MS-DRG) is short or where the stay is atypically short or low-cost relative to other cases within the same DRG. CMS also asks how to determine the appropriate payment once a short stay has been identified, and specifically inquires about a payment modeled on the existing transfer payment policy.

We think these are open questions and each of these options should be thoroughly evaluated by CMS in simulations, before adopting a new policy. CMS should determine which policy will make clinical and fiscal sense, and should employ a methodical approach in making such a determination. We welcome the opportunity to work with CMS as it develops an approach to such testing, and will be happy to provide our views on the results.

CMS also asks under what circumstances the IPPS payment amount should be limited to the Outpatient Prospective Payment System payment amount and under what circumstances might it be appropriate for the payment amount to be higher. We expect that there will be some conditions where there will be a significant difference in the severity of the patient condition seen in the inpatient and outpatient setting, and we posit that there should be a difference in payment within each of those settings.

We are also very concerned about reports from physicians that some hospital observation units, which were previously under physician guidance, are now being managed solely by non-physician practitioners such as nurse practitioners. Not only is this potentially problematic from a patient safety perspective, but it may also have a significant negative impact on teaching hospitals' ability to use observation units to educate resident physicians and medical interns. Residents and interns must have physicians as their preceptors, and hospital observation units can offer an important and valuable learning environment and a wide range of teaching opportunities. Despite the widely recognized physician shortage, there are simply not enough residency slots to fill the demands of medical school graduates. Each year hundreds of medical school graduates are unable to find residency slots. Keeping observation units under physician supervision and leadership would maintain their ability to be used for such important medical education. **We strongly urge CMS to review this important issue and evaluate the impact of this trend on training and educational opportunities for physicians.**

Finally, the AMA has long advocated that CMS should rescind the three-day inpatient stay requirement for the coverage of SNF care, or at least allow outpatient observation care days to count toward the three-day stay requirement. In that vein, we strongly support S. 569/H.R. 1179, the "Improving Access to Medicare Coverage Act of 2013."

IV. O. Suggested Exceptions to the Two-Midnight Benchmark

In regard to suggested exceptions to the two-midnight benchmark, while we appreciate that CMS has made this option available, we are concerned that many suggested exceptions are being submitted to CMS without follow-up or resolution. The AMA and medical specialty societies put forward several exceptions in April 2014 and have not yet been informed as to whether these exceptions are still awaiting review, have been accepted, or have not been accepted. Physicians and other stakeholders who take the initiative to submit a potential exception should be told in a timely manner whether CMS will review or accept the exception. As CMS has only granted one exception to date, we think that more robust processes should be put in place to ensure that appropriate exceptions are adopted.

VI. C. Proposed Revision of the Requirements for Physician Certification of Critical Access Hospital (CAH) Inpatient Services

We support CMS' proposal to amend the regulations governing the timing of the 96-hour certification requirement for CAHs such that physician certification is required no later than one day before the date on which the claim for payment for the inpatient CAH service is submitted. We agree that CMS should remove the requirement that certification of the 96-hour requirement must be completed prior to discharge and reinstate the timing requirement that was in place prior to October 1, 2013. From electronic health records to multiple certification requirements, physicians in CAHs and other hospital settings are inundated with administrative work that can detract from direct patient care. In that vein, we urge CMS to apply this proposal to other hospitals in addition to CAHs. Physicians and hospitals should have the flexibility they need to duly complete certification requirements.

IX. A. Hospital Inpatient Quality Reporting (IQR) Program

Beginning with the FY 2017 payment determination, CMS is proposing to use three years of data to calculate both currently adopted and future condition-specific, claims-based measures, unless it specifies otherwise. In other words, the proposed three-year reporting period would apply to all future calculations of condition-specific measures already adopted in the Hospital IQR program and any condition-specific measures that may be subsequently adopted in future years. The AMA is concerned that CMS' proposal to change the numbers of years to calculate measures might alter the statistical validity of the measures and demonstrate that there is not a gap in care and the need to measure a particular condition. We are aware that some measures in the IQR program only used two years' worth of data during the measure testing process. Therefore**, we urge CMS to test all current and future measures in the IQR program with three years of data. In addition, we are concerned that expanding the data collection period by an additional year will, for some quality measures, capture providers' performance before they knew they were being evaluated.**

Hospital IQR Program Measures for the FY 2016 Payment Determinations

In the FY 2014 IPPS/ LTCH final rule, CMS finalized its proposal to include two stroke outcomes measures in the IQR Program for FY 2016, despite numerous concerns with the measures and their failure to meet NQF endorsement criteria. The AMA reiterates our concerns regarding these measures. **We strongly urge CMS to withdraw its proposal to include the Stroke Mortality and Stroke Readmission measures in the IQR until they can be properly constructed, tested, and risk-adjusted.**

Hospital 30-day, All-cause Risk Standardized Rate of Mortality Following an Admission for Acute Ischemic Stroke (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 and has more discriminatory power than all other variables combined. A published *Journal of the American Medical Association (JAMA)* article also demonstrates the importance of including the NIHSS.[5] It has been established that risk models based on

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

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 (the 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 to revise this measure to include adjustment for stroke severity, prior to implementation in the IQR.**

Hospital 30-day, All-Cause Risk-Standardized Rate of Readmission Following Acute Ischemic Stroke (Stroke Readmission) Measure: There is a growing body of evidence that suggests the primary drivers of variation in 30-day readmission rates involve variables that are neither included in this model nor captured in administrative claims data. Such variables include poor social supports, poverty, and inadequate community resources, which are all factors beyond the control of hospitals and physicians. The Stroke Readmission measure also does not exclude those patients who die post-discharge. This measure will not identify 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. The panel also noted concerns related to the risk adjustment strategy, the importance of readmissions, and the potential for unintended consequences.

Hospital IQR Program Measures for FY 2016 Payment Determinations

In the 2013 IPPS Final Rule, CMS finalized for use in the FY 2016 IQR payment determination the *Hospital-level risk-standardized 30-day episode-of-care payment measure for acute myocardial infarction (AMI),* despite the measure not completing NQF review. The AMA is highly concerned about CMS moving forward with implementing this measure given the results of testing presented during NQF's review. Those results demonstrate that extensive revisions are required for the measure to be considered valid and for the ability of CMS to implement the measure. The AMA also agrees with the NQF committee's assessment that the r-squared values of 0.03-0.05 demonstrate that the measure as developed does not explain the variation observed as it does not adequately capture the factors that legitimately increase the cost of a patient's care. If implemented, the measure could result in adverse/unintended consequences.

Furthermore, the measure failed to receive the recommendation for endorsement by the NQF Cardiovascular Technical Advisory Panel (TEP) and twice failed to receive endorsement by NQF's Cost and Resource Use Standing Committee. It was only after CMS pressured NQF to hold a third vote on the measure by the Standing Committee that the measure received a passing vote. The measure is also still undergoing NQF review, as the next step in the NQF process is NQF member vote. Therefore, it is premature for CMS to adopt the measure.

Proposed Additional Hospital IQR Program Measures for the FY 2017 Payment Determinations and Subsequent Years

CMS is proposing to add a total of 11 measures to the measure set for the FY 2017 payment determination and subsequent years. **The AMA does not support CMS' expansion of the program. The AMA is specifically concerned that the following new measures have not completed the NQF**

review process, have poor attribution, and CMS' risk adjustment model fails to account for SES and other demographic factors.

- Hospital-level, risk-standardized 30-day episode-of-care payment measure for pneumonia
- Hospital-level, risk-standardized 30-day episode-of-care payment measure for heart failure

The AMA does not support the proposed 30-day episode of care measures for heart failure and pneumonia. The measures, as currently drafted, do not accurately capture the reasons for underlying differences in the cost of care and are still undergoing NQF review. The NQF review specifically highlights concerns with attribution of 30-day expenses and risk-adjustment as major issues needing further validation, with which the AMA agrees with. Although it would be easier to attribute 30-day post-discharge care to the hospital, the current structure of our healthcare system does not make this realistic. Hospitals clearly need to make appropriate post-discharge arrangements for care but have little control over the total care patients seek or receive post-discharge. There are very few instances in medicine in which one provider can be deemed solely responsible for the cost of care. **Therefore, rigorous testing of potential cost measures will be necessary in order to confirm the accuracy of attribution methodology. Furthermore, we recommend multi-level testing by CMS and its contractor to determine the appropriate level for use of each measure.**

Hospital-level, risk-standardized 30-day episode-of-care payment measure for heart failure. The AMA agrees with the NQF committee's assessment that the r-squared values of 0.03-0.05 demonstrate that the measure as developed does not explain the variation observed, since it does not adequately capture the factors that legitimately increase the cost of a patient's care. The measure also failed to receive the recommendation for endorsement by the NQF Cardiovascular Technical Advisory Panel (TEP) and twice failed to receive endorsement by NQF's Cost and Resource Use Standing Committee. It was only after CMS pressured the NQF to hold a third vote on the measure by the Standing Committee that the measure received a passing vote by the Standing Committee. Furthermore, the measure is still undergoing NQF review, as the next step in the NQF process is NQF member vote. Therefore, it is premature for CMS to adopt the measure.

In regard to *Hospital-level, risk-standardized 30-day episode-of-care payment measure for heart failure,* we are specifically concerned with the implementation of this measure and the statement made by the NQF Cardiovascular TEP that accountability for this measure lies with the ambulatory care/primary care provider. The severity of congestive heart failure (CHF), and whether an individual is Class I (mild) or Class IV (severe and sometimes pre-terminal) determines the level of accountability. CHF patients are followed in a wide range of settings by providers with different experience and skills, from pre-transplant CHF clinics to physician offices, and by heart failure specialists, general cardiologists, and primary care providers.

The AMA is highly concerned about CMS' direction and expansion of measuring overuse and appropriateness in cardiovascular care and other clinical areas as there are patient scenarios that are not addressed by the available evidence. As a result, recommendations applicable to those scenarios are not included in clinical practice guidelines. Further, not all patient scenarios are captured by appropriateness and overuse criteria. Therefore, proper evaluation of the reliability and validity of application of appropriate use criteria is often lacking, and this will continue until the evidence is developed. Fortunately, studies to fill these evidentiary gaps are ongoing and specialty clinical data registries can

assist with filling these gaps. Until the evidence base is established to support creation of such measures, we recommend that CMS to halt the expansion of developing and implementing such measures into its quality programs.

Mandatory Electronic Quality Measure Reporting for FY 2018 Payment Determination

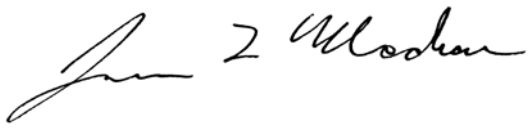
CMS anticipates that as electronic health record (EHR) technology changes and improves, hospitals will electronically report all clinical process-of-care and healthcare-associated infection (HAI) measures that are currently part of the Hospital IQR Program, or which have been proposed for adoption into the program. Therefore, CMS intends to propose to require the reporting of electronic clinical quality measures (eCQMs) for the Hospital IQR Program beginning with the calendar year 2016 reporting period or FY 2018 payment determination.

The AMA does not support CMS' current plan to require reporting of eCQMs. We believe this is premature, as both the agency and the providers are simply not ready. CMS itself does not yet have the ability to seamlessly accept eCQMs. Furthermore, many hospitals, physicians, and other providers are also unable to implement Stage 2 Meaningful Use and/or adopt version 2014 Certified EHR Technology (CEHRT). In addition, this would de facto require hospitals to participate in the EHR Incentive Program and purchase and maintain CEHRT. The EHR Incentive Program is a separate program. While the reporting of eCQMs may ease the burden for the agency, this should remain optional. It should be up to each hospital to determine the most appropriate method to report clinical quality measures. Finally, hospitals that have Meaningful Use exemptions and are not currently required to adopt CEHRT or report eCQMs would be particularly burdened and should be excluded from any such requirement.

Conclusion

We greatly appreciate this opportunity to share the views of the AMA regarding the proposals, issues, and questions which CMS has raised in 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 2015 Rates* [CMS-1607-P]. If you should have any questions regarding this letter, please feel free to contact Cybil Roehrenbeck, Assistant Director, Department of Federal Affairs, at cybil.roehrenbeck@ama-assn.org or 202-789-8510.

Sincerely,



James L. Madara, MD