



Michael D. Maves, MD, MBA, Executive Vice President, CEO

August 29, 2008

Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1404-P
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Proposed Changes to the Hospital Outpatient Prospective Payment System and
CY 2009 Payment Rates; 73 Fed. Reg. 41,416 (July 18, 2008).

Dear Acting Administrator Weems:

The American Medical Association (AMA) appreciates the opportunity to provide our views concerning certain provisions in the hospital outpatient prospective payment system (OPPS) proposed rule. We have several concerns regarding certain provisions relating to OPPS quality measures, as discussed further below. Further, the AMA strongly opposes non-payment for hospital acquired conditions and healthcare associated conditions 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. Thus, the AMA has grave concerns about extending the Medicare Hospital Acquired Conditions payment policy in the inpatient setting more broadly to Medicare payment settings, including physician practices.

Application of Non-payment for Healthcare Associated Conditions to Other Settings

In the proposed rule, the Centers for Medicare and Medicaid Services (CMS) discusses that the inpatient prospective payment system Hospital Acquired Conditions Medicare non-payment policy could be applied more broadly to other Medicare payment systems, including the OPPS, ambulatory surgical centers, skilled nursing facilities, home health care, end-stage renal disease facilities and physicians' practices. CMS specifically requests comments on options and considerations, including statutory authority, related to extending the inpatient prospective payment system Hospital Acquired Condition policy to the OPPS.

Mr. Kerry N. Weems

August 29, 2008

Page 2

Under the Deficit Reduction Act of 2005, Congress specifically provided CMS with the authority to begin applying the Hospital Acquired Condition policy to the hospital inpatient setting. If CMS were to extend this policy to other settings, it would need similar statutory authority granted by Congress. **Thus, without this statutory authority, CMS cannot extend the inpatient Hospital Acquired Condition policy to the OPPIs nor to other settings, such as physician office practices.**

Further, the AMA strongly opposes non-payment for Healthcare Associated Conditions 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 Hospital Acquired Conditions do not meet that criteria, we have grave concerns about extending this policy to other payment settings, including physician practices.

It is unacceptable that CMS is expanding the inpatient Hospital Acquired Conditions policy beyond the original eight conditions identified last year when the first phase of the program has not even begun. CMS has not yet conducted any analysis of: 1) the impact of the current Hospital Acquired Conditions inpatient policy on quality of care relative to the additional Medicare costs required to comply with the Hospital Acquired Conditions policy requirements; 2) the need for better risk adjustment techniques; 3) attribution issues with respect to when, where and why a condition has occurred; and 4) the reasonable number of expected incidence of these conditions in individual hospitals, especially with regard to high-risk patients—when evidence-based guidelines are followed.

We, therefore, urge CMS to conduct an analysis of the current Hospital Acquired Conditions policy, in consultation with technical experts, physician organizations, hospitals and other impacted providers. Such analysis must also occur before considering extension of this approach to other settings. It would defy logic to extend an approach to other settings without a cost-benefit analysis to determine whether any quality improvements it achieves outweigh its potential to increase Medicare spending and create incentives for delay or denial of needed care for challenging patients.

As we observed in our June 13, 2008 comments on the hospital inpatient prospective payment system proposed rule for fiscal year 2009, many provisions proposed for the inpatient Hospital Acquired Conditions policy will present confusion and unintended consequences for both the individual beneficiary and Medicare. Although the Hospital Acquired Conditions that CMS proposed at that time were supposed to be “reasonably preventable,” there is strong and unequivocal disagreement with that premise throughout the medical community. Subsequent to our June 13 comments, CMS finalized a list of conditions subject to the inpatient Hospital Acquired Conditions non-payment policy, and we continue to stand by our comments in our June 13 letter.

Mr. Kerry N. Weems

August 29, 2008

Page 3

The AMA continues to work aggressively to improve quality and efficiency for patients, but simply not paying for complications or conditions that are not entirely preventable is not good for patients or the Medicare program. In the race to improve health care quality, HHS is confusing events that should never happen in a hospital, like wrong-patient surgery, with often unavoidable conditions, like surgical site infections. To be reasonably preventable, there should be solid evidence that by following guidelines, the occurrence of an event can be reduced to zero or near zero. This is not the case for many of the now-banned conditions. Focusing on determining whether or not medical conditions exist when the patient enters the hospital will increase Medicare spending on tests and screenings with questionable benefit to patients.

Finally, we emphasize that expanding the inpatient Hospital Acquired Conditions non-payment to other settings would be extremely problematic, especially in physician offices because the payment approach is completely different from the hospital setting. For example, in the inpatient setting, Medicare denies the portion of payment associated with care complications when the complications are associated with a condition on the Hospital Acquired Conditions. However, there is no clear way to determine some portion of a physician's payment that would be denied due to presumed mismanagement of a reasonably preventable condition. The appropriate level of an evaluation and management service is based on the conditions managed at a given encounter and the time and intensity of the work associated with those conditions. Because the presence and severity of additional conditions present during the visit will vary greatly among patients, identifying and valuing the work attributable to a preventable condition managed by the physician at a visit would be very difficult.

In addition, the lack of adequate risk adjusters is an even greater problem in physician practices than in hospitals because some physicians specialize in treating the riskiest patients and do not have the ability to make up for losses on these patients through care of patients with below-average risks. Further, patient compliance outside of the physician office setting would be extremely difficult to assess and monitor, which also could seriously hamper any risk adjustment techniques. Many factors outside of a physicians' control could cause a patient to acquire various conditions while under a physician's care.

We are pleased that CMS recognizes in the proposed rule that the implications of applying the inpatient Hospital Acquired Conditions payment policy approach "would be different for each setting, as each payment system is different and the reasonable preventability through the application of evidence-based guidelines would vary for candidate conditions over the different settings." **Rather than considering any similar approach for physician practices, we urge CMS to instead focus its efforts on encouraging compliance with evidence-based guidelines by health care professionals.**

Proposed Update of the Revised Ambulatory Surgical Center (ASC) Payment System

Calculation of the ASC Conversion Factor and ASC Payment Rates

While the AMA supports the use of ASC rates that are tied to the hospital OPPS, we are concerned that CMS is employing a methodology that is undermining that goal. Specifically, the methodology is expanding the gap between ASC and OPPS payment rates and creating inequitable and inexplicable variations in the ASC to OPPS ratio among different types of service.

A key factor in the diverging ASC and OPPS rates is CMS's continued application of a secondary budget neutrality adjustment or rescaler to OPPS weights that have already been adjusted for budget neutrality. In 2008, the first year under the new ASC payment system, ASC weights were set at 65 percent of OPPS rates but then fell to 63 percent after rescaling. An analysis by the ASC industry estimates that continuation of this policy will lead to a 16 percent gap between the two sites of service by 2013.

CMS is not required to "rescale" the weights once they have been established for the OPPS system and there is no justification for such a significant difference in payments between these two very similar sites of service with comparable costs. To add to the problem, the agency lacks a complete data set on which to base such adjustments and has made questionable assumptions about the expected migration of certain services from physicians' offices to ASCs.

Other CMS decisions will also contribute to the growing gap between OPPS and ASC rates. The wage index used for ASCs is lower than that of the hospital outpatient departments and creates rates that for some outpatient surgeries are more than 45 percent lower in ASCs than in hospital outpatient departments. In addition, once ASC rates are unfrozen in 2010, CMS plans to use an inflation index (the urban consumer price index) that has been averaging about half a percentage point lower each year than the hospital marketbasket used to measure inflation for outpatient hospital departments. These decisions will understate ASC costs and produce unwarranted differentials between two very similar sites of care that provide overlapping services and have closely related costs and staffing requirements.

In recommending a new payment system for ASCs, various federal advisory bodies sought to create a system where both physicians and patients would choose the least costly ambulatory care site that could safely perform the needed procedure. The previously mentioned policies undermine this goal by underpaying ASCs relative to outpatient departments. CMS then compounds the problem with other payment adjustments that generate ASC-to-OPPS ratios that vary by type of service and further de-link payments between the two systems. As discussed in more detail below, a particular concern here is the policy that caps payments for "office-based" services that are new to the list of ASC-covered procedures and can also be provided in a physician's office.

ASC-Covered Surgical Procedures and Ancillary Services

CMS is proposing to add five procedures to the list of “office-based procedures.” While the AMA has long supported policies that will “assist in leveling the playing field across all sites of service,” we do not believe that simply capping ASC payments for services that are often provided in a physician’s office at the Medicare’s physician fee schedule amount will achieve that goal unless the policy is also applied to hospital outpatient departments. As currently designed, because ASCs cannot afford to do certain procedures at Medicare’s payment rates, this policy will simply force patients who have comorbidities or other conditions that make office-based surgery inappropriate, to have surgery in a more expensive hospital outpatient department. If CMS insists on retaining this policy in ASCs, it should at least increase the current 50 percent threshold for identifying these capped services and take some account of regional differences in the preferred setting for some procedures.

Finally, we wish to raise two other areas of concern. First, although we are pleased that CMS is phasing in the new ASC system and adopting OPPS policies for ancillary services and new technology, we are worried that for some services the discounted ASC rate will not be adequate to cover the cost of the procedure and the ancillary services. We also do not believe that payment for some procedures that involve implanted devices are adequate in the early years of the transition. CMS should create special transitional policies to deal with these issues.

Second, we greatly appreciate the substantial expansion CMS made in 2008 in the list of procedures that qualify for Medicare coverage when performed in an ASC. However, we believe that the list could, and should, be expanded—especially since this expansion would reduce surgical costs for both Medicare and its beneficiaries. For example, CMS is proposing to allow hospital outpatient departments to perform 10 procedures that previously were covered only when performed in the inpatient setting. Several of these procedures could also be performed safely in an ASC. It is our recommendation that any previously restricted services that are considered for coverage in the outpatient department should also be considered for ASC coverage. CMS should also provide a specific rationale whenever it deems a service that is allowed in the outpatient department to be unsafe in the ASC.

This Administration has made “transparency” and “efficiency” in Medicare payment its mantra. An ASC payment methodology that produces ASC-to-OPPS ratios that shift from year to year and that vary by type of service is counterproductive to both those goals. Without an even-handed policy, ASCs will not be able to make their more efficient services available to Medicare patients and without a consistent and obvious relationship between the two settings, patients will not be able to discern and take advantage of the lower out-of-pocket costs they would face in an ASC.

Proposed Quality Measures for CY 2010 Hospital Outpatient Payment Determination

For a hospital to receive the full outpatient update payment factor in 2010, CMS proposes reporting on four new imaging efficiency measures, along with continued reporting on the seven quality measures in place during the initial measurement reporting implementation of the Hospital Outpatient Quality Data Reporting Program (HOP QDRP) in 2008.

The AMA is extremely concerned that the four new imaging measures proposed for reporting in 2009 to be included in the 2010 payment year are still in the developmental phase. These measures have not yet received National Quality Forum (NQF) endorsement nor have they been considered for adoption by the Hospital Quality Alliance (HQA). Adoption of appropriate performance measures and continued progress in constructively improving quality of care requires meaningful public comment on quality measures that have been broadly vetted at the stakeholder level, and this occurs through adoption of measures by the HQA and endorsement by the NQF. As imaging measures are directly related to the practice of physicians, input should also be included from organizations such as the Physician Consortium for Performance Improvement (PCPI) which are best qualified to consider the appropriateness of imaging for any given condition. Moreover, measures that relate to physician performance in the hospital outpatient setting should be aligned with physician measures utilized in other CMS quality programs, such as the Physician Quality Reporting Initiative (PQRI). Further, since the imaging measures are still in the developmental process, CMS was not able to propose such critical information about the proposed measures, such as measure specifications, an appropriate rationale for each measure, discussion of the evidence underlying the measures, nor an explanation of the expected value of putting the measure into place. (CMS also requests comments regarding an additional 18 measures that might be used in hospital outpatient quality reporting in 2011 or later. This list is extremely broad and does not provide the foregoing critical information about each measure.)

The rulemaking process is intended to provide the due process right to notice and opportunity for public comment, but this cannot be achieved when a proposal is so vague as to prevent meaningful comment. Thus, when proposing new measures for public comment, such as the imaging efficiency measures, it is critical that CMS provide essential information, including measure specifications and other material information, as discussed above, so that the public is able to make informed comments. CMS' current proposal with regard to these imaging measures is unclear and thus we are unable to provide meaningful comment on them at this time.

Accordingly, we urge CMS to not adopt the four imaging measures at this time and to re-evaluate the measures at such time as essential measure specification, NQF endorsement, and HQA consideration can be accomplished.

Mr. Kerry N. Weems

August 29, 2008

Page 7

In addition to the aforementioned issues, CMS apparently intends to use 2008 data to assess physician compliance with efficiency standards that were not even proposed until more than half the year had passed. The AMA opposes the use of CY2008 claims to calculate compliance with the imaging efficiency measures for payment determination in CY2010. If physicians are expected to realize the full potential of internal quality improvement generated from the reporting of efficiency measures, physicians and hospitals must be made aware up front how their behavior is being monitored and measured. Further, any comparative data developed from 2008 claims should not be made available to the public.

In addition, we urge CMS to work with stakeholders, especially the PCPI, NQF and the HQA, to prioritize any new measures and to work to ensure that newly selected measures align with overall national goals for quality improvement. The newly enacted *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA) calls for the Secretary to contract with a consensus-based organization like the NQF to develop and report annually to the Secretary and Congress on goals and priorities and specific measures to help health care providers meet those goals and procedures, and for the Secretary to then set national goals. It seems that the outcome of such a priority-setting process could greatly inform and focus future measures to be considered in the outpatient setting.

Finally, the Secretary is required to make data collected under the HOP QDRP available to the public. CMS states in the proposed rule that it intends to make this data public by posting it on the CMS Web site, but CMS does not state exactly where the data will be posted. **We urge CMS to post the data using the existing infrastructure provided through the Hospital Compare web site.**

We appreciate the opportunity to comment on these critical matters and we stand ready to work with CMS to achieve successful resolution of the issues raised above.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Maves", written over a thin horizontal line.

Michael D. Maves, MD, MBA