



*"We Understand Health Care"*

May 14, 2008

Thomas Valuck, MD, JD

Director, Special Program Office for Value-Based Purchasing

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1390-P

via. <http://www.regulations.gov>

Mail Stop C4-26-05

7500 Security Boulevard,

Baltimore, MD 21244-1850

Dear Dr. Valuck:

We are writing to convey our initial comments on several Value Based Purchasing (VBP) related issues in the proposed Inpatient PPS rule for FFY2009.

We previously provided testimony and comments on VBP and strongly support the movement toward aligning incentives by linking payment and quality. One of our greatest areas of concern in this movement is to avoid unintended consequences along the way that can impede progress. We are particularly concerned with those which add new perverse incentives to our already confusing and mis-aligned health care payment process.

There are new VBP proposals in the rule including reduced payments for potentially avoidable Hospital Acquired Conditions (HACs) and measures being incorporated into public reporting (both for the annual payment update and posting on the Medicare Compare website.) Many measures rely on administrative (MEDPAR) diagnosis and procedure data collected as part of the payment process. While this saves much time and effort in data collection, it raises accuracy and appropriateness issues that need to be validated prior to implementation. Concerns include:

- Ensuring risk adjustment for adverse events which are unavoidable when following current evidence-based guidelines, to avoid adverse selection of patients at high risk for the event.
- Ensuring that the duration of an acute stay is long enough to capture the event, so that length of stay and discharge decisions do not bias the proposed measures.
- Ensuring consistent, complete, and accurate documentation and coding of ICD-9-CM diagnoses and procedures used to define adverse events.
- Ensuring that the MEDPAR limitation of 9 diagnosis and 6 procedure positions does not bias the accuracy and frequency of adverse event reporting or necessary risk adjustment.

We will illustrate our major concerns over these issues with three specific examples:

1. Deep Vein Thrombosis/Pulmonary Embolism (DVT/PE) (Proposed HAC)
2. Post-op infection after knee replacement (Proposed HAC)
3. Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicator (PSI) for Accidental puncture or laceration (Proposed for public reporting)

### **Example 1. Deep Vein Thrombosis/Pulmonary Embolism (DVT/PE) (Proposed HAC)**

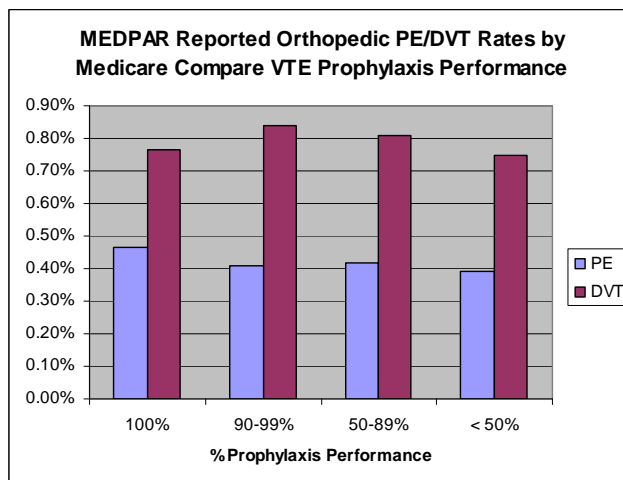
As I had indicated at the Hospital Acquired Condition/Present on Admission (HAC/POA) listening session on December 17, 2007, most DVT/PE reported in administrative data do NOT represent potentially avoidable conditions, since:

- There are large (order of magnitude) differences in the likelihood of DVT/PE **that are easily predictable** (see attached chart – which I presented in December.) This makes it easy to “avoid” a DVT/PE simply by avoiding the high risk patient – a perverse incentive.
- The proposed rule noted that “...because the manifestations of pain, redness, and swelling may develop some time after the venous clot forms...but it is possible that a patient may have a DVT that is difficult to detect on admission”. DVT manifests approximately 4-14 days after related surgery. Patients admitted for rehabilitation are at highest risk for being diagnosed with a DVT. High DVT risk patients (i.e. trauma, hip/knee joint replacement, or sepsis cases) are frequently transferred to rehabilitation **in a different facility** after 3-4 days of an acute stay, before the clot becomes symptomatic. This results in significant “attribution bias” for the adverse event. See attached chart for supporting data.
- CMS acknowledged in the proposed rule that many DVT/PEs cannot be prevented even with the “best” evidence-based guidelines and asked for additional input. We compared raw rates reported for all Orthopedic patients in 2006 MEDPAR for 3,461 hospitals, grouped by their VTE Prophylaxis Performance reported by Medicare Compare (3/08 data load). We confirmed that **“residual” rates for reported PE/DVT are similar across prevention performance** for Orthopedic patients - including “best” prophylaxis:

We linked rates of DVT/PE for all Orthopedic cases in MEDPAR with reported rates for **both** VTE-1 and VTE-2 measures to define “performance” vs. the evidence based clinical guidelines (i.e. 100% = 100% on both).

We divided hospitals into 100% on both, 90-99 percentiles, 50-89 percentiles, and remaining facilities below average.

Residual PE/DVT rates reported do not differ significantly regardless of degree of adherence to evidence based prophylaxis guidelines.



- The National Quality Forum (NQF) specifically did NOT endorse using “raw” DVT/PE rates, even for public reporting. Use as a HAC would violate CMS’s commitment to **only utilize NQF validated measures** for their Value Based Purchasing initiatives.
  - Note: NQF did endorse “Incidence of preventable VTE (VTE-8)” for patients that have a DVT/PE and did NOT receive recommended prophylaxis to prevent the clot. The NQF endorsement discussions indicated that the real improvement potential was in the medical and community settings. That was the opinion of the technical panel which evaluated this area in conjunction with the JCAHO for two years. Note: This is one of the CMS proposals for public reporting in 2010.

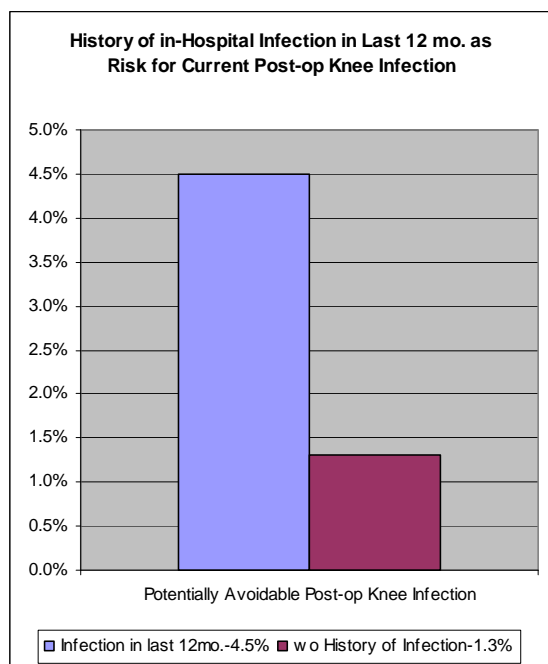
Patient specific use of reported PE/DVT as a HAC is perversely biased and should not be implemented except in cases where patients did not receive recommended prophylaxis (VTE-8).

## **Example 2. Post-op Infection After Knee Replacement (Proposed HAC)**

There is a new HAC in the proposed rule for infections of either joint prosthesis (996.66) or wound (998.59) associated with elective primary Total Knee Replacements (TKA - 81.54). It was selected with the stated assumption that “patients selected as candidates for elective surgeries should have a relatively low-risk profile for surgical site infections.” In reality, many elective TKA patients are easily predictable to be at high risk for post-op infection. Infections could therefore easily be “avoided” by hospitals by avoiding admission of these high risk patients. Implementation of this HAC measure would again inject perverse incentives into the payment system, and systematically penalize those hospitals willing and able to treat the high risk patient.

The CDC clinical guidelines quoted in the proposed rule for support of including these patients summarizes risk factors (in Table 5) as either:

- **Patient Risk Factors** – Age, nutrition status, diabetes, smoking, obesity, coexistent infections at a remote body site, colonization with microorganisms, altered immune response, and length of preoperative stay, or
- **Operational Risk Factors** – Duration of surgical scrub, skin antisepsis, preoperative shaving, preoperative skin prep, duration of operation, antimicrobial prophylaxis, operating room ventilation, inadequate sterilization of instruments, foreign material in the surgical site, surgical drains, and surgical technique (poor hemostasis, failure to obliterate dead space, tissue trauma.)



Many patient risk factors are common in the Knee replacement population, including age, diabetes, obesity, infections at a remote body site (e.g. about 10% of orthopedic infections are associated with dental surgery), chronic infections, etc.

Not only are the patient risk factors common and predictable, their relative risk impact is large. For example, patients with a major composite risk predictor (history of an in-hospital infection in the previous 12 months) have a likelihood of a current infection 3.5 times greater than patients without. (Source: Linked longitudinal data with POA indicator in NYS SPARCS data – 2005-2006)

Our data also shows that with today’s short stays, at least 75% of post-op knee infections were not diagnosed until re-admissions several days later.

- This proposed patient specific HAC will provide a strong perverse incentive to avoid admitting patients with a high risk of post-op infection, and should NOT be implemented.
- We note that many of the operational factors that can affect infection rates are already included in the measures for public reporting, which are in turn scheduled to be incorporated into VBP payments over the next few years. They should, however, be risk adjusted.
- Since the majority of post-op knee infections are not identified until the patient is in post-acute care and/or the community, regional cross-setting efforts over time should be a priority. These efforts should include the patient, their informal caregivers, and physician office visits.

### **Example 3. Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicator (PSI) for Accidental puncture or laceration (Proposed for public reporting)**

The AHRQ PSI-15 for Accidental puncture or laceration was endorsed by NQF for public reporting last fall. We had uncovered several areas of systematic bias in this measure last year as part of our quality improvement work with the Hospital for Special Surgery in New York City. We brought these concerns and several viable solutions to the attention of both NQF and AHRQ (as the measure developer) during the endorsement consideration process. We provided additional analysis and had further discussions regarding measure refinements to address the bias issues with AHRQ. NQF then endorsed the measure with the expectation that future refinements would be implemented by AHRQ in their ongoing measure refinement process.

The bias issues involved a component of PSI-15 relating to dural tears during spine surgery that are coded to the same ICD-9-CM code for Accidental punctures or laceration (998.2) as lacerations of blood vessels, the bowel, bladder, and other organs.

- Dural tears are fairly common and unavoidable in complex spine surgery (e.g. around 10% for fusions).
- They represent 13% of cases with a 998.2, but 40% of the facility variation in the measure.
- We found that only half of facilities actually report dural tears at all. The reasons appear to relate to the physician's view of avoidability. Code 998.2 appears to presume that its components are avoidable accidents, while from the physician's perspective, they are routine, incidental, and expected during complex spine surgery.
- Also, only about 1/3 of facilities perform spine surgery, and the more complex cases are typically referred to only a few centers.
- In addition, there is a wide and predictable variation in "likely" dural tear ranging from less than 1% for laminectomies for lateral spinal stenosis to as high as 33% for complex revision surgery and patients with severe central stenosis in the spinal canal. We also demonstrated that these differences are NOT measured in the current AHRQ risk adjustment.

We worked with AHRQ to address refinements in a 3 step process:

- AHRQ excluded spine surgery from the denominator in their latest update (AHRQ QI Software Version 3.2, released March, 2008). This version is necessary to avoid bias.
- We requested a new ICD-9-CM code to specifically identify dural tears separately from the other low volume punctures and lacerations in the current 998.2 code. We presented this at the March 20, 2008 ICD-9-CM Coordination and Maintenance meeting, and expect implementation on October 1, 2008.
- We are working with the Hospital for Special Surgery, one of the 13 centers participating in the Spine Patient Outcomes Research Trial (SPORT), to access the SPORT data to help validate a more refined set of risk adjustors based on MEDPAR and other administrative data. We will then work with the AHRQ PSI team to incorporate refinements into future updates of the PSI software to incorporate valid comparisons for spine surgery patients.
  - (Note: We also found that almost 20% of the risk factors identified so far for the complex spine surgery cases would likely be "trimmed" by the MEDPAR limitation of 9 diagnoses and 6 procedures, thus invalidating the risk adjustment unless positions are expanded.)

These three current examples illustrate the major concerns we have outlined in our previous policy testimony and comments. They also support the need to vigorously validate each of the current proposed measures in the rule, not just the three used as examples:

- Conditions identified by administrative data (whether MEDPAR or State All-payor databases) are unlikely to be completely avoidable. **Risk Adjustment for predictable patient variability is necessary in most real world measures being proposed to avoid perverse incentives for patient selection.**
  - Patient Level risk adjustment can and should be accomplished by exclusion of elevated risk patients from consideration for any patient specific HAC.
  - Hospital Level risk adjustment can and should be accomplished by computing risk-adjusted expected rates compared to actual rates for ALL publically reported measures and those considered for inclusion in Value Based Purchasing.
  - Community Level risk adjustment can be used to identify regional targets for adverse event reduction efforts that span multiple delivery setting “silos,” that include patient and informal caregiver effects, or need to be addressed over time.
- Today’s short lengths of acute care stay are not long enough for a number of potentially avoidable conditions to be detected until after discharge, as is the case for both DVT/PE and infections above. In addition, once the patient has been discharged, they are under the care of another post-acute care provider, themselves, or a friend/family member. This care after the patient’s discharge can significantly affect outcomes, and cannot be reasonably be prevented by the hospital or attributed to them. **Cross-setting collaboration with the patient is needed to make many of these conditions “potentially avoidable” – but only by the entire care team, not just isolated care silos.**
- Current documentation and coding is neither consistent nor accurate as illustrated above. **Each new proposed use – for each proposed ICD-9-CM code – for each patient population or subpopulation must be specifically validated to see if what it actually measures is what it was intended to measure.**
- The demands of both payment and risk adjustment have now far exceeded the ability of the current MEDPAR 9 diagnosis and 6 procedure positions to accurately support Value Based Purchasing. While parallel collection of Quality data from States is one proposal, we strongly urge CMS to **bring MEDPAR into HIPAA compliance**, as all other interested parties must, and collect all 25 diagnoses and procedures.

We hope to complete some more in-depth analysis of these areas, and a number of others, once more current data are available. We wanted to share these analyses, comments, and recommendations with you as early in the process as possible, since we know that most comments are submitted close to the deadline.

Please contact us if you have any comments or need some clarifications on this material.

Sincerely,



John D. Shaw  
President

Enc.

## PE/DVT Risk in 10 Most Frequent Medicare Categories (Hospital Acquired - NOT POA)

