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To Err is Human - Hospitals Will be Paying the Price, but at What Cost?

On October 1, 2008, the Centers for Medicare and Medicaid Services (CMS) implemented a new rule, which denies payment to hospitals for the cost of treating certain medical conditions caused by errors that could have been reasonably prevented.¹ CMS has outlined its list of certain hospital-acquired conditions (HACs) that it deems can be reasonably prevented if a hospital follows accepted evidence-based practices.² CMS has made it clear that hospitals will bear the burden of the extra expenses for treating certain HACs caused by the hospital errors.³

No doubt, the treatment expenses for HACs will be costly to hospitals, but this new rule could potentially impose an even higher price tag for hospitals beyond the scope of treatment expenses. The rule could potentially create implications for increased costs associated with pre-admission diagnostic screening, defending medical malpractice litigation and defending violations of the False Claims Act.

Background Information on the Non-Payment Rule:

The list of preventable HACs is outlined in CMS' Inpatient Perspective Payment System (IPPS) FY 2009 Final Rule and includes the following 11 categories:

1. foreign object retained after surgery;
2. air embolism;
3. blood incompatibility;
4. pressure ulcers, stages III and IV;
5. falls and trauma;
6. catheter associated urinary infection;
7. vascular catheter associated infection;
8. manifestations of poor glycemic control;
9. surgical site infection, mediastinitis following coronary artery bypass graft;
10. surgical site infection following certain orthopedic procedures and bariatric surgery; and

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11. deep vein thrombosis and pulmonary embolism following certain orthopedic procedures.⁴

CMS does not intend to reimburse hospitals for the increased costs of care attributed to or made necessary by these HACs.⁵ If any one of the above-listed HACs is not present upon hospital admission, but then is subsequently acquired during the hospital stay, the hospital will have to bear the burden of the expense incurred in treating the HAC.⁶ As consistent with CMS payment rules, the hospital cannot hold the patient responsible for the additional cost.⁷ In other words, CMS will reimburse the hospital as though the HAC – the secondary diagnosis – was never present.⁸ Thus, hospitals are impliedly encouraged to prevent adverse events and improve the reliability of care provided to its Medicare patients.⁹

Some commentators opine that CMS' expectations for good, quality hospital service may be analogous to expectations for a good auto mechanic.¹⁰ "If an auto mechanic breaks your windshield while trying to repair the engine, he would never get away with billing you for fixing his mistake."¹¹ CMS applied this same logic when it decided to stop paying hospitals for the added cost of treating patients who are injured while in their care.¹² CMS' decision to refuse payment has influenced other payors, including Aetna, Blue Cross Blue Shield, Cigna and WellPoint, to set similar criteria for non-payment.¹³

The current list of HACs represents the culmination of extensive review and the ongoing subject of debate.¹⁴ CMS took into consideration the landmark 1999 Institute of Medicine (IOM) report, "To Err is Human: Building a Safer Health System," in which it found that medical errors, and particularly HACs, were the leading cause of morbidity and mortality in the United States.¹⁵ The IOM report noted that the number of Americans who die each year as a result of HACs could be as many as 98,000, at a cost of up to \$29 billion.¹⁶ CMS also gave consideration to the 2002 publication issued by the National Quality Forum (NQF), an organization that researches methods for improving the nation's healthcare system.¹⁷ The publication identified a list of 27 "never events," which have been defined as preventable medical errors that should never occur and will result in serious consequences to patients and unnecessary costs.¹⁸ In 2006, the NQF added one more event to its list of "never events," which include such serious errors as surgery on the wrong body part.¹⁹

Congress passed the Deficit Reduction Act of 2005 (DRA), authorizing CMS to adjust IPPS hospital payments²⁰ in an attempt to reduce and encourage prevention of HACs.²¹

Pursuant to the DRA, in 2007, CMS proposed an initial list of eight HACs.²² In August 2008, CMS revised the initial list of HACs, adding three more to the list, which now includes four "never events."²³ CMS officials have indicated that linking HACs to Medicare payments is likely to increase in the future.²⁴

General Implications of the Non-Payment Rule:

CMS asserts the new rule is designed to promote its goal of transforming CMS to a prudent purchaser of health care services, paying for quality of services, and not just quantity.²⁵ Hospitals have had approximately one year to prepare for this non-payment rule.²⁶ The CMS acting administrator, Kerry Weems, stated, "While it may be some time before we can begin to assess the real impact of the steps on patient care, we are hearing from hospitals around the country about efforts they have undertaken in the past year to improve staff training and other measures to reduce incidents of these preventable conditions."²⁷ The rule has reinforced a new focus on reducing hospital medical errors²⁸ by promoting staff training on simple infection control techniques, such as handwashing, and implementing innovative efforts to reduce errors in the operating room, in matching blood types and in administering medications.²⁹ Moreover, hospitals have implemented procedures for additional pre-admission diagnostic assessments to capture data for making accurate pre-admission diagnoses, such as tracking a urinary tract infection on admission.³⁰

Other Costly Implications of the Non-Payment Rule:

It may not be too soon to address the potential for other costly implications the rule may have on medical malpractice litigation or alleged violations of the False Claims Act (FCA) and the significant expenses hospitals may incur in defending and/or settling such claims. In medical malpractice litigation, if the incident at issue involves an HAC, the plaintiff may pursue a *negligence per se* theory of liability in an attempt to avoid the burden of proving standard of care. With respect to the FCA, hospitals must be mindful of the potential for a violation if the submitted claim for payment includes a non-reimbursable HAC.

The FCA, as set forth in 31 U.S.C. §3729, outlines the elements of FCA liability. To incur liability under the FCA, a

person must knowingly present (or cause to be presented) a false or fraudulent claim, record or statement to the United States Government.³¹ A "person" under the FCA is broadly construed to mean a corporation or partnership (thus a hospital), and such entities are generally held vicariously liable for the acts and omissions of their employees and agents.³²

The term, "knowingly" under the FCA means the person either (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.³³ *No proof of specific intent to defraud is required.*³⁴ A "claim" under the FCA includes any request or demand . . . for money . . . if the United States government provides any portion of the money or property that is requested or demanded.³⁵ Liability damages may include a civil penalty of not less than \$5,000 and not more than \$10,000, plus three times the amount of damages.³⁶

Because potential FCA violations or alleged violations could arise with the submission of a hospital's claim for payment, hospitals should exercise extra caution in filing submissions, specifically until the CMS can publish further guidance on issues arising from this new rule.

¹CMS Office of Public Affairs, *CMS Improves Patient Safety for Medicare and Medicaid by Addressing Never Events*, Fact Sheets, August 4, 2008, available at <http://www.cms.hhs.gov/apps/media/press/factsheets> (website last visited on October 3, 2008); see also Center for Medicare Advocacy, Inc., *CMS to Hospitals: If It Should Never Happen, We Will Never Pay*, available at, http://www.medicareadvocacy.org/Reform_08_09.25.NeverEvents.htm. (website last visited on 10/13/08).

²*CMS Improves Patient Safety for Medicare and Medicaid*, *supra* note 1; see also CMS Office of Public Affairs, *Medicare and Medicaid Move Aggressively to Encourage Greater Patient Safety in Hospitals and Reduce Never Events*, Press Release, July 31, 2008, available at <http://www.cms.hhs.gov/apps/media/press/release> (website last visited on October 3, 2008).

³*CMS Improves Patient Safety for Medicare and Medicaid*, *supra* note 1; see also CMS Office of Public Affairs, *Medicare Takes New Steps to Help Make Your Hospital Stay Safer*, Fact Sheets, available at <http://www.cms.hhs.gov/apps/media/press/factsheets> (website last visited on October 3, 2008).

⁴*CMS Improves Patient Safety for Medicare and Medicaid*, *supra* note 1.

⁵*CMS to Hospitals*, *supra* note 1; see also Mike Mitka, *Public Private Insurers Refusing to Pay Hospitals for Cost of Avoidable Errors*, Vol. 299, *Jama* No. 21, 2495 (June 4, 2008).

⁶*Medicare and Medicaid Move Aggressively*, *supra* note 2.

⁷*Id.*

⁸*CMS to Hospitals, supra* note 1.

⁹*Medicare and Medicaid Move Aggressively, supra* note 2.

¹⁰Kevin Sack, *Medicare Won't Pay for Medical Errors*, The New York Times, October 1, 2008, available at, [http://nytimes.com/2008/10/01/us/01mistakes.html?](http://nytimes.com/2008/10/01/us/01mistakes.html?ref=health&pagewanted=print)

[ref=health&pagewanted=print](http://nytimes.com/2008/10/01/us/01mistakes.html?ref=health&pagewanted=print) (website last visited on 10/03/08).

¹¹*Id.* at 1.

¹²*Id.* at 1.

¹³*Id.*; see also *Mitka, supra* note 5, at 2.

¹⁴See *Preventable Hospital-Acquired Conditions (HACs), Including Infections*, 73 Fed. Register 48434, 48471 (2008).

¹⁵Institute of Medicine, *To Err Is Human: Building a Safer Health System*, November 1999.

¹⁶*Id.*

¹⁷ *Medicare and Medicaid Move Aggressively, supra* note 2.

¹⁸National Quality Forum, *Serious Reportable Events in Healthcare: A Consensus Report*, 2002.

¹⁹*Medicare and Medicaid Move Aggressively, supra* note 2.

²⁰Medicare law requires CMS to pay acute care hospitals for inpatient stays under the IPPS that establishes prospectively set rates based on the patient's diagnosis. Under the IPPS, the hospital receives a single payment rate for the case based on the Medicare Severity Diagnosis Related Groups (MS-DRG) assigned at discharge. This payment is considered full payment for all costs incurred by the hospital in treating the patient, other than physician services which are paid separately to the physician under the Medicare physician fee schedule.

²¹See *Preventable Hospital-Acquired Conditions (HACs), Including Infections*, 73 Fed. Register 48434, 48471 (2008).

²² *Medicare and Medicaid Move Aggressively, supra* note 2.

²³*Id.*; see also *CMS Improves Patient Safety for Medicare and Medicaid, supra* note 1; *CMS to Hospitals, supra* note 1.

²⁴BNA's Health Care Daily Report, *CMS Cuts Number of "Never Events" For Which It Won't Pay*, Vol. 13 No. 148, August 1, 2008.

²⁵*Medicare and Medicaid Move Aggressively, supra* note 2.

²⁶*CMS Improves Patient Safety for Medicare and Medicaid, supra* note 1; see also Robert Pear, *Medicare Says It Won't Cover Hospital Errors*, The New York Times, August 19, 2007, available at <http://www.nytimes.com/2007/08/19/washington/19hospital.html>. (website last visited on October 3, 2008).

²⁷*Medicare and Medicaid Move Aggressively, supra* note 2.

²⁸Sack, *supra* note 10, at 2.

²⁹*Id.* at 3-4.

³⁰Pear, *supra* note 26.

³¹Robert S. Salcido, *False Claims Act & The Healthcare Industry: Counseling & Litigation*, American Health Lawyers Association, at 28 (Second Ed. 2008).

³²*Id.* at 29.

³³31 U.S.C. § 3729(b).

³⁴*Id.*

³⁵31 U.S.C. § 3729(c).

³⁶*Id.*

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