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WHEN NEVER HAPPENS: IMPLICATIONS OF MEDICARE'S NEVER-EVENT POLICY

Hudson T. Rowland*

NEVER-EVENTS AND HOSPITAL-ACQUIRED CONDITIONS

In 2000, the Quality of Health Care in America project, an organization chartered by the National Academies of Science's Institute of Medicine whose purpose is to improve quality within the American health care system, published *To Err is Human: Building a Safer Health System.* To Err is Human contained many surprises about the status of the health care system. One glaring revelation was that in Colorado and Utah, errors occurred in 2.9% and 3.7% of hospitalizations, respectively. Of these errors, 6.6% resulted in the death of the patient. To make matters worse, in New York State 13.6% of all hospital errors resulted in the patient's death. Extrapolating the data from the Colorado and Utah study, the Institute found that these medical errors resulted in between 44,000 and 98,000...

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2. *Id.* at 1
3. *Id.*
4. *Id.*
deaths per year at a cost of between $17 and $29 billion dollars.\textsuperscript{5}

Realizing that medical errors were far too frequent, the Quality of Health Care Committee, a branch of the Institute of Medicine, developed nine recommendations to improve medical care.\textsuperscript{6} The Committee's recommendations focused on improving the quality of health care on four levels, from creating a national Center for Patient Safety, which would set patient safety goals as well as research ways to prevent errors\textsuperscript{7} to creating various systems within health care organizations themselves to ensure safe practices are followed.\textsuperscript{8}

Following the publication of \textit{To Err is Human}, many states implemented various recommendations from the study.\textsuperscript{9} Many of the recommendations implemented by the various states focus on reporting serious medical errors to a central governmental department, usually the state's department of health.\textsuperscript{10} The statutes making error-reporting mandatory vary by state, with eleven of the twenty-one states with error-reporting requirements analyzed by Weissman allowing confidential reporting and ten states requiring public disclosure.\textsuperscript{11}

Having had their eyes opened to the prevalence of errors in health care, in 2005 Congress enacted a statute which authorized the Centers for Medicare and Medicaid Services (CMS) to adjust the Inpatient Prospective Payment System (IPPS) to encourage hospitals to prevent errors.\textsuperscript{12} The following year, the Deficit

\textsuperscript{5} Id.
\textsuperscript{6} Id. at 5-14
\textsuperscript{7} Id. at 6-8
\textsuperscript{8} Id. at 13-14
\textsuperscript{10} Ind. Exec. Order No. 05-10, 410 IAC 15-1.4-2 et al.; 105 MASS. CODE REGS. 130.331 (2003).
\textsuperscript{11} Weissman, \textit{supra} note 9, at 1360.
\textsuperscript{12} Preventable Hospital-Acquired Conditions (HACs) Including Infections, 73 Fed. Register 23,547-23,548 (April 30, 2008).
Reduction Act (DRA) of 2005 was signed into law. The DRA required the Secretary of the Department of Health and Human Services (HHS) to select International Classification of Diseases-Clinical Modification (ICD-9-CM) diagnosis codes which have a high cost or high volume or both, are within a diagnosis-related group (DRG) "that has a higher payment when the code is present as a secondary diagnosis," and "could reasonably be prevented through the application of evidence-based guidelines." 13

In the year following the enactment of the DRA the HHS and CMS, collaborating with the Centers for Disease Control (CDC) and other health-minded professionals and organizations, began identifying possible Hospital Acquired Conditions (HACs). 14 Along with following the statutory criteria, the HHS looked for conditions which would not occur, so long as the hospital and its staff are engaging in good medical practice. 15 During the collaborative effort, the CMS and CDC prepared a list of thirteen conditions ranging from surgical site infections and pressure ulcers, to Methicillin-Resistant Staphylococcus Aureus (MSRA) and Clostridium Difficile (C. diff.). 16 Following the creation of the list of potential HACs to be included in the rule, the CMS and CDC then began to accept comments to determine which HACs met the statutory criteria. 17

Following the discussion period, CMS and HHS declared that eight HACs met the statutory criteria resulting in the loss of Medicare reimbursement when they were coded as being a secondary diagnosis in Medicare Fiscal Year 2008, beginning on

15. Id.
16. Id. at 24, 717-18
17. Id.
Included in the list are 1) Foreign object retained after surgery; 2) air embolism; 3) blood incompatibility; 4) stage III and stage IV pressure ulcers; 5) fractures, dislocations, and intracranial injuries as well as any crushing injury or burn; 6) catheter-associated urinary tract infection; 7) vascular catheter-associated infection; and 8) surgical site infection-mediastinitis after coronary artery bypass graft surgery. In addition to the eight HACs already selected, CMS and HHS are considering nine conditions to add for Fiscal Year 2009: 1) surgical site infections following total knee replacement, laparoscopic gastric bypass and gastroenterostomy, and ligation and stripping of varicose veins; 2) Legionnaires' disease; 3) diabetic ketoacidosis, nonketotic hyperosmolar coma, diabetic coma, and hypoglycemic coma; 4) iatrogenic pneumothorax, 5) delirium; 6) ventilator-associated pneumonia; 7) deep vein thrombosis and pulmonary-associated embolism; 8) Staphylococcus aureus septicemia; and 9) C. diff.-associated disease. As the commentary period for the Fiscal Year 2009 rules has just ended and HHS' analysis has not yet been published, the following discussion will only cover the conditions selected for Medicare Fiscal Year 2008.

**IMPLICATIONS OF NEVER-EVENTS**

The Centers for Medicare and Medicaid Services (CMS) created the never-event and hospital-acquired condition (HAC) regulation to ensure a high standard of patient care within hospitals. However, by enacting this regulation, hospitals and healthcare providers are suffering unintended consequences.

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19. Id. at 23,550-51.
In 2002 the National Quality Forum (NQF) first promulgated a list of twenty-seven events which they deemed "serious, largely preventable, and of concern to both the public and healthcare providers for the purpose of public accountability." The goal of this list was to encourage hospitals to self-report serious events and in turn improve patient knowledge of hospital practices. The events on the list encompassed events including surgery performed on wrong body part, wrong patient, or wrong surgery; stage III and IV pressure ulcers; death or disability associated with air embolism; sexual assault on a patient; infant discharged to wrong person; and patient death or disability associated with patient elopement, which are not included on the CMS list. The NQF updated their list of serious reportable events in 2006 to include artificial insemination with the wrong donor sperm or donor egg.

Following the NQF update on Serious Reportable Events, the Leapfrog Group, a group comprised of insurers, government entities, and other private organizations whose goal is to "trigger giant leaps forward in the safety, quality and affordability of health care" called for hospitals to enact new policies regarding never-events. This recommendation urged hospitals to report whenever any of the NQF never-events

22. Id.
23. Id.
To promote the reporting of events, Leapfrog stated that hospitals adopting the never-event reporting policy would be included in the Leapfrog Hospital Quality and Safety Survey, a respected online database of hospital information.

Many states have responded to the calls that hospitals report never events. In 2003 Minnesota became the first such state to enact a never-event reporting law. The statute contained a mandatory “adverse health event” reporting requirement covering all of the never-events listed by the NQF. By enacting the Adverse Health Events Reporting law, Minnesota aimed to change the way hospital errors were treated. The legislature hoped to move away from the traditional “blame and train” mindset, where health care providers were often blamed for health care errors, then given training to prevent future mistakes, to a collaborative effort where health care providers have the ability to learn from their mistakes and near-mistakes.

Minnesota’s Adverse Health Events Reporting law requires hospitals to notify the Commissioner of the Minnesota Department of Health of any adverse event within fifteen days of the event’s discovery. Following the Department’s notification, the hospital is required to complete a root cause analysis and corrective action plan and file these two reports with the Commissioner. The Commissioner then is to analyze the root cause analysis and corrective action plan to determine

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27. Id.
31. Id.
32. MINN. STAT. § 144.7065 (2007); MINN. STAT. § 144.7065 (2003).
33. MINN. STAT. § 144.7067(1) (2005).
where the hospital failed and how best to correct these failures.\textsuperscript{34} Once hospitals have received feedback from the Commissioner, they have thirty days to alter their corrective action plan to comply with the Commissioner's recommendation.\textsuperscript{35} Each year the Commissioner is required to publish an annual report which describes the adverse events reported, the corrective action plans, and findings of root cause analyses, and which makes recommendations for modification of state health care operations.\textsuperscript{36} Since the enactment of the law, Minnesota has published four reports on adverse health events in the state. In the first year of reporting (July 1, 2003 – October 6, 2004) ninety-nine events were reported, with the majority of events being surgery-related (fifty-two).\textsuperscript{37} Following a spike in 2005-2006 with 154 total events,\textsuperscript{38} Minnesota had 125 adverse events reported in its most recent report.\textsuperscript{39} Although designed to reduce the number of adverse health events, Minnesota saw a gradual rise in reported events from 2003 to 2006 only to see the number of events drop in 2007. Nowhere is this more prevalent than in surgical procedures, which saw fifty-two events in 2003, only to spike at seventy-four in 2006 and drop to sixty in 2008.\textsuperscript{40} However, Minnesota has made no determination as to why there was such a spike in adverse events in 2006.

Following Minnesota's lead, many states have enacted similar reporting laws. With the exception of Oregon, all of the

\begin{itemize}
\item \textsuperscript{34} MINN. STAT. §144.7067(2) (2005).
\item \textsuperscript{35} MINN. STAT. § 144.7067 (2005); Minnesota Department of Health, Patient Safety, Adverse Events Reporting System, Background on Minnesota's Adverse Health Events Reporting Law, http://www.health.state.mn.us/patientsafety/ae/index.html.
\item \textsuperscript{36} MINN. STAT. §144.7067(2) (2005).
\item \textsuperscript{37} Minnesota Department of Health, Adverse Health Events in Minnesota Hospitals, Public Report (2005), http://www.health.state.mn.us/patientsafety/ae/aereport0105.pdf.
\item \textsuperscript{38} Minnesota Department of Health, Adverse Health Events in Minnesota Hospitals, Public Report 9 (2007), http://www.health.state.mn.us/patientsafety/ae/aereport0107.pdf.
\item \textsuperscript{39} Id.
\item \textsuperscript{40} See generally Minnesota Department of Health, Adverse Health Events in Minnesota Hospitals, Public Reports (2005-2008), http://www.health.state.mn.us/patientsafety/publications/index.html.
\end{itemize}
twenty-five states who have enacted adverse event reporting laws have made reporting mandatory.\textsuperscript{41} Although each state's reporting law was enacted as a result of different circumstances and has differing requirements as to what is required to be reported, these laws have been a resounding success.\textsuperscript{42}

\textit{Payment}

When an error occurs, not only do hospitals have to treat the patient, but they face a decision as how to bill the patient. The current trend is for hospitals to discuss the occurrence of the event with the patient and refrain from billing for serious hospital errors.\textsuperscript{43} Although not statutorily required, one state has entered into an agreement with its state hospital association for hospitals not to bill for medical errors. Following the suggestions of numerous patient safety groups, Minnesota chose to require hospitals to refrain from billing patients if the patient experiences a never-event.\textsuperscript{44} The events selected are the same as the NQF never-events, and are updated whenever the NQF updates its list.

While Minnesota's agreement looks good to consumers, the selection of some of the NQF listed events will not have much of an effect on the hospital's bottom line. This is because generally, when errors occur, hospitals first speak with the patient to inform them of the occurrence of the event. Following the


patient consultation, hospitals then take steps to analyze the patient's bill and ensure only costs associated with their primary diagnosis are billed. This billing policy is in line with Minnesota’s, which requires the same actions by its hospitals.\textsuperscript{45} By following these steps, hospitals have been able to reduce the instances of malpractice lawsuits and improve patient satisfaction after a medical error.\textsuperscript{46}

**INSURANCE**

While hospitals have generally not billed for certain serious events, this is about to change as insurers generally cover the cost of the less-serious never-events. However, many insurers have followed the lead of CMS, Leapfrog, and the NQF and implemented a policy of not reimbursing hospitals when never-events take place.\textsuperscript{47} Insurers across the country, such as Aetna, CIGNA, HealthPartners, and WellPoint have begun testing or fully implementing policies of non-reimbursement around the country.\textsuperscript{48}

One of the first insurers to begin a trial of not paying for never-events was WellPoint, the nation’s largest insurer. Beginning in early 2008, WellPoint began stopping payment for four never-events in Virginia with its Anthem brand.\textsuperscript{49} After testing the program for four months, WellPoint decided to implement the non-payment policy for the eleven CMS listed events,\textsuperscript{50} with the addition of surgeries performed on the wrong

\textsuperscript{45} Id.

\textsuperscript{46} Telephone interview with anonymous representative from hospital, in Ft. Wayne, Ind. (July 15, 2008).


\textsuperscript{48} Id.


body part or wrong patient and wrong surgery performed on a patient.

Like CMS, WellPoint will ensure that no patient or the company is charged when an incorrect surgical procedure takes place. On the other hand, WellPoint will only pay for necessary charges when the eight CMS never events occur. This allows for hospitals to recover some expenses for never-event related care. According to Sam Nussbaum, M.D., executive vice president for clinical health policy and chief medical officer, the decision to follow CMS' lead is a way to ensure patients receive a high standard of care.  

CIGNA, the United States' fifth largest insurer, has also followed CMS' policy. Like WellPoint, CIGNA has chosen to stop paying for the CMS-listed never events beginning October 1, 2008. However, CIGNA's policy is somewhat different. The company has chosen to split the CMS list into "never-events" and "acquired hospital conditions," with different reimbursement policies for each.

Similarly to Medicare's and WellPoint's policies, CIGNA has chosen to refuse payment for "never-events." Never-events are described in CIGNA insurance policies as being "[s]urgical procedures that are performed on the wrong side, wrong site, wrong body part, and wrong person." In coming to this decision, CIGNA stated that these events will not be reimbursed as they are "not medically necessary to diagnose or treat an

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Aimed at Preventing Serious Medical Errors; Company Committed to Protecting Members' Health and Finances by Not Reimbursing Major Preventable Adverse Events (April 2, 2008), http://phx.corporate-ir.net/phoenix.zhtml?c=130104&p=irol-newsArticle_general&t=Regular&id=1124709&..

51. WellPoint Announces Initiative Aimed at Preventing Serious Medical Errors, supra note 50.


54. Id.

55. Id.; CIGNA Corp., CIGNA HealthCare Reimbursement Policy, Never Events and Avoidable Hospital Conditions, p. 2 (effective 10/01/08).
illness, injury, or disease, and is therefore not reimbursable." 56

What makes CIGNA different from WellPoint and Medicare is that CIGNA does not refuse all payment for the other CMS-listed HACs, which are called "acquired hospital conditions" by CIGNA. In CIGNA's reimbursement policy for never-events and avoidable hospital conditions, CIGNA states reimbursement may be denied only when additional inpatient days directly and exclusively resulting from the avoidable hospital condition, contract permitting. 57 This policy allows hospitals more leeway in recovering HAC-related expenses due to the requirement that the extra hospital days were exclusively related to the HAC. As longer hospital stays are generally not attributed to many of the HACs alone, CIGNA's proposal will likely have a lesser impact on the hospital's bottom line.

While Medicare, WellPoint, and CIGNA are not compensating for events listed by the CDC, two insurers have chosen to adopt the proposals by the Leapfrog Group and National Quality Forum in its entirety. Aetna, the third largest health insurer, 58 and HealthPartners, a non-profit insurer only serving customers in Minnesota, 59 have chosen to go farther than their competitors and not reimburse for any of the 28 NQF listed "never-events." 60

Beginning in 2005, HealthPartners chose to implement a policy of not reimbursing hospitals for never-events as well as not allowing hospitals to charge patients for never-event related costs. 61 HealthPartners chose to fully implement the Leapfrog Group's proposals, requiring all hospitals to report to

56. Promoting Patient Safety, supra note 53.
57. CIGNA HealthCare Reimbursement Policy, supra note 55.
58. Fuhrmans, supra note 47.
HealthPartners the details surrounding a never-event in addition to reporting to the state reporting act. By implementing this plan, HealthPartners hopes to accomplish the same goals as Leapfrog, NQF, and CMS, by pushing hospitals to improve patient care. Furthermore, as HealthPartners' clients are generally from Minnesota, the policy stands lockstep with the directives of the state of Minnesota in requiring hospitals to report errors and forbidding hospitals from charging patients for never-events.

While HealthPartners primarily insures patients in Minnesota, a state with strict never-event laws, Aetna has chosen to implement a policy of never reimbursing for never-events throughout its entire network. Following Leapfrog's recommendation that hospitals refrain from charging hospitals for never-event-associated costs, Aetna began considering ways the company could improve patient safety. Aetna then decided to include language in their hospital contracts which requires hospitals to report never-events to one of three organizations within ten days of becoming aware of the never-event. Furthermore, Aetna will not reimburse hospitals for never-event associated expenses and will require hospitals to not bill a patient for any of these costs. According to Troyen Brennan, M.D., Aetna's chief medical officer, implementing Leapfrog's recommendations were done in order to "lead to broader adoption of quality measures and reporting, and [to]

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63. Statement on Never Events, supra note 60.
65. Id.
encourage others in health care to support this effort." 68

Altogether, the decision by WellPoint, CIGNA, HealthPartners, and Aetna will affect over sixty-four million individuals in the United States. 69 While each insurer's policy varies, these decisions have the ability to have a major effect on hospitals and patients.

DO THE CHOSEN EVENTS MEET THE STATUTORY GUIDELINES?

The Deficit Reduction Act of 2005 required the Secretary of the Department of Health and Human Services to select at least two conditions for which Medicare would stop payment. 70 The conditions selected were required to meet the statutory criteria of being: 1) high cost, high volume, or both; 2) be identifiable through individual ICD-9-CM codes as a complicating condition (CC) or major complicating condition (MCC) which would result in a higher paying diagnosis-related group (DRG) if present as a secondary diagnosis, and 3) be reasonably preventable through the application of evidence-based guidelines. 71 As discussed earlier, the Secretary has selected eight conditions he believes meet the statutory criteria. Among those events, three were considered "serious preventable events" and have faced little criticism. 72

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68. Aetna Incorporates Patient Safety Language into Hospital Contracts, supra note 66.


FOREIGN OBJECT RETAINED AFTER SURGERY

For many patients who undergo surgery, being told by their doctor that an item was left behind inside their body is a large fear. To prevent this from occurring, CMS proposed adding "foreign object retained after surgery," a serious preventable event, to their list of events Medicare would not pay for.73 To meet the statutory guidelines, CMS reviewed patient data from 2006 and found 746 cases of a retained object with an average cost of $61,962.74 While not a high volume condition, the statutory requirement of being high cost is present. The second statutory requirement is also met as ICD-9-CM code 998.4 (Foreign body accidentally left during a procedure) is considered a CC by CMS.75 While the website CMS refers to in the Federal Register does not include evidence-based practices to prevent objects from being retained during surgery, many articles have been written on how to prevent these events from occurring.76 Hospitals and other health-care providers agreed with CMS that objects should never accidentally be left inside a patient, and therefore there has been no outcry by hospitals for the inclusion of this event on both the CMS list and the NQF list.

AIR EMBOLISM

Air embolisms occur when an individual experiences gas

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73. CMS Proposes Additions to List of Hospital-Acquired Conditions for Fiscal Year 2009, supra note 71.
bubbles in the bloodstream. While generally non-fatal, there is the potential for an air embolism to cause death.\(^7\) Air embolisms are usually found after SCUBA diving, in a hospital setting they occur when air is inserted into a patient's bloodstream.\(^7\) The frequency of air embolisms is less than retained objects (only forty-five in Fiscal Year 2006), while the cost for each occurrence is similar (average of $66,007 per air embolism).\(^7\) Additionally, the code for air embolisms, 999.1 (Complications of medical care, not otherwise specified (NOS), air embolism), is considered a CC by CMS.\(^8\) Air embolisms are highly preventable, such as performing steps to ensure all air is out of syringes before injecting a patient, placing the patient in the Trendelenburg position prior to inserting a central-venous catheter (CVT), and requiring the patient to perform the Valsava maneuver before removing a CVT.\(^8\) Much like retained objects, there is little concern with this event being added to the list.\(^8\)

**BLOOD INCOMPATIBILITY**

Blood incompatibility occurs when an individual is given the wrong blood type.\(^8\) After a transfusion of the wrong blood type, the patient's blood will begin to clot, resulting in fever, back pain, bloody urine, or renal failure.\(^8\) Blood (ABO) incompatibility is a rare event, only occurring thirty-three times

\(^7\) E. Wesley Ely et al., *Venous Air Embolism from Central Venous Catheterization: A Need for Increased Physician Awareness*, 27 CRITICAL CARE MEDICINE 2113 (1999).

\(^8\) Id.; Franklin R. Smith, *Air Embolism as a Cause of Death in SCUBA Diving in the Pacific Northwest*, 52 CHEST 15 (1967).

\(^7\) Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47, 207.

\(^8\) Id.


\(^8\) Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47, 207.


for Medicare patients in Fiscal Year 2006. Although rare, at an average cost of $46,492 per event, blood incompatibility meets the first requirement, as it is a high cost condition. Blood incompatibility meets the second statutory requirement of having a diagnosis code which is a CC (999.6, Complications of medical care, NOS, ABO incompatibility reaction). Further, there are evidence-based practices which make ABO incompatibility reactions easily preventable by simple steps, such as ensuring the blood meant for the patient matches the patient’s blood type and that the patient’s blood type was accurately recorded in his or her file.

Although blood incompatibility may seem like an event which never should occur, there were objections. The main objection by commentators was that there was no exception for instances when patients are deliberately given unmatched blood, such as when a patient with a rare blood type is suffering from massive blood loss. In response, CMS stated that while there may be a rare emergency when compatible blood may not be available in a hospital, there were no ICD-9-CM diagnosis codes to cover this event. CMS also stated that without a scenario that would fit within existing or new ICD-9-CM codes, an exception to necessary blood incompatibility would not be made.

Hospitals, insurers, and HHS all generally agree that the serious preventable events—objects left during surgery, air embolisms, and blood incompatibility—should never happen. However, the events included on the CMS list, which are not
considered serious preventable events, are more contentious.

**Pressure Ulcers**

CMS believes that one of the most preventable conditions within a hospital setting is pressure ulcers. Pressure ulcers, also known as decubitus ulcers, occur when a person remains in a position for a long period of time without shifting their weight. Depending on the duration of the pressure on the skin, the symptoms range from a reddened area of skin that does not turn white when depressed (Stage I), blistering (Stage II), cratering of the skin (Stage III) and finally skin loss so immense that bone and muscle is exposed and damaged (Stage IV). Since stage I and II pressure ulcers are relatively innocuous and easy to treat, CMS is refusing payment for pressure ulcers which reach stages III or IV.

The selection of pressure ulcers was based on CMS' belief that pressure ulcers should not occur during hospital stays and that patients deserve close examination of their skin during the admission process. With this in mind, CMS analyzed data from Fiscal Year 2006 to determine whether pressure ulcers met the statutory criteria. CMS found that in Fiscal Year 2006, pressure ulcers were diagnosed as a secondary condition 322,946 times with an average cost of $40,318. These figures meet the first criteria of the condition being high cost, high volume, or both, as pressure ulcers are a very common condition within

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93. Id.


95. Id.

96. Id.
The prevalence of pressure ulcers is an issue in and of itself. CMS researched the prevalence of pressure ulcers as a whole, without determining how many Stage III and IV pressure ulcers occurred. Without this information, it is impossible to determine whether the statutory criteria of high cost or high volume is met. Second, the condition is considered a CC or an MCC under current CMS DRGs. Codes 707.00 (Decubitus ulcer, unspecified site), 707.01 (Decubitus ulcer, elbow), and 707.09 (Decubitus ulcer, other site) are CCs while codes 707.02 through 707.07 are MCCs (Decubitus ulcer, upper back, lower back, hip, ankle, and heel respectively).

Lastly, pressure ulcers have known prevention guidelines. In the Federal Register, CMS uses the National Institute of Health guidelines for the prevention of pressure ulcers, and in addition, a PubMed search of "prevention pressure ulcer" and "guideline pressure ulcer" comes up with 3,674 hits.

While there was little mentioned among health care providers regarding the prevalence of pressure ulcers specifically, there was concern among them regarding the inclusion of pressure ulcers in the list. The main concern among those commenting was that, many times, patients enter the hospital with pressure ulcers, making hospitals worried about the ability to be reimbursed for instances where a patient had a pressure ulcer upon admission. Some fears were removed when CMS stated that when "the condition is present on admission, the provision will not apply." This requires hospitals to make a concerted effort to check each patient for

101. Id.
102. Id.
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pressure ulcers upon admission to ensure reimbursement for the condition. However, CMS does admit that "there is some question as to whether all cases with developing pressure ulcers can be identified on admission." This creates a problem if the condition worsens to an easily identifiable pressure ulcer, the decision by CMS to only withhold payment for stage III and IV pressure ulcers should quell this fear.

While CMS makes an exception for pressure ulcers present on admission, it is unknown how most insurers are treating this condition. Aetna and HealthPartners are following the NQF guidelines and refusing to reimburse for any never-event. Within its descriptions of never events, "Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility" are included. This wording is ambiguous. Hospitals should ensure than when negotiating any contract with Aetna or HealthPartners, that the NQF language is not construed to mean every instance a stage III or IV pressure ulcer occurs reimbursement is refused, but that only instances when no pressure ulcer is present on admission do insurers refrain from payment.

Although Medicare will pay for treatment when a pressure ulcer is present on admission (POA), the exceptions should be broadened. Evidence-based medicine shows that, in some instances, pressure ulcers may be unavoidable, a point ceded by HHS. For example, studies have shown an increased risk of pressure ulcers after a patient has experienced at least one stage IV ulcer. Additionally, as Medicare is choosing to pay for instances when a pressure ulcer is POA, there will no doubt be instances when a pressure ulcer is developing, but is unable to be identified when the patient is admitted to the hospital, another point conceded by CMS. Because of these

103. Id.
106. Id.
107. Id.
acknowledged concerns, CMS should create exceptions to the proposed rule. First, for patients who have history of pressure ulcers, CMS should pay for the use of pressure-reducing surfaces, which it does not do now. Pressure-relieving beds have been shown to reduce the instance of pressure ulcers by at least 24% and up to 70%,\textsuperscript{108} and reimbursing for the more expensive care will save money in the long run and improve patient care. Second, Medicare should work with hospitals and physicians in a concerted effort to create better, more well-defined guidelines for pressure ulcer diagnosis. As there are many instances when a pressure ulcer is "borderline," having a better standard would do wonders in improving patient care. With this in mind, CMS should allow for a patient review when patients had a borderline pressure ulcer on admission which might not have been considered a pressure ulcer. This way, CMS would be able to keep its goal of improving patient care intact as well as save money for treatment of "pressure ulcers" which were in fact not present.

WellPoint and CIGNA follow the CMS guidelines. CIGNA has already stated that they will not pay for conditions that are not present on admission "[i]f it is determined that there were additional hospital inpatient days . . . which directly resulted from an avoidable hospital condition (not present on admission) reimbursement for such additional inpatient days may be denied."\textsuperscript{109} Therefore, if an individual is admitted to the hospital with a pressure ulcer of any stage and is insured by CIGNA, CIGNA will continue to reimburse treatment for the pressure ulcer. WellPoint’s policy, however, is somewhat vague. In an April 2, 2008 press release, the company states that it will only pay the “appropriate payment” and ensure “no additional charges are incurred” if HACs occur.\textsuperscript{110} As this policy is “in its


\textsuperscript{109} CIGNA Corp., CIGNA HealthCare Reimbursement Policy, Never Events and Avoidable Hospital Conditions p. 5 (effective 10/01/08) (emphasis in original).

\textsuperscript{110} WellPoint Announces Initiative Aimed at Preventing Serious Medical Errors, supra note 50.
early stages of implementation" hospitals should work alongside WellPoint during the consultation period provided to ensure that when a pressure ulcer of any stage is present on admission, WellPoint continues to reimburse in the unfortunate circumstance of the ulcer progressing into stage III or IV.

**FALLS AND TRAUMA RELATED INJURIES**

The more contentious selection made by CMS is falls and trauma-related injuries. Included in this selection are any fractures, dislocations, intracranial injuries, crushing injuries, or burns resulting from a fall or other trauma within the hospital setting. In performing research as to falls and trauma (and their associated injuries), HHS realized that there were no diagnosis codes for falls and trauma in the hospital. With this in mind, ICD-9-CM code 884.4 (fall from bed) was analyzed. In Fiscal Year 2006 it was found that 2,519 individuals had fallen out of bed at an average cost of $24,962. To prevent falls, CMS directs health-care providers to the Agency for Healthcare Research and Quality, stating that the AHRQ's guidelines for serious preventable events are sufficient.

The selection of falls and trauma is clearly in violation of the statute. First, section 1395ww(d)(2)(D)(iv) requires the Secretary to choose a code which has a high-volume, high-cost, or both. However, in its discussion of the decision to include falls and fractures in the HAC list, the CMS states in the Federal Register that "there is not a code to identify" falls and trauma.

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111. Id.
112. Id.
114. Id.
115. Id.
116. Id.
118. Id.
Second, to analyze whether falls and trauma should be included on the list, CMS only analyzed code 884.4. Finding that implementing code 884.4 and similar codes would be too difficult to implement, CMS decided upon a list of codes that it believes “should not occur during a patient’s hospitalization.”

The codes selected include: 800-829 (fractures), 850-854 (dislocations), 925-929 (crushing injuries), 940-949 (burns), and 991-994 (other and unspecified effects of external causes).

While CMS does state that there were over 175,000 fractures and other traumas in the Medicare population in Fiscal Year 2006, CMS does not have data as to how often these events occur within a hospital setting. These events were chosen without analyzing the statutory requirement that they be high-volume and/or high-cost, and therefore, they do not meet the first element of the statute.

While the first element is not met, fall and trauma-related injuries do meet the second element. All codes selected by CMS for inclusion within the HAC list are considered CCs or MCCs when occurring as a secondary diagnosis.

CMS’ explanation of the rule does not meet the third element of the statute. Although the statute requires the conditions selected to be prevented through evidence-based guidelines, CMS has given hospitals no guidelines to prevent these injuries. In fact, CMS admits that “we have not identified specific prevention guidelines for the conditions described by the above range of codes.” That statement in itself should disqualify falls and trauma from the list. However, recent research has shown that among the sixty-five and older population, the likelihood of one falling is 27%, with up to a 50% chance for individuals having fallen within the past year. Evidence shows that although multifactorial interventions

120. Id. at 47, 214-15.
121. Id. at 47, 215.
122. Id.
123. Id.
reduce the rate of falls by 30% to 40%, it should be limited to patients with a high risk of falls. Because of this, it is impossible to prevent falls in individuals without known risk factors, and therefore it does not meet the criteria for being reasonably preventable by evidence-based medicine.

This situation is similar to CMS' discussion regarding ventilator-associated pneumonia (VAP). VAP was considered for inclusion in the 2008 HAC list but was rejected because the condition was without a unique ICD-9-CM code, or prevention guidelines. As CMS was unable to study the frequency and cost of VAP, it chose not to add VAP to the list, stating that the statutory conditions had not been met. Similarly, CMS has not studied the frequency and cost of any of the fall and trauma-related injuries and therefore does not know if they meet the statutory criteria. CMS also stated that VAP's prevention guidelines were not well known, which parallels falls and trauma. Because not even CMS knows of prevention guidelines, CMS should follow its VAP decision and not include falls and trauma in its list of HACs. While everyone agrees that falls are not something to be desired within a hospital setting, CMS is bound to follow the statute, and just because CMS "believe[s] that these types of injuries should not occur in the hospital" does not mean that the criteria set forth by Congress was met.

**CATHETER-ASSOCIATED URINARY TRACT INFECTIONS**

The most common nosocomial infections found in health care facilities are those of the urinary tract. According to the *American Journal of Medicine*, over one million separate cases of

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125. Id.
127. Id.
128. Id. at 47, 215.
urinary tract infections (UTI) occurred in 1997 alone.\textsuperscript{130} Nearly ten years later, the results were not much improved. In Fiscal Year 2006 alone, the CDC reported 561,667 cases of catheter-associated UTIs.\textsuperscript{131} To make matters worse, studies show that approximately half of all women will suffer from a UTI at least once in their lifetime, with one third of women having a UTI requiring antimicrobial therapy before the age of twenty-four.\textsuperscript{132}

The first element of the statute requires the code selected to have high-cost or high-volume or both.\textsuperscript{133} For catheter-associated UTIs, the average cost of the entire inpatient stay was $40,347 with a total of 11,780 Medicare patients suffering from the condition in Fiscal Year 2006.\textsuperscript{134} Because the average total cost of an individual with a catheter-associated UTI is over $40,000, CMS believes that the statutory requirement of the code being high-cost is met. However, CMS states that “each episode of symptomatic urinary tract infection adds $676 to a hospital bill.”\textsuperscript{135} The discrepancy between the two sums is based on when catheter-associated UTIs are most likely to occur.

Because more than thirty million urinary catheters are used each year, prevention of catheter-associated UTIs is a priority.\textsuperscript{136} The majority of guidelines for catheterization and the prevention of UTIs from catheterization have stated that catheters should be avoided unless medically necessary.\textsuperscript{137} While between 15% and 25% of patients have a catheter in place during their stay in a hospital, the vast majority of urinary catheters are in place for a short duration.\textsuperscript{138} In fact, nearly one-third of patients have

\begin{thebibliography}{99}
\bibitem{130} Id.
\bibitem{131} Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47, 203.
\bibitem{132} Id.; Foxman, \textit{supra} note 129, at 55.
\bibitem{134} Hospital-Acquired Conditions, Including Infections, 72 Fed Reg. 47, 203.
\bibitem{135} Id.
WHEN NEVER HAPPENS

catheters in place for less than one day, and the mean and median duration of catheterization is two and four days respectively.\textsuperscript{139} This is significant as studies have shown that individuals with open-ended catheters in place for longer than four days will nearly always develop a UTI.\textsuperscript{140} As individuals' time in the hospital increases, inevitably the cost of the hospital stay increases as well. Therefore, it is understandable how hospital costs where individuals have a catheter-associated UTI are over $40,000. However, because a single UTI episode only costs on average $676 (with some studies placing the cost as low as $400 per episode\textsuperscript{141}), the high cost requirement of UTIs is not met.\textsuperscript{142}

With the high-cost requirement not met, UTIs must be high-volume to fit the statutory requirements. CMS states that there were 516,667 CDC-reported cases of UTI during Fiscal Year 2006. Of those, 11,780 occurred in Medicare patients.\textsuperscript{143} With nearly forty-four million Medicare beneficiaries,\textsuperscript{144} this equals one infection per 3,735 beneficiaries, or 0.0268%. Moreover, while nearly 40% of Medicare beneficiaries undergo catheterization while hospitalized,\textsuperscript{145} the rate only increases to one infection per 1,500 catheterizations, or 0.066%. With UTIs being so infrequent, the CDC has not met the requirement of the code being high-volume.

The statute requires that there be a code identifying the condition and that the code is either a CC, MCC, or both.\textsuperscript{146} This requirement is not an issue. ICD-9-CM codes 996.64 (Infection

\textsuperscript{139} Id.
\textsuperscript{140} Wong & Hooton, supra note 137; Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47, 203.
\textsuperscript{141} Walter E. Stamm & S. Ragnar Norrby, Urinary Tract Infections: Disease Panorama and Challenges, 183 J. INFECTIOUS DISEASES S1, S1 (2001).
\textsuperscript{142} Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47, 203.
\textsuperscript{143} Id.
\textsuperscript{145} Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47, 203.
and inflammatory reaction due to indwelling urinary catheter) and 559.0 (Urinary tract infection site not specified) are current ICD-9-CM codes. Further, 996.64 is considered a CC by CMS. Therefore, UTIs meet the second element of the statute.

The third requirement is that the condition be reasonably preventable through evidence-based medicine. Commenters to the CMS rule stated their concern that UTIs were not always preventable, such as in cases where the patient was immunosuppressed or when catheters were used for a long period of time, and that there was not enough evidence-based medicine to prevent UTIs from occurring.

To prevent catheter-associated UTIs, CMS points to prevention guidelines from the CDC, which were published in 1981. Since then, much research has been done on UTIs, resulting in conflicting suggestions. CMS and the CDC guidelines state that no open-ended catheter should be in place for longer than four days because infection is inevitable after the four-day mark. However, England's National Health Service infection control guidelines state that "[t]here is no definitive evidence as to the optimal interval for changing catheters in patients." The same guidelines cite a study which found a higher rate of infection is associated with frequent catheter changes. This requires hospitals to face a double-edged sword: follow the CMS and CDC guidelines, change the catheter frequently, and risk having a patient's risk of infection increase.

147. ICD-9 Data, Volume 1 Diagnosis Codes, Injury and Poisoning, Complications of Surgical and Medical Care Not Elsewhere Classified; Complications to Certain Specified Procedures; Volume 1 Diagnosis Codes, Diseases of the Genitourinary System, Other Diseases of the Urinary System, available at https://www.icd9data.com (last visited Feb. 6, 2009).
149. Id. at 47, 204.
150. Id.; Wong & Hooton, supra note 137.
153. See id.
or allow the catheter to remain within the patient for longer than four days, which nearly always results in a UTI.

Closed-system catheterization is generally thought of as being a safer alternative to open-ended systems. While safer, closed-systems are not without their risks. Individuals with closed-systems can develop UTIs from the bacteria in their urine within the storage bag. Although hospitals have placed antimicrobial drugs within the bag, this practice is not recommended because the constant addition of drugs requires the closed system to be broken, allowing for an influx of bacteria into the system. Although patients still develop UTIs while undergoing closed-system catheterization (approximately 20% of patients will develop a UTI during closed-system catheterization), the Scottish National Health Service has found there to be no causative link between the catheterization and UTI. Because there is still debate as to whether UTIs are reasonably preventable, this does not meet the third element of the statute.

The selection of UTI does not meet the statutory criteria set forth in the statute. First, UTIs are not a high-cost condition within hospitals, as each case costs an average of $676, with other estimates as low as $400. The condition is also low-volume, as only 11,780 Medicare patients suffered from catheter-associated UTIs during Fiscal Year 2006 for a total catheter-associated cost of approximately $7,963,280 (out of a total HHS budget of $67.2 billion). Second, UTIs are not always

154. Saint & Lipsky, supra note 137, at 800.
155. Id.
156. Wong & Hooton, supra note 137.
158. Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47, 203; Stamm & Norrby, supra note 141, at SI.
reasonably preventable. As the CDC guidelines state, while hospitals are urged to move patients to closed-system catheters, the infection rate is still above 20%. Therefore, UTIs do not meet the requirements that the condition be reasonably preventable through evidence-based medicine, as the evidence CMS uses states that UTIs are not reasonably preventable.

While everyone agrees that the prevention of UTIs is a noble goal, because the condition does not meet the statutory guidelines, it should be removed, and Medicare should continue to reimburse for any catheter-associated UTI expense. In keeping with the spirit of the statute, Medicare should look into instances and costs of catheter-associated UTIs when individuals had the same catheter in place for more than four days. Because evidence since the 1950's has shown that catheterization for longer than 4 days in an open-ended system will lead to UTIs, as long as CMS is able to show that these events are high cost or high volume, the statutory requirement will be met.

**VASCULAR CATHETER-ASSOCIATED INFECTION**

Vascular catheters are used for a wide variety of medical procedures, from pacemaker implantation to angioplasties. Because of the prevalence of vascular catheters, CMS began to analyze whether vascular catheter-associated infections (VCAIs) met the statutory criteria to be considered for CMS' HAC list.

When CMS first began analyzing VCAI, the department had trouble analyzing the prevalence of the condition. The code for VCAI, 996.62, identifies a wide array of infections and therefore was unsuitable for research purposes. CMS then called for a new coding structure to be used, where 996.62 would be the first

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161. CMS Proposes Additions to the List of Hospital-Acquired Conditions for Fiscal Year 2009, supra note 71.
162. Warren, supra note 138, at 299.
code used, followed by an additional code for the infection in order to identify the VCAIs. Finding this rule to be too onerous, CMS created a new code, 999.31 (infection due to central venous catheter), which was implemented October 1, 2007.

Before the creation of the new code, CMS analyzed data for Fiscal Year 2006 to determine whether VCAIs were prevalent or expensive enough to satisfy the statutory criteria. Because no specific code had been created, CMS looked to the disease reports issued by the CDC. CMS found there to be 248,678 total central line bloodstream infections. However, CMS was not able to identify Medicare data for VCAI, as there was no code available. Further, CMS was unable to determine a cost for VCAI, only stating that "it appears to be . . . high cost."

After opening the floor for comments, CMS received many requests for exceptions if VCAI was to be chosen by the department. Some of the most vocal requests for exceptions revolved around a suggestion that CMS exempt "vascular surgery, implantable device codes, and other obvious sources of existing conditions that cause blood stream infection prior to catheter placement."

Commentators also requested that CMS exclude long-term catheter insertions, such as tunneled CVCs. CMS was receptive to the concerns of the commentators, stating that CMS "[would] consider exceptions to the policy in the circumstances provided in the public comments . . . before the provision becomes effective in FY 2009." As of the writing of this report, however, CMS had not decided upon exceptions to the rule.

Similarly to falls and other trauma, CMS did not have a concrete number regarding the number of times VCAIs occurred

165. Id.
166. Id. at 47, 211.
167. Id. at 47, 210.
168. Id.
169. Id. at 47, 211.
170. Id.
171. Id.
or their average cost. This alone should exclude VCAIs from being considered for implementation in Fiscal Year 2009. However, because it is unlikely that CMS would discard this choice as a whole, there are exceptions that should be considered.

One of the most obvious exceptions that should be included is when the patient has a bloodstream infection prior to the placement of the CVC or from other sources known to cause infection. Some of these concerns are likely to be dismissed by CMS because a patient with a blood stream infection POA or diagnosed prior to the insertion of the CVC will already have his infection costs covered by Medicare. However, it should be reaffirmed by CMS that hospitals will still be reimbursed for these costs because coding problems could arise, leading to confusion regarding when the infection occurred. As for the concern of other existing conditions which predispose one to infections, research has shown that obesity, nicotine use, and HIV/AIDS, among others, correlate to an increased risk of infection. Because in most cases these circumstances that predispose one to having an infection are often uncontrollable, hospitals should not be punished for not being able to prevent the unpreventable.

Because the vascular catheter is so widely used, the fact that a catheter is in place prior to an infection does not mean that the catheter was the cause of the infection. With this in mind, there are additional exceptions that should be considered by CMS. Surgeries have known risks, including the risk of infection. Vascular surgery is no different. For example, patients undergoing lower extremity revascularization have a substantially increased risk of developing infection if vein grafts were part of the procedure. This is in addition to the known

174. Safdar et al., supra note 172, at 467.
175. Jeanette K. Chang et al., Risk Factors Associated with Infection of Lower...
risk factors such as diabetes, malnutrition, and obesity.\textsuperscript{176}

Over 150 million intravascular devices are used per year in the United States, including five million central vascular catheters.\textsuperscript{177} Because the device is used so pervasively in modern health care, CMS should take the advice of the commentators and include exceptions for the HAC payment rule related to infections following vascular surgery, for example instances when the patient has conditions causing infection prior to the placement of the catheter and other similar situations. This would create a more equitable solution to the absolute non-reimbursement CMS is seeking and would help hospitals improve patient care without suffering a large economic loss.

\textbf{SURGICAL SITE INFECTION – MEDIASTINITIS AFTER CORONARY ARTERY BYPASS GRAFT SURGERY}

The final condition included in the CMS list is mediastinitis after coronary artery bypass graft surgery (CABG). CMS initially proposed adding all surgical site infections in the HAC list.\textsuperscript{178} However, CMS began to realize that there would be extensive coding issues, such as the need to develop an ICD-9-CM code to identify the various types of surgical site infections.\textsuperscript{179} The coding issues created a barrier which was too high to overcome in the 2008 proposed rule.\textsuperscript{180} However, during the comment period, "a number of commenters" requested that mediastinitis after coronary artery bypass surgery be considered.\textsuperscript{181}

Following the suggestion of the commentators, CMS began

\textsuperscript{176} Extremity Revascularization: Analysis of 365 Procedures Performed at a Teaching Hospital, 17 ANNALS VASCULAR SURGERY 91, 93 (2003).

\textsuperscript{177} Id. at 94; H.M. Richet, Analysis of Risk Factors for Surgical Wound Infections Following Vascular Surgery, 91 AM. J. MED. 107S, 170S (1991).


\textsuperscript{179} Hospital-Acquired Conditions, Including Infections, 72 Fed. Reg. 47, 212.

\textsuperscript{180} Id.

\textsuperscript{181} Id.
to study mediastinitis after bypass surgery to determine whether the condition met the statutory requirements. First, CMS analyzed Fiscal Year 2006 data for patients receiving CABG (codes 36.10-36.19) who also had ICD-9-CM code 519.2 (mediastinitis) as a secondary condition. Research found a total of 108 instances of Medicare patients developing mediastinitis. The average charge of each case of mediastinitis was $304,747, making the condition high cost, but not high volume. Finally, CMS stated that mediastinitis is reasonably preventable so long as the CDC surgical site infection guidelines are followed.

Much research has been done on the prevention of surgical site infections. From this research, the risk factors for developing an infection after surgery are widely known. In fact, the CDC guidelines discuss nicotine use, steroid use, and malnutrition as risk factors for post-surgical infection. However, the CDC study looked at surgical site infections as a whole, and did not analyze the risk factors for mediastinitis independent of other infections.

One of the more recent studies, a review of 117 patients who underwent cardiac surgery between 1995 and 2001, analyzed various risk factors for mediastinitis. In this study, researchers found obesity and smoking to be among the two largest risk factors for a patient to acquire mediastinitis. These risk factors differed from an earlier study, which found that along with diabetes, obesity, cigarette smoking, and steroid therapy were independent risks for developing mediastinitis.

182. Id.; ICD-9 Data, supra note 147.
185. Id. at 254-55.
186. Id. at 250.
188. Id. at 676.
An earlier study of mediastinitis risk factors came up with slightly different results. In a ten-year review of CABG patients, variables such as renal failure, sex, age, diabetes status, smoking, and chronic obstructive pulmonary disease (COPD) were analyzed. COPD was found to be a significant risk factor for patients undergoing CABG, mirroring previous studies linking COPD and mediastinitis. It is hypothesized that patients with COPD have a higher colonization of bacteria, increasing the susceptibility to infection.

In addition to patient characteristics, studies have analyzed elements of the patient's care to determine if there is anything the hospital can do to lower the risk of mediastinitis. Abboud et al. analyzed various studies which assessed risk factors for mediastinitis. Among controllable factors, it was found that in four of ten studies analyzed, reoperation was a significant risk factor, making it the most common risk factor found (along with obesity). Another study also found similar results, finding reoperation to be a significant risk factor.

The differing opinions on mediastinitis show that prevention is not always reasonably possible. Other infections have widely known, evidence-based risk factors and prevention guidelines. Mediastinitis, on the other hand, is not well understood. Studies on mediastinitis differ regarding the accepted risk factors. Furthermore, "[t]he exact mechanism by which mediastinitis develops is unknown . . . so much so that the several studies performed do not agree among themselves." This lack of knowledge, coupled with studies

191. Id.
192. Id.
194. Baskett et al., supra note 190, at 464.
195. Id. at 462..
196. Abboud et al., supra note 187, at 677.
197. Id. at 680.
198. Id. at 677.
finding that the risk factors for mediastinitis are beyond the hospital's control, shows that mediastinitis is not reasonably preventable except in circumstances of reoperation. As the statutory criteria are not met, mediastinitis after coronary bypass surgery should not be included on HHS' list of hospital-acquired conditions unless the patient must undergo a second procedure. Therefore, CMS should alter the list only to contain mediastinitis after a second coronary artery bypass surgery because this would meet the statutory criteria.

Research has found that the majority of the conditions selected for Medicare's Fiscal Year 2008 HACs list do not meet the statutory criteria. In fact, of the eleven events selected, only three, foreign object left after surgery, air embolism, and blood incompatibility, meet the statutory requirements. As many of the issues with the current selected conditions have to do with prevention guidelines, Medicare should look to Wisconsin's state health plan, which uses evidence-based practices to improve the health of the state.

HEALTHIEST WISCONSIN 2010 – AN EVIDENCE-BASED PLAN

Every ten years the state of Wisconsin is statutorily required to develop a state public health plan. With the enactment of its latest health plan, Healthiest Wisconsin 2010 (HW2010), Wisconsin aimed to increase the well-being of its citizens in eleven priority areas. In working towards meeting its goals, the state used evidence-based practices reviewed by the various teams that worked together to create HW2010. To develop the

202. Id.
program's guidelines, the Department of Health Services created a six-step process to find sufficient evidence-based medicine to improve public health.\textsuperscript{203} The process began with researchers reviewing the implementation plan for HW2010 and then creating search terms for a web-based search. Reviewers then searched evidence-based practice websites, such as the CDC and the National Guideline Clearinghouse, as well as medical journals.\textsuperscript{204} After research had been done, the researchers then reviewed the findings and summarized the information into categories based on effectiveness.\textsuperscript{205} This allowed Wisconsin to prioritize its spending on the most effective programs for meeting its goals and to avoid repeating the mistakes of others with programs found to be ineffective.

Wisconsin's research turned up numerous programs and ideas to help reach its targets. Of the eleven priority areas, nine have enumerated evidence-based practices with only Existing, Emerging, and Re-Emerging Communicable Diseases and Mental Health and Mental Disorders without practice guidelines.\textsuperscript{206} The nine remaining priority areas have three to five guidelines considered "sufficient evidence for effectiveness," meaning that the research done by HW2010 staff found the program or idea to be consistently supporting the recommendation.\textsuperscript{207} The programs and ideas used by HW2010 range from training of state employees to spot warning signs to public-private partnerships which give children a place to go after school.\textsuperscript{208} Using these programs, HW2010 was commenced to improve Wisconsin's overall health.

Five years after developing HW2010, the Department of Health Services issued a status report discussing HW2010 and

\textsuperscript{204} Id. at 2.
\textsuperscript{205} Id. at 4.
\textsuperscript{206} Wis. Dept. Health Serv., Evidence-Based Practices for Healthiest Wisconsin 2010 http://dhs.wisconsin.gov/statehealthplan/practices/index.htm\#priorities (last visited Jan. 6, 2009)
\textsuperscript{207} Id. Follow each link listed below "Health Priorities."
\textsuperscript{208} Id.
any progress that had been made. The research team found that of the 108 total objectives, fifty-nine had seen improvement, with only seventeen objectives having regressed from the 2000 baseline. Of the eleven areas selected for improvement, the largest gains were found in alcohol and other substance use and addiction, (100% improvement, five total objectives), tobacco use and exposure (86% improvement, 12 of 14 objectives, no regression), and social and economic factors that influence health (75% improvement, six of eight objectives, no regression). The least amount of progress made was in the areas of intentional and unintentional injuries and violence (50% improvement, five objectives worse than baseline) and existing, emerging, and re-emerging communicable diseases (20% improvement, two objectives worse than baseline, 6 objectives had no change).

The area Wisconsin found the most improvement in was alcohol and other substance use and addiction. Within this area, Wisconsin created goals to reduce the percentage of high school students a) binge drinking in the past 30 days, b) using marijuana in the past 30 days, c) smoking cigarettes in the past 30 days, d) reporting alcohol use before the 13th birthday, and e) reporting marijuana use before the 13th birthday. From the 2000 baseline, each objective had seen between 3% and 15% improvement.

To reach its goals, Wisconsin developed programs designed to educate students on the dangers associated with substance abuse. One of its largest successes was the CASASTART (Striving Together to Achieve Rewarding Tomorrow) program. CASASTART is a program developed by CASA (Center on Addiction and Substance Abuse, a program developed by health

210. Id. at 4.
211. Id. at 7, 9.
212. Id. at 4.
213. Id.
professionals to help combat substance abuse)\textsuperscript{214} to reduce the use of drugs and alcohol among students eight to thirteen.\textsuperscript{215} Designed as a partnership between CASA, the state department of health, and various schools, the program consists of eight "core services," individually tailored to each student during his participation in the CASASTART after-school program.\textsuperscript{216} To assist students, CASA pairs each student and his family with a case manager, meeting at least once per week.\textsuperscript{217} Wisconsin chose to use the CASASTART program based on its effectiveness. CASASTART has been shown to reduce the likelihood of a student using drugs and increase the test scores of a school.\textsuperscript{218} Using past performance as a guide, Wisconsin's choice to participate in CASASTART helped reduce the percentage of students using alcohol, cigarettes, and marijuana dramatically.\textsuperscript{219}

Wisconsin's program has shown that by using a well-researched plan, governments are able to increase the well-being of their citizens. In the five years since the implementation of HW2010, Wisconsin has seen improvement in 55% of its objectives, with many of the improved areas meeting their goal five years early.\textsuperscript{220} HW2010 demonstrates that a partnership between governmental agencies, universities, researchers, and other individuals in the private sector can create a plan based on intrinsic evidence which can be used to improve the health of all.

\textsuperscript{214} The National Center on Addiction and Substance Abuse at Columbia University, About CASA, http://www.casacolumbia.org (last visited Feb. 6, 2009).
\textsuperscript{216} CASA, supra note 214, at Youth Programs.
\textsuperscript{218} Id.
\textsuperscript{219} Annual Status Report, 2005, supra note 209.
\textsuperscript{220} Id.
CONCLUSION AND RECOMMENDATIONS

The statute was implemented to improve patient care through a denial of payment to hospitals when a selected condition takes place. On the other hand, the state of Wisconsin has created a program to improve the state’s overall health through a partnership between the state department of health, universities, and other health providers. While the two programs have their differences, CMS can learn from Wisconsin and HW2010 to create a more reasonable plan to improve patient safety.

Very few individuals argue that there are conditions which should never occur under a hospital’s watch. CMS identified three of these conditions (retained object, air embolism, blood incompatibility) which were selected without much discord. Furthermore, CMS reiterated its stance on wrong site, wrong type, and wrong patient surgery, stating that these procedures had not been paid by Medicare in the past and would continue to not be paid in the future.

Dissent arises, however, when health care providers move further down the CMS list. Many comments were received regarding falls, pressure ulcers, and the three types of infection included on the list; “Is there evidence showing that these conditions are truly preventable?” “Do these conditions meet the other statutory requirements?” In addition, hospitals have to be concerned by the decision by Aetna and HealthPartners not to reimburse hospitals for any condition selected by the NQF. While CMS and insurers have patient safety in mind, a noble goal, these organizations are going about achieving their goal in the wrong way.

To improve patient safety, CMS should implement a four-step plan. First, CMS should follow the statutory requirements and continue to include retained objects, air embolisms, and blood incompatibility on the list of conditions which should not take place in a hospital. Second, a public-private partnership should be created whose purpose is to create a list of conditions which meet the statutory requirements and to analyze relevant
research on the prevention of the proposed conditions. Third, benchmarks should be created from the conditions selected in step two, allowing for a longer transition for the implementation of the conditions. Finally, a review panel should be created whose purpose is to analyze the currently-selected conditions, ensuring new research has not made the condition unavoidable.

The first step of my proposed plan is to remove pressure ulcers, falls and trauma, and the three infections from the list of HACs. Implementing step one of the proposed plan would be of little difficulty. The statute requires at least two diagnosis codes to be selected, which would be met by preserving retained object after surgery, air embolism, and blood incompatibility. As discussed in their respective sections, the conditions proposed for removal do not meet the statutory criteria for being selected. For example, CMS admits that there is no evidence it can find to help prevent falls.221 By removing the conditions, Medicare is able to remove ambiguity from the program and spend more time analyzing prevention guidelines.

The second step of my proposed plan is to create a partnership that would function similarly to Healthiest Wisconsin 2010's research team and would consist of individuals from CMS, CDC, HHS, insurers, universities, and health-care providers. The group would first create a list of conditions to analyze based on internal discussion and public comment, much like the way in which the current HAC list was created. Researchers would then evaluate the conditions, ensuring that the statutory criteria are met. Because the most contentious element of the statute is that the conditions be "reasonably preventable," researchers would analyze relevant research on the prevention of the conditions much like HW2010 selected its evidence-based practices. The group would then assign points to each condition based on the research found, with points being given when research shows the preventability of the condition and points subtracted when conflicting studies or research

shows that the condition cannot be prevented. The group would then select a cutoff point where any condition exceeding the number of points would be selected for the HAC list (as long as the other conditions are met).

An issue that could arise with this plan is the analysis of a condition which is found not to have an individualized ICD-9-CM code. This, however, is of little concern. In creating the current HAC list, CMS faced this same problem with vascular catheter associated infections. While ultimately not selected for the HAC list, CMS created a specific code for VCAIs, allowing the condition to meet the coding element of the statute.\textsuperscript{222} If this problem was to come up during the analysis period, the partnership should go through the process necessary to create a new ICD-9-CM code and determine whether it meets the requirement of being high cost, high volume, or both in one year’s time after the code can be properly analyzed.

HW2010 has shown that a public-private partnership works in this capacity. HW2010 researchers were able to analyze research on 109 different health goals, ranking the studies by effectiveness. By evaluating research, HW2010 staff was able to determine whether their goals were attainable within ten years, and to adjust the goals according to research. As of its last report, HW2010 has seen an improvement in over half of its goals, and other goals were fully met five years ahead of schedule. By using HW2010’s methods as a model, CMS will be able to create a more complete and equitable list of conditions meeting the statutory criteria.

A major issue with CMS’ current plan is how sudden it is put into effect. Hospitals will go from being reimbursed for these conditions one day to not being reimbursed the next. With this in mind, step three proposes that the partnership team mentioned in step two create benchmarks for improvement in the selected conditions. The benchmarks would tie reimbursement to the number of times the selected condition

\textsuperscript{222} Id. at 47, 210
takes place within a hospital. For example, if Condition X occurs in 5% of patients and is found to be reasonably preventable, benchmarks would be established so that X would only occur in 3% of patients after one year and 1% of patients after two years. Reimbursement would then be tied to the hospital’s improvement, where if the 3% benchmark was not met, hospitals would not receive reimbursement for any time the condition occurred past the benchmark, continuing until the benchmark period was finished.

The creators of HW2010 realized that major improvements in health cannot be done overnight. However, this fact seems to have been overlooked by CMS. By easing into the new regulations, health care facilities will be able to have at least a full year to implement research-based best practices to prevent the conditions from taking place. The current plan forces hospitals to radically alter their finances as conditions for which they once were reimbursed are suddenly being taken off the table, which is an unfair proposition.

The final step of my proposed plan is to have a committee review the selected conditions on a biannual basis. While the current law allows for conditions to be removed from the list, there are no processes in place to allow for this to happen. Because advances in health care are constantly occurring, the review process must be ensured. The proposed review process would analyze any new research on the conditions up for review. If sufficient evidence is found to show that the condition is no longer reasonably preventable, or that benchmarks need to be reworked, the committee would be permitted to make this decision.

Requiring an evaluation ensures that the conditions still meet the statutory criteria of being reasonably preventable. In the current HAC list, three conditions are infections, and with more types of bacteria becoming resistant to antibiotics, it is possible that conditions considered reasonably preventable on their selection will be preventable. Furthermore, research may show that the best practices suggested by the partnership were
not as good as suggested. The review period would allow for benchmarks to be adjusted accordingly, so that a condition which once seemed on track to be greatly reduced during its transition period could have its targets readjusted to stay in line with current research.

As it stands now, CMS' plan to refuse payment for eleven HACs creates an unfair burden on hospitals. By implementing the four-step plan allowing for a committee to propose, review, and revise conditions which are being considered for admission onto the HAC list, CMS will be able to achieve its goal of improving patient care while using best practices and evidence-based medicine.