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June 9, 2008

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1390-P  
P.O. Box 8011  
Baltimore, MD 21244-1850

**RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians**

Dear Administrator:

The North American Spine Society (NASS) would like to thank the Centers for Medicare and Medicaid Services for the opportunity to provide comment on proposed rule CMS-1390-P. NASS is a multispecialty medical organization with over 4,500 physician and affiliated healthcare members dedicated to fostering the highest quality, evidence-based, ethical spine care by promoting education, research and advocacy. NASS members include MDs, DOs and PhDs in 24 spine-related specialties including orthopedics, neurosurgery, physiatry, pain management and other disciplines, including allied health professionals. NASS has taken the opportunity to comment on specific portions of the proposed rule as referenced below.

**II. F. Proposed Changes to Medicare Severity DRG (MS-DRG) Classifications and Relative Weights: Preventable Hospital-Acquired Conditions (HACs), Including Infections**

We all understand that medical errors and adverse events occur during the course of patient care; these events can seriously impact patients' well-being (physical, mental and financial), care providers, healthcare facilities and payers. NASS continues to work to provide its members with the best possible information on how to prevent these incidents. NASS understands CMS' desire to provide incentives to minimize these occurrences in the interest of patient care and cost savings. As a provider organization, NASS' interest in this rule is that, although these rules are currently proposed for hospitals, they will have impact upon patient care and we believe ultimately may be extended to physician and allied health care providers. CMS policies are also frequently adopted by other payers. NASS supports non-punitive reporting on a reasonable list of conditions, however, we would like to point out, for your consideration, the following issues and suggestions regarding the proposed changes:

- Errors and adverse events are not the same thing. Medical errors caused by hospital systems or providers are not necessarily the same as an adverse event, which may not be "caused" by anyone, but occur all the same. Hence, assuming that all adverse events are preventable is misleading or that institutions should be accountable for all of them is inaccurate.
- Some of the HACs selected are not necessarily medical errors, nor 100% preventable (surgical site infections, DVT, patient falls, etc.).
- The HAC selection criteria state that the conditions must be high cost/high volume, result in a complication and be reasonably preventable through application of evidence-based

guidelines. “Preventability” is a subjective concept, difficult to determine and often influenced by decisions about expenditures. (American Association of Neurological Surgeons/Congress of Neurological Surgeons. Medicare “Never Events” Payment Policy. American Medical Association House of Delegates Resolution A-08). In addition, unless guidelines selected have been implemented and tested, there is no way to determine that an HAC could have been reasonably prevented by their application.

- The original development of “never event” lists by the National Quality Forum and Leapfrog Group were intended as quality improvement activities to help identify errors and adverse events through non-punitive means, encouraging both reporting and appropriate responses to such events once they occurred. Using and developing lists for punitive payment policies is an inappropriate application. NASS believes that non-punitive, confidential reporting is an important preventive measure. Found in other industries with established safety systems, the goal of non-punitive, confidential reporting is to identify errors, including near misses, for the purpose of correction and prevention—not punishment or liability. Identification can result in corrective action, achieving the same goals (improved patient care, cost savings) without punitive measures to healthcare systems already in financial crisis.
- We agree with the American Hospital Association that errors/adverse events selected must be preventable, under the control of the hospital and must be the result of a mistake made in the hospital. We also agree that “any process for identifying non-payable events would have to have some element of case-by-case review.” (Principles, Partial or Non-Payment for Serious Reportable Events. American Hospital Association. July 12, 2007). These reviews would need to take into consideration patient compliance, patient risk, co-morbidities, etc.
- Naming undesired, adverse events, which occur outside the typical never event lists, as “never events” sets up a scenario for increased liability. A “never event” implies that these events should never occur, which we know is inaccurate for many of these conditions. How many hospitals will want to say “I’m sorry” for a “never event” for which they may be sued? (CD Brown, KN Mitchell, KP Scott. Litigation of Never Events. American Health Lawyers Association).
- There may be unintended consequences related to refusal of Medicare patients. If Medicare does not pay for conditions, regardless of where the condition was acquired, these costs may be passed on to patients who can least afford them.

#### Suggestions/Alternatives:

- CMS may wish to encourage hospitals, through non-punitive incentives, to report on whether appropriate preventive measures were taken for each condition, not whether a condition occurred, since some of these events are not preventable. This would also spur hospitals into the specific actions desired, as this is what would be measured.
- Application of risk adjustment to increase accuracy of payment is encouraged. We understand that the current state of the art precludes individual level risk adjustment; however, risk adjustment at a facility case-mix level, either overall or by condition, is supported.
- We would also support designating certain patient risk factors as exemptions to application of the HAC payment policy.

### **II. F.7.a & g. HACs Under Consideration as Additional Candidates; Surgical Site Infections Following Elective Surgeries; Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE)**

NASS’ concerns about HACs center around the proposed conditions of surgical site infections (SSIs) and deep vein thrombosis (DVT)/pulmonary embolism (PE), which are not 100% preventable. We believe there may be unintended consequences from failure to pay for these events. Although the proposed procedures for HAC candidate SSI are total knee replacement,

laparoscopic gastric bypass and gastroenterostomy, ligation and stripping of varicose veins, NASS is commenting on the use and preventability of SSI generally and related to spine surgery specifically.

### **Subpart (a) – Surgical Site Infections Following Elective Surgery**

While NASS recognizes that steps can be taken to minimize the frequency of surgical site infections (SSI) following elective surgery, NASS strongly opposes the consideration of SSIs as hospital acquired conditions qualifying as never events, and urges CMS to carefully assess the evidence that irrefutably indicates that SSIs are not entirely preventable, even when optimal care is delivered consistent with appropriate prophylaxis regimens.

In the course of developing an evidence-based guideline, published in 2007, addressing the appropriate use of prophylactic antibiotics in spine surgery, NASS performed a comprehensive review of the scientific literature to formulate recommendations to assist in the prevention of surgical site infections. The guideline can be accessed in pdf form at [www.spine.org](http://www.spine.org) and is also submitted as an attachment. The guideline establishes the presence of moderate level evidence supporting the efficacy of antibiotic prophylaxis in the prevention of surgical site infections; however, it is very clear from the spine literature that a percentage of patients will develop SSIs, despite adherence to the most appropriate prophylactic measures.

An excerpt from the guideline is included below, and highlights the relative efficacy of prophylactic antibiotics in preventing SSIs when compared with control groups of patients who did not receive antibiotic prophylaxis.

Barker et al. described a meta-analysis based on a systematic review of the literature concerning the efficacy of prophylactic antibiotics on the incidence of postoperative spinal infection.<sup>1</sup> By pooling data from six randomized controlled trials (RCTs), they found a 2.2% (10 of 451) infection rate if antibiotics were given and a 5.9% (23 of 392) infection rate if antibiotics were not administered. Whereas each of the individual studies did not find a statistical difference, the pooled data did ( $p < .01$ ). In critique of this analysis, the individual studies included in the meta-analysis did not show a statistically significant difference in infection rate with antibiotic use. However, the pooled results did show a significantly lower rate of infection with prophylactic antibiotic use. These data offer Level II evidence that antibiotics can lead to lower rates of infection for general spine surgical procedures.

Pavel et al. reported a prospective, randomized, control trial comparing the use of antibiotic prophylaxis with cephalozidine with a placebo on the rate of postoperative infection in orthopedic surgical procedures.<sup>18</sup> When separately analyzed, the infection rate after spinal procedures was 9.2% in the placebo group, compared to 3% in the group who received cephalozidine. In critique of this study, the numbers were too small in the spine subgroup to detect a statistically significant difference. While this is a Level I study relative to orthopedic procedures, it provides Level II evidence that the use of perioperative cephalosporin antibiotic can significantly reduce the rate of perioperative infection in the subgroup of patients undergoing orthopedic spinal procedures.

Rubinstein et al. conducted a double-masked, randomized, controlled trial comparing the efficacy of cefazolin prophylaxis in 141 patients who underwent “clean” spinal surgery.<sup>27</sup> A 12.7% rate of wound infection occurred in the placebo group and a 4.3% rate was found in the antibiotic group. Details of the two groups concerning the use of instrumentation were not reported. In critique of this study, the influence of potentially influential co-variables, such as the use of instrumentation, was not analyzed. Although the data demonstrate a strong trend in favor of prophylaxis, it did not reach statistical

significance indicating that the study was underpowered. Based on the above critique, these data offer Level II evidence that intravenous cefazolin prophylaxis decreases the chance for postoperative infection after spinal surgery.

Given the fact that there is a significant body of scientific evidence demonstrating that SSIs are not 100% preventable by the physician and/or hospital, the classification of SSIs as never events is completely inappropriate. If hospitals are not reimbursed for expenses related to SSIs following elective surgeries, some of the most complicated spine patients (eg, diabetics, trauma patients and cerebral palsy patients) may find their access to care significantly compromised. Patients with co-morbidities that may increase their likelihood of developing an SSI may encounter difficulties finding physicians and hospitals that will take the risk in caring for them due to reimbursement concerns and, even worse, liability issues.

Rather than inappropriately categorizing SSIs as never events, CMS may wish to consider encouraging hospitals to adopt appropriate antibiotic prophylaxis measures. Hospitals should be provided with the evidence-based protocols to minimize the occurrence of SSIs. Implementation would be strongly encouraged by denying payment to those hospitals who fail to implement proper prophylaxis measures, when indicated. In cases where appropriate prophylactic measures are followed, yet the incidence of SSIs remains consistently two standard deviations above the national mean ( $p < .01$ ), the hospital should be encouraged to provide an appropriate explanation for the increased incidence. If the hospital is unable to justify the increased SSI rate, it should be encouraged to work with the Centers for Disease Control and Prevention to identify the root cause of the high infection rate.

Again, NASS strongly opposes inclusion of SSI as a hospital acquired condition qualifying as a never event, and urges CMS to recognize that a condition that is not 100% preventable is inappropriate for consideration as such.

#### **Subpart g – Deep Vein Thrombosis (DVT)/ Pulmonary Embolism (PE)**

NASS also strongly opposes inclusion of DVT/PE as an HAC. DVT/PE is not 100% preventable and can be difficult to diagnose upon admission to the hospital. According to one of CMS' own selected guidelines on this topic:

- “Fewer than one third of patients with DVT present with the classic signs of calf discomfort, edema, distended veins or foot pain.”
- “Both DVT and PE may be asymptomatic and difficult to detect.”
- “The risk of developing DVT extends for at least three months after joint replacement surgery. The risk is greatest two to five days after surgery; a second peak development period occurs about 10 days after surgery, after most patients have been discharged from the hospital.”

(Deep Vein Thrombosis. American Academy of Orthopaedic Surgeons. 2007)

Following these facts, DVT is difficult to diagnose, making it hard to identify at admission. There are also certain cases in which it may not be preventable, such as with trauma and joint replacement. Certain patient characteristics, such as obesity, also play a role, taking the condition outside the control of the care provider.

NASS is currently developing an evidence-based guideline addressing antithrombotic therapies in spine surgery. A selection of the studies that were reviewed in developing the guideline thus far is included below and highlights why this condition is not 100% preventable.

Piasecki et al. performed a prospective cohort study examining the incidence of DVT/PE following elective combined anterior/posterior adult reconstructive surgery in 66 consecutive patients. All patients received mechanical prophylaxis via foot pumps. DVT

was confirmed via magnetic resonance venography and bilateral lower extremity Doppler ultrasound, while contrast-enhanced spiral computed tomography scans were obtained for clinical suspicion of PE. The authors reported an overall DVT rate of 9.1% (6/66) and a 7.6% (5/66) rate of PE. (Piasecki DP, Poynton AR, Mintz DN, Roh JS, Peterson MG, Rawlins BA, Charles G, Boachie-Adjei O. Thromboembolic disease after combined anterior/posterior reconstruction for adult spinal deformity: a prospective cohort study using magnetic resonance venography. *Spine*. Mar 15 2008;33(6):668-72.)

Wood et al. reported results of an RCT conducted on patients undergoing elective anterior or posterior thoracic, thoracolumbar, or lumbar multilevel decompressions and/or spinal fusions. They compared two different types of prophylactic protocols (elastic stockings/foot wraps versus elastic stockings/pneumatic compression boots) for the prevention of DVT/PE after complex spinal surgery. Of the 136 consecutively assigned patients, data was available on 134. Mechanical prophylaxis via elastic stockings and foot wraps was used for 75 patients, while 59 received elastic stockings and pneumatic compression boots. The authors reported a 1.5% (2/136) incidence of DVT and a 0.7% (1/136) incidence of PE. (Wood KB, Kos PB, Abnet JK, Ista C. Prevention of deep-vein thrombosis after major spinal surgery: a comparison study of external devices. *J Spinal Disord*. Jun 1997;10(3):209-214.)

Rokito et al. prospectively studied the incidence of DVT after elective major adult spinal surgery in order to identify the optimal mode of prophylaxis. Of the 329 patients included in the study, 110 patients were prospectively randomized to one of three study groups. Group 1 (42 patients) received bilateral thigh-high thrombosis embolic deterrent (TED) compression stockings. Group 2 (33 patients) received TED stockings and thigh-length cuffs that provided sequential pneumatic compression to the calf and thigh. Group 3 (35 patients) received TED stockings and low dose Coumadin. The 219 patients not randomized received either TED stockings alone or TED stockings and pneumatic compression boots for DVT prophylaxis. The authors reported that 0.3% (1/329) of patients was diagnosed with a DVT. Moreover, they also found that 5.7% of patients treated with Coumadin experienced bleeding complications. (Rokito SE, Schwartz MC, Neuwirth MG. Deep vein thrombosis after major reconstructive spinal surgery. *Spine*. Apr 1 1996;21(7):853-858; discussion 859.)

Voth et al. conducted an RCT to determine the incidence of DVT and PE comparing use of once daily dosing of low molecular weight heparin (LMWH) with dihydroergotamine (DHE) to twice daily dosing of heparin with DHE as prophylaxis in routine, elective lumbar disc surgery. Of the 179 consecutively assigned patients included in the study, 87 received LMWH/DHE once daily and 92 received heparin/DHE once daily with a second placebo dose to maintain patient blinding. The authors reported that 4.6% (3/87) of patients who received LMWH/DHE prophylaxis and 3.3% (3/92) of patients who received Heparin/DHE prophylaxis were later diagnosed by radiofibrinogen uptake test with a DVT. Additionally, the authors noted that 4/92 (4.3%) of the Heparin/DHE patients experienced excessive intraoperative bleeding; intraoperative blood transfusion was required in 5.8% of patients prophylaxed with LMWH/DHE and 4.4% with Heparin/DHE. (Voth D, Schwarz M, Hahn K, Dei-Anang K, al Butmeh S, Wolf H. Prevention of deep vein thrombosis in neurosurgical patients: a prospective double-blind comparison of two prophylactic regimen. *Neurosurg Rev*. 1992;15(4):289-294.)

In contrast to our position on SSI and DVT/PE, NASS does support non-payment for “never events” when appropriately supported by data and research. NASS has been an active proponent of wrong-site surgery prevention, which very clearly is a never event. Despite national implementation of the JCAHO Universal Protocol, according to JCAHO, reports of

wrong-site surgeries continue to climb, although it is unclear whether this is due to increased numbers of incidents or reporting effect. In addition, these are events for which claims are paid without contest by insurance providers. NASS would clearly support non-payment of wrong-site surgeries. In addition, we would also support non-payment for HACs such as a foreign object retained in patient after surgery.

## **II. J. Proposed Add-On Payments for New Services and Technologies; 4. FY 2009 Applications for New Technology Add-On Payments; c. Oxiplex®**

According to the proposed rule, FzioMed, Inc. submitted an application for new technology add-on payments for FY 2009 for **Oxiplex**. **Oxiplex** is an absorbable, viscoelastic gel made of carboxymethylcellulose (CMC) and polyethylene oxide (PEO) that is intended to be surgically implanted during a posterior discectomy, laminotomy or laminectomy. The manufacturer asserts that the gel reduces the potential for inflammatory mediators that injure, tether or antagonize the nerve root in the epidural space by creating an acquiescent, semi-permeable environment to protect against localized debris. The manufacturer also asserts that **Oxiplex** is a unique material in that it coats tissue, such as the nerve root in the epidural space, to protect the nerve root from the effects of inflammatory mediators originating from either the nucleus pulposus, from blood derived inflammatory cells, or cytokines during the healing process.

Members of the North American Spine Society reviewed the available literature on the **Oxiplex** technology:

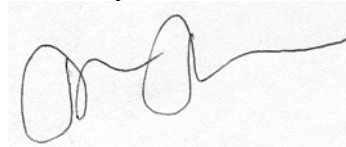
*KD Kim, JC Wang, DP Robertson et al, Reduction of Radiculopathy and Pain with Oxiplex/SP Gel after Laminectomy, Laminotomy, and Discectomy, Spine 2003, Vol 28, Number 10, pp 1080-1088.*

*KD Kim, JC Wang, DP Robertson et al, Reduction of Leg Pain and Lower Extremity Weakness for 1 Year with Oxiplex/SP Gel after Laminectomy, Laminotomy, and Discectomy, Neurosurg Focus 2004, Vol 17, Number 1, pp 1-6.*

These two articles report the same small industry-sponsored safety study concluding that the product did not have an increase in adverse events. There was a non-statistically significant improvement in a smaller subgroup with higher starting levels of leg pain. However, overall there was not much benefit. The recently completed randomized study is not in print or available. Based upon the literature in print and available for review, NASS believes that the evidence demonstrating efficacy is not sufficient at this time to support an add-on payment for Oxiplex.

In conclusion, we again wish to thank you for the opportunity to submit the above comments. Questions related to this comment may be addressed to Pam Hayden, Director of Research & Quality Improvement, 815.675.0021 or phayden@spine.org.

Sincerely,



Tom Faciszewski, MD  
President