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NOTE

NEVER SAY NEVER: “NEVER EVENTS” IN MEDICARE

John Crist[†]

INTRODUCTION

In 2004, James Klotz suffered a heart attack. After he was admitted to the hospital, surgeons surgically implanted a pacemaker in him.¹ While he recovered from surgery in the hospital, Klotz developed a drug-resistant staph infection that required fifteen additional operations and eighty-four additional days in the hospital.² Klotz subsequently “lost his right leg, part of his left foot, a kidney, and most of his hearing.”³ Klotz sued his heart surgeon for medical malpractice. In 2008, a jury awarded Klotz and his wife \$2.5 million.⁴

Who should bear the cost when medical errors⁵ such as this occur?⁶ Critics of the traditional fee-for-service reimbursement model –

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¹ Betsy McCaughey, *Hospital Infections: Preventable and Unacceptable*, WALL ST. J., Aug. 14, 2008, at A11.

² *Id.*

³ *Id.*

⁴ *Id.*

⁵ This Note generally differentiates medical *risks* from medical *errors*, or *mistakes*. For purposes of this Note, a medical risk is the chance that the patient will suffer from a known, yet unintended, consequence of care that exists despite proper care of the doctors and/or staff. An example of a medical risk is the risk of an infection. In contrast, a medical mistake is a serious breach of proper care. An example of a medical mistake is an operation on the wrong limb.

⁶ There is no universally accepted definition of what a medical error is. However, Albert W. Wu, et al. provide a helpful definition. They define a medical mistake as “[a] commission or an omission with potentially negative consequences for the patient that would have been judged wrong by skilled and knowledgeable peers at the time it occurred, independent of whether there were any negative consequences.” Albert W. Wu et al., *To Tell The Truth: Ethical and Practical Issues in Disclosing Medical Mistakes to Patients*, 12 J. GEN. INTERNAL MED. 770, 770 (1997). Though Wu uses the term “mistake” instead of “error,” the two are oftentimes used

in which physicians are paid for each service performed – argue that it focuses too heavily on the quantity of care given, without regard to quality, outcomes, or overall costs of care.⁷ Thus, they argue that the traditional model is flawed because it bases a doctor's compensation on the number of services rendered, instead of the overall health of the patient.⁸ In other words, "providers [that] deliver suboptimal care may end up earning more for subsequent consultations, hospitalizations, and procedures than those whose skill yields a quick, definitive diagnosis and cure."⁹ Some commentators have suggested replacing the traditional model with a "pay-for-performance model,"¹⁰ which would predicate a physician's pay upon the health of the patient treated.¹¹ Accordingly, the doctor would only receive payment if the treatment proved to be helpful to the patient.

Recently, academics, the government, and the media have all, in various ways, suggested that a pay-for-performance model would help reduce preventable medical errors (PMEs). Their suggestions culminated in a change of the reimbursement policy used by the Centers for Medicaid and Medicare Services (CMS) and many private insurers. In October 2008, CMS halted reimbursements for eight categories of hospital-acquired conditions (HACs) – conditions that CMS determined to be serious and reasonably preventable.¹² In its 2009 final rule, CMS expanded the number to ten.¹³ Generally, these conditions are widely referred to as Never Events because they are events that should ideally never happen.¹⁴ As a result, health care payers (includ-

interchangeably. See, e.g., Richard T. Penson et al., *Medical Mistakes: A Workshop on Personal Perspectives*, 6 *ONCOLOGIST* 92, 94 (2001).

⁷ See William M. Sage, *Pay for Performance: Will it Work in Theory?*, 3 *IND. HEALTH L. REV.* 305, 310 (2006).

⁸ See Robin J. Fisk, *What Are Never Events and Why Do They Matter?*, Nov. 6, 2008, <http://www.passionforsubro.com/never-events/what-are-never-events-and-why-do-they-matter/>; see also *CTRS. FOR MEDICARE & MEDICAID SERVS., ELIMINATING SERIOUS, PREVENTABLE, AND COSTLY MEDICAL ERRORS - NEVER EVENTS* (2006), <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1863>.

⁹ Sage, *supra* note 7, at 310.

¹⁰ Pay for Performance is perhaps best described by William M. Sage as a system that "[rewards] physicians for health rather than illness." *Id.* at 307.

¹¹ See *id.*

¹² Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems, 72 *Fed. Reg.* 47,130, 47,218 (Aug. 22, 2007) (to be codified at 42 *CFR* pts. 411, 412, 413, 489).

¹³ Bureau of Nat'l Affairs, *CMS Cuts Number of 'Never Events' For Which it Won't Pay, Issues Other Rules*, 17 *BNA'S HEALTH L. REP.* 1069 (2008).

¹⁴ McCaughey, *supra* note 1.

ing CMS) subject these conditions to reduced reimbursement and/or to reporting requirements.¹⁵

Refusing to reimburse hospitals for a preventable class of events should, theoretically, deter hospital complacency to the occurrence of those events.¹⁶ By making the hospital (instead of the insurance company, or, alternatively, the patient) bear the costs of a medical error, the hospital will likely take enhanced preventative measures to avoid wasted costs that would thereby reduce the occurrence of the events.¹⁷

This Never Events policy represents a schism in the health care community. While CMS and private insurers argue that this policy will reduce medical errors and improve quality of care,¹⁸ other commentators have suggested that the Never Events policy will have the opposite effect and adversely affect care.¹⁹ In particular, these entities argue that the Never Events policy will negatively affect fundamental hospital relationships, such as the physician-client relationship²⁰ and the hospital-physician relationship.²¹ Additionally, they argue that the Never Events policy will affect malpractice insurance premiums and coverage²² and will restrict the access of those with poor health to healthcare services.²³

The purpose of this Note is to discuss the history of Never Events and to illuminate how these events have evolved. This Note begins by briefly explaining what Never Events are, in broad terms. Section II explains the creation and evolution of the Never Events policy – tracing it from nonprofit patient advocacy organizations to the federal and state governments. Section III argues that this policy unfairly punishes hospitals by refusing to reimburse for conditions that are not preventable. Finally, Section IV recommends that CMS should revise its Never Events policy to include only conditions that hospitals can truly prevent.

¹⁵ See generally Fisk, *supra* note 8.

¹⁶ *Id.*

¹⁷ Hence, by refusing to reimburse the hospitals for the costs of care associated with these events, insurers create an incentive for doctors to invest in preventative measures that could presumably reduce hospitals errors. See *id.*

¹⁸ E.g., Rachel Deutsch, *The Federal Role in Reducing Hospital-Acquired Conditions: Are Medicare Reimbursement Incentives Enough?* 42 COLUM. J.L. & SOC. PROBS. 1 (2008); see also Sheryl Tatar Dasco et al., *The "Never Events": What It Means For Physicians*, 10 J. HEALTH CARE COMPLIANCE 33, 33 (2008).

¹⁹ Dasco et al., *supra* note 18, at 34.

²⁰ *Id.*

²¹ *Id.*

²² *Id.* at 35.

²³ CTR. FOR MEDICARE ADVOCACY, INC., CMS TO HOSPITALS: IF IT SHOULD NEVER HAPPEN, WE WILL NEVER PAY, http://www.medicareadvocacy.org/InfoByTopic/Reform/Reform_08_09.25.NeverEvents.htm (last visited May 3, 2010).

I. WHAT ARE NEVER EVENTS?

At a general level, a Never Event is a preventable condition that a patient acquires at a hospital. By definition, Never Events are secondary diagnoses, which are conditions concurrent to primary conditions.²⁴ In other words, Never Events are conditions that are distinct from the condition for which the hospital admitted the patient. Thus, Never Events are usually thought to be conditions that patients acquire in a hospital, although, as this Note will show, this belief does not always prove to be true.²⁵ Accordingly, because a “Never Event” typically occurs while the patient is in the hospital, it is crucially important that hospitals correctly diagnose and classify what conditions its patients present upon admission. To this end, CMS requires that hospitals indicate when a condition is present on admission through the use of a claim code.²⁶ Practically, this means that hospitals must have two specialists on staff: a doctor to diagnose what conditions the patient has; and a coding specialist, who must rely on the doctor’s notes to determine what claim codes CMS requires.²⁷

Depending on the source, the term can refer to different conditions. For example, the National Quality Forum (“NQF”) originally listed twenty-eight preventable medical errors that it considered Never Events,²⁸ whereas CMS uses the term to refer to ten categories of preventable HACs.²⁹

²⁴ For an explanation of primary and principal diagnoses, see generally, JOANN C. ROWELL & MICHELLE A. GREEN, UNDERSTANDING HEALTH INSURANCE: A GUIDE TO PROFESSIONAL BILLING 123 (7th ed. 2004).

²⁵ This is so because a patient could develop a non-apparent condition before her admittance to a hospital and unless the condition is detected by the hospital during admission her condition could be labeled as a “Never Event.” For example, a stage-one pressure ulcer is difficult to detect, especially in individuals with dark skin tones. WOUND OSTOMY & CONTINENCE NURSES SOC’Y, POSITION STATEMENT: PRESSURE ULCER STAGING (2007), http://www.wocn.org/pdfs/WOCN_Library/Position_Statements/PressureUlcerStaging.pdf.

²⁶ See Fisk, *supra* note 8.

²⁷ See Linda Wilson, *POA Coding Challenges: Concern Grows Over Quality of Documentation*, MODERN HEALTHCARE, June 2, 2008, at 10.

²⁸ NAT’L QUALITY FORUM, SERIOUS REPORTABLE EVENTS IN HEALTHCARE – 2006 UPDATE: A CONSENSUS REPORT (2007), http://www.qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare%E2%80%932006_Update.aspx [hereinafter NAT’L QUALITY FORUM 2006].

²⁹ These Hospital Acquired Conditions are: (1) foreign object retained after surgery; (2) air embolism; (3) blood incompatibility; (4) stage III and IV pressure ulcers; (5) falls and traumas (fractures, dislocations, intracranial injuries, crushing injuries, burns and electric shock); (6) manifestations of poor glycemic control (diabetic ketoacidosis, nonketotic hyperosmolar coma, hypoglycemic coma, secondary diabetes with ketoacidosis, secondary diabetes with hyperosmolarity); (7) catheter-

II. THE BACKGROUND OF NEVER EVENTS

For over ten years, various policy groups have attempted to shed light on Preventable Medical Errors (PMEs). In 1999, the Institute of Medicine ("IOM") published *To Err is Human: Building a Safer Health Care System*.³⁰ In that report, the IOM relied on different studies that estimated PMEs are responsible for the deaths of up to 98,000 patients each year,³¹ making medical errors a leading cause of morbidity and mortality in the United States.³² In other words, PMEs lead to more annual deaths in the United States than breast cancer, motor vehicles accidents, or AIDS.³³

In addition, the IOM estimated that the total cost of PMEs falls somewhere between seventeen and twenty-nine billion dollars.³⁴ In a follow-up study, the Centers for Disease Control and Prevention ("CDC") estimated that hospital-acquired infections cost the U.S. health care system five billion dollars annually.³⁵ Other studies suggest that hospitals generally do not follow the recommended guidelines to avoid preventable hospital-acquired infections.³⁶ Accordingly, these studies suggest that doctors and staff could significantly reduce costs, save lives, and increase care by simply practicing rigorous hygiene – including washing hands, sterilizing equipment, and other simple precautions.³⁷ One report in particular suggested that

associated urinary tract infection; (8) vascular catheter-associated infection; (9) surgical site infection following: coronary artery bypass graft, bariatric surgery (laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery), orthopedic procedures (spine, neck, shoulder, elbow); and (10) deep vein thrombosis. Fisk, *supra* note 8.

³⁰ INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 2000), available at <http://orsted.nap.edu/openbook/0309068371/html/>.

³¹ *Id.* at 1.

³² *Id.*; see also Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, 73 Fed. Reg. 48,434, 48,471 (Aug. 19, 2008) (to be codified at 42 C.F.R. pts. 411, 412, 413, 422, 489).

³³ INST. OF MED., *supra* note 30, at 1.

³⁴ *Id.* at 2.

³⁵ Nat'l Inst. of Child Health & Human Dev., Nat'l Inst. of Health, *Story of Discovery: The First Vaccine Against Hospital-Acquired Infection*, Sept. 1, 2006, <http://www.nichd.nih.gov/news/resources/discovery/2004/staph.cfm>.

³⁶ Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, 73 Fed. Reg. at 48,471.

³⁷ See BETSY MCCAUGHEY, *UNNECESSARY DEATHS: THE HUMAN AND FINANCIAL COSTS OF HOSPITAL INFECTIONS 1* (2nd ed. 2006) (summarizing efforts taken by Denmark, Holland, and Finland that have successfully reduced hospital infections).

eighty-seven percent of hospitals fail to take the recommended steps to avoid four of the most common infections.³⁸

Expectedly, these pronouncements reverberated throughout the health care community.³⁹ Almost immediately afterwards, policy groups began to draft and discuss solutions that would, hopefully, decrease the occurrence of PMEs.⁴⁰

In 2002, the National Quality Forum (NQF)⁴¹ released *Serious Reportable Events in Healthcare*,⁴² a report that listed twenty-seven clearly identifiable and preventable medical errors that posed serious consequences for patients.⁴³ In 2006, NQF updated the list to include

³⁸ The four common infections are aspiration and ventilator associated pneumonia, central venous catheter related bloodstream infection, surgical site infection, and influenza (staff vaccination against the flu). Press Release, Leapfrog Group, Eighty-Seven Percent of Hospitals Do Not Take Recommended Steps to Prevent Infections (Sept. 10, 2007), http://www.leapfroggroup.org/media/file/Leapfrog_hospital_acquired_infections_release.pdf.

³⁹ E.g., H.T. Stelfox et al., *The "To Err is Human" Report and the Patient Safety Literature*, QUALITY & SAFETY HEALTH CARE, Apr. 2006, at 174 (2006); see also Stephen M. Sullivan et al., *Ensuring "Never Events" Never Happen: CMS Halts Reimbursement to Providers for Certain Conditions*, 23 DENNIS BARRY'S REIMBURSEMENT ADVISOR 3, 3 (2007).

⁴⁰ See, e.g., Randall R. Bovbjerg & Laurence R. Tancredi, *Liability Reform Should Make Patients Safer: "Avoidable Classes of Events" Are a Key Improvement*, 33 J.L. MED. & ETHICS 478 (2005) (arguing that Never Events claims should be paid promptly through an insurance process rather than through adjudication).

⁴¹ NQF is a not-for-profit membership group, established to develop and implement a national strategy for health care quality measurement and reporting. NQF endorses quality measures for national use through the use of evidence-based quality information to develop preferred practices for all types of settings. JOINT COMM'N RES., TOOLS FOR PERFORMANCE MEASUREMENT HEALTH CARE: A QUICK REFERENCE GUIDE 14 (2nd ed. 2008).

⁴² NAT'L QUALITY FORUM, SERIOUS REPORTABLE EVENTS IN HEALTHCARE: A CONSENSUS REPORT (2002), http://www.qualityforum.org/Publications/2002/Serious_Reportable_Events_in_Healthcare.aspx [hereinafter NAT'L QUALITY FORUM 2002].

⁴³ The 27 events are: unintended retention of a foreign object in a patient after surgery or other procedure; patient death or serious disability associated with patient elopement (disappearance); patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration); patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products; patient death or serious disability associated with an electric shock or elective cardioversion while being cared for in a healthcare facility; patient death or serious disability associated with a fall while being cared for in a healthcare facility; surgery performed on the wrong body part; surgery performed on the wrong patient; wrong surgical procedure performed on a patient; intraoperative or immediately post-operative death in an ASA Class I patient; patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility; patient death or serious disability associated with the use or function of a device in patient care, in

"artificial insemination with the wrong donor sperm or wrong egg" as a Never Event, bringing the total number to twenty-eight.⁴⁴ The NQF placed each event under one of six categories,⁴⁵ including patient protection (i.e., infant discharged to the wrong person), criminal events (i.e., sexual assaults on patients in a healthcare setting), and surgical events (i.e., surgery performed on the wrong body part), among others.⁴⁶

Notably, the NQF primarily sought to establish a consensus among healthcare stakeholders about which events to select.⁴⁷ To facilitate this, NQF adopted a rigorous screening process to each proposed event and sought a consensus from physicians, hospitals, and healthcare providers, including "public and private purchasers; national, regional, state, and local groups representing consumers; accrediting bodies; supporting industries; and organizations involved in healthcare research or quality improvement."⁴⁸

which the device is used or functions other than as intended; patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility; infant discharged to the wrong person; patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility; maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care facility; patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility; death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates; stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility; patient death or serious disability due to spinal manipulative therapy; any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substance; patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility; patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility; any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider; abduction of a patient of any age; sexual assault on a patient within or on the grounds of the healthcare facility; and death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare facility. *See id.* at 6-7.

⁴⁴ NAT'L QUALITY FORUM 2006, *supra* note 28, at 14.

⁴⁵ The categories are: surgical, product of device, patient protection, care management, environment, or criminal. NAT'L QUALITY FORUM, SERIOUS REPORTABLE EVENTS (SRES): TRANSPARENCY & ACCOUNTABILITY ARE CRITICAL TO REDUCING MEDICAL ERRORS, http://www.lumetrasolutions.com/uploadedFiles/consulting/about-lumetra/enewsletters/lqi/about-lumetra/NQF_NeverEvents_Factsheet%281%29.pdf (last visited May 3, 2010) [hereinafter NAT'L QUALITY FORUM SRE].

⁴⁶ *Id.*

⁴⁷ *See* NAT'L QUALITY FORUM 2006, *supra* note 28, at 2.

⁴⁸ *See* NAT'L QUALITY FORUM SRE, *supra* note 45.

The 2006 NQF report termed these conditions “serious reportable events” or Never Events, indicating that these events should never happen in a hospital.⁴⁹ In reality, NQF applied a lower than “never” standard – stating that the conditions need be “largely preventable, and very serious.”⁵⁰ NQF hoped that the list would be the basis for a nationwide reporting system that would subsequently reduce the occurrence of these events.⁵¹

Soon after, other organizations began to support similar initiatives. For example, the Leapfrog Group for Patient Safety⁵² endorsed the NQF’s list of Never Events.⁵³ Additionally, Leapfrog announced that it would publicly recognize hospitals that: (1) apologized to the patient/family affected by the event; (2) reported the event to at least one reporting agency; (3) performed a root cause analysis; and (4) waived all costs directly related to the event.⁵⁴ Leapfrog has subsequently encouraged its members to support its policy, leading to public support of the plan by Aetna, GM, IBM, and others.⁵⁵

States also adopted similar policies. In 2003, Minnesota began requiring hospitals to report the original twenty-eight Never Events as described by the NQF.⁵⁶ As of July 2008, nearly half of the hospitals participating in a Leapfrog survey have adopted Leapfrog policies.⁵⁷ In addition, hospital associations from Vermont, Massachusetts, and Washington have since agreed to stop billing for all or part of the er-

⁴⁹ LEAP FROG GROUP, FACTSHEET: NEVER EVENTS (2008).

⁵⁰ Press Release, The Nat’l Quality Forum, National Quality Forum Updates Endorsement of Serious Reportable Events in Healthcare 1 (Oct. 16, 2006), http://s.wsj.net/public/resources/documents/WSJ_PR_SeriousReportableEvents_10-15-06.pdf.

⁵¹ *Id.*

⁵² Leapfrog Group for Patient Safety is an advocacy group that represents many of the nation’s largest corporations and purchasers of health benefits with a stated goal of “mobilizing employer purchasing power to alert America’s health industry that big leaps in health care safety, quality and customer value will be recognized and rewarded.” Leapfrog Group, About Us, http://www.leapfroggroup.org/about_us (last visited May 3, 2010).

⁵³ Leapfrog Group, Leapfrog Group Position Statement on Never Events, http://www.leapfroggroup.org/for_hospitals/leapfrog_hospital_quality_and_safety_survey_copy/never_events (last visited May 3, 2010).

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ MINNESOTA DEP’T OF HEALTH, ADVERSE HEALTH EVENTS IN MINNESOTA: 5TH ANNUAL PUBLIC REPORT 1 (2009), <http://www.health.state.mn.us/patientsafety/ae/09ahereport.pdf>.

⁵⁷ Press Release, Nat’l Bus. Coal. on Health, National Business Coalition on Health Endorses New CMS ‘Never Events’ Policy (Sept. 29, 2008), <http://nbch.org/index.asp?bid=78>.

rors identified by NQF.⁵⁸ State Medicaid programs have also begun to follow suit. For example, both Pennsylvania and New York announced that they would terminate reimbursement for PME's because they were not medically necessary to treat illnesses.⁵⁹

Private insurers have also taken notice of Never Events. Well-Point and CIGNA announced that they would cease to pay hospitals when "serious preventable errors" occur.⁶⁰ Specifically, CIGNA would discontinue payments for conditions that could have been avoided by use of widely accepted industry standard procedures.⁶¹

The Federal Government soon began to take similar actions to reduce preventable medical errors. Most notably, Congress passed the Deficit Reduction Act of 2005⁶² ("DRA"), which aimed to cut Medicaid and Medicare expenses by requiring the Secretary of Human Health and Services to choose at least two "high-cost or high-volume" preventable, hospital-acquired conditions that the CMS would no longer reimburse.⁶³ The DRA required that any the condition had to meet at least two out of the three guidelines:

- (1) be either high cost, high volume, or both;
- (2) be reasonably preventable through the application of evidence-based guidelines;⁶⁴ and

⁵⁸ Fisk, *supra* note 8.

⁵⁹ JoNel Aleccia, *More States Shred Bills for Awful Medical Errors*, MSNBC.com, Aug. 12, 2008, <http://www.msnbc.msn.com/id/26081421>.

⁶⁰ Cigna denies complete reimbursement for serious preventable errors and grants only partial reimbursement for "avoidable hospital conditions." Cigna defines serious preventable errors as "surgical procedures that are performed on the wrong side, wrong site, wrong body part or wrong person." Cigna defines avoidable hospital conditions as: "objects left inside a patient during surgery; air embolism, or sudden artery blockage from air bubbles introduced during surgery; use of the wrong blood type during transfusions; infections from urinary catheters; pressure ulcers, also known as bed sores; infections from central vein catheters; mediastinitis, an often fatal inflammation in lung tissue; and hospital-acquired injuries, such as fractures, dislocations, and burns." CIGNA HEALTHCARE, PROMOTING PATIENT SAFETY: CIGNA TO STOP REIMBURSING HOSPITALS FOR NEVER EVENTS AND AVOIDABLE HOSPITAL CONDITIONS (2008), http://newsroom.cigna.com/article_display.cfm?article_id=888.

⁶¹ Fisk, *supra* note 8.

⁶² The Deficit Reduction Act of 2005, codified at 42 U.S.C. § 1395ww(d)(4)(D)(iv) (2007).

⁶³ *Id.*

⁶⁴ § 1395 ww(d)(4)(D)(iv)(I-II) (2006). In explaining "evidence-based guidelines," CMS stated: "[s]elected conditions must be considered reasonably preventable through the application of evidence-based guidelines. By reviewing guidelines from professional organizations, academic institutions, and entities . . . we evaluated whether guidelines are available that hospitals should follow to prevent the condition from occurring in the hospital." Thus, evidence-based guidelines might be described as any guidelines that would help a hospital avoid these events. Medicare

(3) have a diagnosis code that clearly identified the condition and assigned the patient to a higher pay rate.⁶⁵

In its 2008 proposed rule, CMS initially considered adopting fourteen categories of HACs that the CMS would exclude from reimbursement and invited the public to comment to ensure that the events complied with the standards set by the DRA.⁶⁶ CMS further distinguished four of the proposed HACs as “serious preventable events”⁶⁷ because these conditions originated from the NQF’s original list of Never Events.⁶⁸ These conditions are as follows: leaving an object in a patient; performing the wrong surgery on a patient (surgery on the wrong body part, wrong patient, or the wrong surgery); failing to prevent air embolisms following certain surgeries; and providing incompatible blood or blood products to patients.⁶⁹

In its 2008 Final Rule, CMS responded to the public comments and chose the following categories of HACs: (1) catheter-associated urinary tract infection (UTI);⁷⁰ (2) pressure ulcers;⁷¹ (3) serious pre-

Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, 73 Fed. Reg. 23,527, 23,549 (Apr. 30, 2008) (to be codified at 42 C.F.R. pts. 411, 412, 413 et al.). A guideline is evidence-based if it is based on clinical research. Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, 73 Fed. Reg. 48,434, 48,474 (Aug. 19, 2008) (to be codified at 42 C.F.R. pts. 411, 412, 413, 422, 489). CMS did not further define the *reasonably preventable* standard or list any criteria that would make a condition reasonably preventable. CMS simply stated that the DRA “does not require that a condition be ‘always preventable’ in order to qualify as an HAC” and that reasonably preventable “. . . implies something less than 100%.” *Id.*

⁶⁵ Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 24,679, 24,716 (proposed May 3, 2007) (to be codified at 42 C.F.R. pts. 411, 412, 413, 489). For an explanation of diagnosis-related groups and the IPPS reimbursement, see generally *id.* at 24,716-24,718.

⁶⁶ *Id.*

⁶⁷ *Id.* at 24,718.

⁶⁸ Although NQF also lists “Stage 3 or 4 Pressure Ulcers” as a Never Event, CMS confusingly does not list Pressure Ulcers as an SPE. See NAT’L QUALITY FORUM 2006, *supra* note 28, at 14.

⁶⁹ See Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. 47,130, 47,218 (Aug. 22, 2007) (to be codified at 42 CFR pts. 411, 412, 413, 489).

⁷⁰ Catheter-Associated UTI is the most common type of healthcare-related infection. CTR. FOR DISEASE CONTROL & PREVENTION, AN OVERVIEW OF CATHETER-ASSOCIATED URINARY TRACT INFECTIONS (UTI) (2009), http://www.cdc.gov/ncidod/dhqp/dpac_uti.html.

⁷¹ A pressure ulcer is a wound in the skin that can be caused by pressure from sitting or lying in one place too long. NAT’L HEALTH QUALITY CAMPAIGN, PRESSURE ULCER FACT SHEET (2008), <http://www.nhqualitycampaign.org/files/factsheets/Staff%20Fact%20Sheet%20-%20Reducing%20Pressure%20Ulcers.pdf>.

ventable event – foreign object left in the body after surgery; (4) serious preventable event – air embolism;⁷² (5) serious preventable event – blood incompatibility; (6) vascular catheter-associated infection; (7) falls/burns/crushing injuries; and (8) surgical site infections following coronary artery bypass graft surgery.⁷³

The next year, CMS selected two additional conditions – manifestations of poor control of blood sugar level and deep vein thrombosis (pulmonary embolism).⁷⁴ CMS also expanded the category of "Surgical Site Infections" to include infections following certain elective procedures.⁷⁵ With the addition of these two categories, CMS brought the total number of HACs to ten.⁷⁶

In order to understand the effect that the Never Events policy will have, it is necessary to possess a brief understanding of how CMS reimbursement policy.⁷⁷ CMS reimburses hospitals through the Inpatient Prospective Payment System (IPPS).⁷⁸ IPPS bases payment upon specific, prearranged rates for hospital care.⁷⁹ Typically, IPPS

⁷² Air embolisms result from gas bubbles entering the arteries, veins or capillaries. This results in poor oxygen delivery to the areas supplied by the affected circulation and can lead to death. Undersea & Hyperbaric Med. Soc'y, Air or Gas Embolism, <http://www.uhms.org/ResourceLibrary/Indications/AirorGasEmbolism/tabid/271/Default.aspx> (last visited May 3, 2010).

⁷³ Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. at 47,217-47,218. In addition, the following were considered but not chosen: (1) ventilator-associated pneumonia; (2) staphylococcus aureus septicemia; (3) deep vein thrombosis/pulmonary embolism; (4) methicillin-resistant staphylococcus aureus; (5) clostridium difficile; and (6) wrong surgery. *Id.*

⁷⁴ Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, 73 Fed. Reg. 48,434, 48,475 48,489 48,481. (Aug. 19, 2008) (to be codified at 42 C.F.R. pts. 411, 412, 413, 422, 489).

⁷⁵ Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, 73 Fed. Reg. at 48,477 48,478 48,479. CMS proposed nine conditions originally, but ended up only selecting two. The nine conditions it proposed are: (1) surgical site infections following certain elective procedures; (2) Legionnaires' Disease; (3) extreme blood sugar derangement; (4) collapse of the lung resulting from medical treatment; (5) delirium; (6) ventilator-associated pneumonia; (7) deep vein thrombosis/pulmonary embolism; (8) staph infection in the bloodstream; and (9) Clostridium Difficile-Associated Disease ("CDAD"). *Id.* at 48,433-49,083.

⁷⁶ Sage, *supra* note 7, at 307; *see also* CTRS. FOR MEDICARE & MEDICAID SERVS., HOSPITAL-ACQUIRED CONDITIONS, http://www.cms.hhs.gov/HospitalAcqCond/06_Hospital-Acquired_Conditions.asp (last visited May 3, 2010).

⁷⁷ *See generally* CTRS. FOR MEDICARE & MEDICAID SERVS., ACUTE INPATIENT PPS: OVERVIEW (2009), <http://www.cms.hhs.gov/acuteinpatientpps/> (describing the payment system for operating costs of acute care hospital inpatient stays under Medicare based on prospectively set rates).

⁷⁸ *Id.*

⁷⁹ Fisk, *supra* note 8; Medicare Program; Proposed Changes to the Hospital

does not take into account the length of the hospital stay.⁸⁰ When a hospital admits a Medicare-insured patient, the hospital must classify the patient's conditions into a diagnosis-related group (a classification with pre-arranged reimbursement rates) and report the primary⁸¹ and secondary⁸² diagnoses.⁸³ When the coding for a Never Event appears during hospitalization, CMS will no longer pay the higher rate for treating the condition unless the present-on-admission code is present.⁸⁴ If the code is not present, Medicare assumes that the condition was hospital-acquired and refuses to pay for the higher reimbursement rates.⁸⁵

III. THE DIFFERENT STANDARDS OF NEVER EVENTS

As previously indicated, the Never Events concept has evolved over time and so has the list of conditions and events to which that the label applies.⁸⁶ Accordingly, as the list changed, so did the standard used by the organization to compile that list. This section will argue that the standard CMS used to compile its list of Never Events was vastly different than the standard used by its predecessors, specifically the NQF.⁸⁷

When NQF adopts a plan, it signifies that the plan has gone through a rigorous vetting process and that its "science . . . and its salience in public reporting have been verified"⁸⁸ This vetting process involves collaboration with all areas of the health care industry – including providers, insurers, employers, consumer groups, professional associations, and labor unions.⁸⁹ NQF refers to its consensus

Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 24679 (May 3, 2007).

⁸⁰ *Id.*

⁸¹ A "primary diagnosis is the most significant condition for which services and/or procedures were provided." ROWELL & GREEN, *supra* note 24, at 123.

⁸² A secondary diagnosis encompasses any concurrent condition that coexists with the primary diagnosis and includes complications – usually conditions that develop subsequent to inpatient admission. *Id.*

⁸³ See Dave Carpenter, 'Never' Land, HOSP. & HEALTH NETWORKS, Nov. 2007, at 34, 37-38.

⁸⁴ Fisk, *supra* note 8.

⁸⁵ *Id.*

⁸⁶ Cf. NAT'L QUALITY FORUM 2002, *supra* note 42, with Fisk, *supra* note 8.

⁸⁷ *Id.*

⁸⁸ Jean DerGurahian, *New Rules Drawing Fire: Hospitals Say CMS' New Policies Lack Direction*, 38 MOD. HEALTHCARE 8, 8 (2008).

⁸⁹ JOINT COMM'N RES., *supra* note 50.

standards as the "gold standard" for the measurement of health care quality.⁹⁰

The same cannot be said about CMS's vetting process. Whereas NQF strives for consensus among the health care industry, CMS seeks consensus within the Department of Human and Health Services and other federal departments.⁹¹ As a result, NQF chooses conditions that medical professionals could easily prevent; whereas CMS chooses conditions that it could easily categorize and define.⁹² Perhaps unsurprisingly, commentators have criticized CMS for its selection process and questioned whether hospitals could actually reduce the occurrence of these events by following CMS's suggestions.⁹³

This distinction is significant, as NQF's list of Never Events would ultimately improve hospital care because each event meets two out of three key characteristics. First, that it is completely avoidable; second, that it is the result of a medical mistake – not simply a risk of hospitalization or an illness; and third, that it is avoidable through the adoption of simple, practical guidelines. As this section will demonstrate, by using a different standard to select Never Events, CMS chose events that are not avoidable, that are not the result of a medical mistake, and that do not have sufficient prevention guidelines to assist the hospital in averting the occurrence of an event.

This section begins by examining the standard set by NQF by analyzing two conditions it adopted as Never Events: "Wrong Site Surgery" and "Foreign Object Retained in the Body Following Surgery." Then, this section analyzes two of the CMS Never Events – "Catheter-Associated Urinary Tract Infections," and "Trauma Caused by Falls." Comparing the two standards, this section then contrasts the two standards to demonstrate how CMS's standard departs from that originally set by NQF.⁹⁴

⁹⁰ Press Release, Nat'l Quality Forum, National Quality Forum Endorses Consensus Standards for Quality of Hospital Care (May 15, 2008), http://www.qualityforum.org/News_And_Resources/Press_Releases/2008/NATIONAL_QUALITY_FORUM_ENDORSES_CONSENSUS_STANDARDS_FOR_QUALITY_OF_HOSPITAL_CARE.aspx.

⁹¹ CTRS. FOR MEDICARE & MEDICAID SERVS., THE RULE MAKING PROCESS FOR ADMINISTRATIVE SIMPLIFICATION: WHAT IS TAKING SO LONG?, <http://www.cms.hhs.gov/HIPAAGenInfo/Downloads/RuleMakingProcess.pdf> (last visited May 3, 2010).

⁹² See DerGurahian, *supra* note 88.

⁹³ See *id.*

⁹⁴ Some commentators have expressed concerns that the Never Events policy could affect medical malpractice suits. See Charles D. Brown et al., *Litigation Impact of Never Events*, HEALTH LAW, NEWS, Feb. 2008, at 27, available at <http://www.fullbright.com/images/publications/Never%20Events%20Article.pdf>. Never Events would likely only aid plaintiffs as a means of discrediting an expert

witness or in support for the argument that the Never Events extend an already-existing inference of negligence.

First, Never Events could serve to discredit an expert witness. *Id.* Consider a scenario in which an elderly woman, recovering from hip displacement, voluntarily leaves her hospital bed and falls, even though the hospital staff implemented all proper fall precautions. *Id.* at 27.

As a result of the fall, the elderly woman suffers painful and costly injuries and sues the hospital for negligence. *Id.* The hospital would rely on an expert witness to argue that the staff did not act unreasonably. The plaintiff could pose the following line of questioning:

Ms. Expert, you have testified that you believe that falls can occur even where no negligence has occurred? You believe that not all falls are preventable? Are you aware that CMS has studied this precise issue?

Id. at 28. Facing this line of questioning, the expert witness has two choices. *Id.* She could admit that she is aware that CMS determined that falls are reasonably preventable through the application of evidence-based guidelines; or admit that she is unaware of CMS's reimbursement policy which could make her look "unqualified, incompetent, and uninformed." *Id.*

Secondly, a plaintiff might argue that Never Events create a rebuttable inference of negligence. Several states adopt a rebuttable inference of negligence for two Never Events – when a foreign object was unintentionally left within the body of the patient following surgery; and when a surgical procedure was performed on the wrong patient, wrong limb or part of the patient's body. Lisa Frye Garrison, *Addressing the Potential Litigation Impacts of CMS's "Never Events" Rules*, http://www.healthcarelawnote.com/media/20080516_handout.pdf (last visited May 3, 2010). A plaintiff could attempt to extend a similar rebuttable inference of negligence to all of the Never Events- and argue that CMS's refusal to reimburse a hospital implies a liability determination.

As a solution, states might consider the implementation of legislation that excludes the use of Never Events determinations as evidence of negligence of the hospital staff. A strong precedent for this is set by the so-called "apology laws." See Marlynn Wei, *Doctors, Apologies and the Law: An Analysis and Critique of Apology Laws*, 39 J. HEALTH L. 104 (2006). These laws exclude apologies from court as evidence of a doctor's liability. *Id.* In other words, as a result of these laws, a doctor can apologize for mistakes to his patient without legal liability implications. MAXWELL J. MEHLMAN & DALE A. NANCE, *MEDICAL INJUSTICE: THE CASE AGAINST HEALTH COURTS* 98 (2007). Supporters of these laws believe that an apology would encourage doctors to disclose errors to patients, and force both parties to move towards reconciliation. Wei, *supra*, at 108.

Never Events share two important similarities to apologies. First, like apology-laws, Never Events were adopted for larger policy reasons – a cost-cutting measure and an incentive for hospitals to improve care – and not as an allocation or indication of fault. Second, like apology-laws, by removing Never Events from the courtroom, states would be encouraging disclosure and reconciliation. Specifically, legislatures would be encouraging the accurate reporting of preventable medical errors. Accordingly, legislatures should enact laws that forbid Never Events from being admitted

A. Foreign Objects Retained in the Body Following Surgery

Take, for example, "Foreign Objects Retained in the Body Following Surgery", a condition on the original NQF list.⁹⁵ Medical professionals accidentally leave a foreign object in a patient's body in one out of every thousand to fifteen hundred intra-abdominal operations.⁹⁶ One report suggests that foreign objects are left nearly indiscriminately throughout the body and in every major cavity following surgery.⁹⁷ Sponges are the most common objects left in the body following surgery, accounting for seventy percent of these events.⁹⁸ Other common objects include towels, instruments and sharps, and device fragments, including pieces of wire or tubes.⁹⁹ Further, retention of a foreign object is nine times as likely to occur in an emergency operation and four times as likely to occur when an operation involves an unexpected change in procedure.¹⁰⁰

This condition demonstrates three important characteristics about the standard that NQF used in selecting a list. First, the event has serious consequences upon the patient. In the present example, leaving a foreign object in the body of a patient has very serious repercussions on that patient's health¹⁰¹ and may even lead to death.¹⁰² A study in the *New England Journal of Medicine* examined twenty-four cases where a foreign object was accidentally left in the abdominal cavity following surgery.¹⁰³ In the twenty-four observed cases, all the patients suffered from serious complications arising from the retained object, and two of the patients died as a result of the foreign object.¹⁰⁴ Other common adverse results include readmission to the hospital,

as evidence in court.

⁹⁵ NAT'L QUALITY FORUM 2002, *supra* note 42; *see supra* note 43.

⁹⁶ Atul A. Gawande et al., *Risk Factors for Retained Instruments and Sponges After Surgery*, 348 NEW ENG. J. MED. 229, 230 (2003).

⁹⁷ *See id.* at 231.

⁹⁸ A. Gonzalez-Ojeda et al., *Retained Foreign Bodies Following Intra-Abdominal Surgery*, 46 HEPATO-GASTROENTEROLOGY 808 (1999).

⁹⁹ Petra S. Berger & Gordon Sanders, *Objects Retained During Surgery: Human Diligence Meets Systems Solutions*, PATIENT SAFETY & QUALITY HEALTHCARE NEWSLETTER (Sept. 2008), available at <http://www.psqh.com/sep0ct08/objects.html>.

¹⁰⁰ Gawande, *supra* note 96, at 232.

¹⁰¹ Cedars-Sinai Health Sys., *Elimination of Retained Foreign Objects Task Force*, http://www.csmc.edu/pf_11749.html (last visited May 3, 2010).

¹⁰² A. Lincourt et al., *Retained Foreign Bodies After Surgery*, 138 J. SURGICAL RES. 170 (2007).

¹⁰³ Gonzalez-Ojeda et al., *supra* note 98.

¹⁰⁴ *Id.*

additional surgery, infection, and small-bowel obstruction.¹⁰⁵ Financially, the costs of removing a foreign object can be extremely costly – costs can run up to \$50,000 per incident.¹⁰⁶

Second, the event is always the result of a hospital mistake. In other words, a foreign object retained in the body following surgery is “a medical error that should never happen, not a risk that every patient must accept.”¹⁰⁷ Of the twenty-four cases, neither the hospital (where the operation occurred) nor the surgeons (who performed the operation) recognized that they had left an instrument inside the patient.¹⁰⁸ Instead, the hospitals discovered the error after the patients reported a wide array of symptoms to their physicians, including non-specified abdominal pain, persistent sinus, intra-abdominal sepsis, and vaginal discharge.¹⁰⁹

Third, the event is avoidable. Many commentators consider the retention of sponges and foreign instruments in the body a completely avoidable event.¹¹⁰ The American College of Surgeons recommends the following guidelines to prevent the retention of objects in the body following surgery: (1) standardized counting procedures for sponges, sharps, instruments; (2) methodical wound exploration exploring wounds before closure; and (3) effective communication among operative team members.¹¹¹ A report in the *New England Journal of Medicine* suggests that by standardizing counting procedures for medical instruments, such as designating team members responsible to methodically explore the wound before closure, hospital staff could greatly reduce any possibility of leaving a foreign object in a body following an operation.¹¹² Further, the U.S. Food and Drug Administration suggests that if medical professionals were to merely inspect devices prior to and immediately following usage, they would be able to determine whether the instrument was likely to be, or had been, damaged during surgery, a leading cause of retention.¹¹³

¹⁰⁵ Berger & Sanders, *supra* note 99.

¹⁰⁶ Gawande, *supra* note 96, at 232.

¹⁰⁷ See generally John R. Clarke et al., *Getting Surgery Right*, 246 ANNALS SURGERY 395 (2007) (reporting on state-wide incidents of wrong-site surgery in hospitals and ambulatory surgical centers).

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ Lincourt et al., *supra* note 102.

¹¹¹ R.R. Cima et al., *Incidence and Characteristics of Potential and Actual Retained Foreign Object Events in Surgical Patients*, 207 J. AM. C. SURGEONS (2008).

¹¹² Gawande et al., *supra* note 96, at 234; see also Cima, *supra* note 111.

¹¹³ U.S. Food & Drug Admin., Public Health Notification: Unretrieved Device Fragments (Jan. 15, 2008), <http://www.fda.gov/cdrh/safety/011508-udf.html>.

Thus, by analyzing "Foreign Objects Retained in a Body Following Surgery," one can learn a great deal about the high standard set by NQF in its selection of Never Events. Namely, that this event fits three important requirements. First, that the event is completely avoidable;¹¹⁴ second, the event is always the result of a medical mistake – not the result of hospitalization or an illness;¹¹⁵ and third, the event is avertable through the adoption of simple, practical guidelines.¹¹⁶

B. Wrong-Site Surgery

Similarly, other NQF Never Events exhibit the same high standard. For example, the NQF also vetted "surgery performed on the wrong body part" (or "wrong-site surgery") before selecting it as a Never Event.¹¹⁷ In so doing, NQF ensured that it selected an event that was completely avoidable; the result of medical mistakes; and avertable through simple guidelines.

A 2006 study by the Archives of Surgery, which examined over two million malpractice liability cases in Massachusetts over a twenty-year period, estimated that non-spine wrong-site surgery occurs once in nearly one hundred thirteen thousand operations.¹¹⁸ If this statistic holds up nationally, it would mean that throughout the country "wrong-site surgery was reported to insurance companies or a lawsuit was filed once every five to ten years at any one hospital."¹¹⁹

According to the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), the number of wrong-site surgeries increased during the years 1996 through 2002.¹²⁰ Wishing to counter-

¹¹⁴ Lincourt et al., *supra* note 102.

¹¹⁵ Gwande, *supra* note 96.

¹¹⁶ *Id.*

¹¹⁷ Of the four NQF events that CMS considered adopting in its 2008 proposed rule, wrong-site surgery is the only one that CMS did not select. Although commentators strongly urged for its adoption as an HAC, CMS could not fit the event into its pre-existing codes. See Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. 47,130, 47,218 (Aug. 22, 2007) (to be codified at 42 CFR pts. 411, 412, 413, and 489). However, some state Medicaid programs still received reimbursement requests for wrong-site surgery. See Medical News Today, New York Medicaid Program to Stop Reimbursing Hospitals for Preventable Errors (June 11, 2008), <http://www.medicalnewstoday.com/articles/110769.php>.

¹¹⁸ Mary R. Kwaan et al., *Incidence, Patterns, and Prevention of Wrong-Site Surgery*, 141 ARCHIVES SURGERY 353, 354 (2006).

¹¹⁹ Clarke et al., *supra* note 107, at 395.

¹²⁰ See Nancy M. Saufi, *Sentinel Event: Wrong-Site Surgery*, 17 J. PERIANESTHESIA NURSING 420, 420 (2002).

act this trend, JCAHO identified a number of factors that increased the risk of wrong-site surgeries.¹²¹ Increased risk was present when more than one surgeon was involved in the operation, when surgeons performed multiple procedures on a patient during a single operation, when unusual time pressures were involved, when emergencies and operations involved unusual patient characteristics.¹²² JCAHO named communication breakdowns as the leading cause of wrong-site surgeries.¹²³ Put another way, wrong-site surgery is a reflection of “the accuracy and completeness of information brought to the point of care, the quality of professional communication, and the degree of teamwork among the members of the operating team.”¹²⁴

As noted, wrong-site surgery is rare, making it difficult to evaluate the effectiveness of guidelines.¹²⁵ However, JCAHO refers to certain protocols as baselines upon which all hospitals would be able to build.¹²⁶ These protocols are applicable to all settings¹²⁷ and include three independent verifications of the surgical site,¹²⁸ unequivocally marking the operation site,¹²⁹ and ensuring agreement of the procedure with the operating surgeon, anesthesiologist, and circulating nurses.¹³⁰ Confirming this, an article in the *Permanente Journal* suggests that a simple pre-operation discussion with operation staff could have a significant impact on reducing the occurrence of wrong-site surgeries.¹³¹ Further, the *Annals of Surgery* study found that hospital staff could have prevented over sixty percent of the incidents by following standard hospital protocol, such as marking the operation site before surgery, using a preoperative verification process, and resolving uncertainties with staff through proper communication.¹³²

¹²¹ *Id.*

¹²² *Id.*

¹²³ Joint Comm’n on Accreditation of Healthcare Orgs., Sentinel Event Alert: A Follow-up Review of Wrong Site Surgery (2001), http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_24.htm.

¹²⁴ Clarke et al., *supra* note 107, at 402.

¹²⁵ Martin A. Makary et al., *Operating Room Briefings and Wrong-Site Surgery*, 204 J. AM. C. SURGEONS 236, 236 (2007) (citing Martin A. Makary, *Patient Safety in Surgery*, 243 ANNALS SURGERY 628, 628 (2006)).

¹²⁶ Joint Comm’n on Accreditation, *supra* note 123.

¹²⁷ *Id.*

¹²⁸ Press Release, N.Y. State Dep’t of Health, New York State Health Department Releases Pre-Operative Protocols to Enhance Safe Surgical Care (Feb. 8, 2001), <http://www.health.state.ny.us/press/releases/2001/preop.htm>.

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ James Defontes & Stephanie Surbida, *Preoperative Safety Briefing Project*, 8 PERMANENTE J. 21 (2004).

¹³² Kwaan et al., *supra* note 118, at 355.

As with "Foreign Retention of Objects in the Body Following Surgery," one can learn a great deal about the high standard set by NQF in its selection of Never Events. First, wrong-site surgery is an avoidable event. Second, wrong-site surgery is "a medical error that should never happen, it is not a medical risk that a patient must accept . . ." ¹³³ It is often the direct result of negligence by the doctors and staff, or the result of a communication breakdown between members of the operating team. ¹³⁴ Third, that a hospital could completely avoid wrong-site surgery through the use of simple guidelines. ¹³⁵ Here, again, NQF chose an event that met the same three key characteristics – the event is avoidable; the result of a medical error; and is avertable through the adoption of simple guidelines.

C. The Standard Set by CMS

As this section will demonstrate, CMS's list of Never Events demonstrates a much lower standard than that applied by the NQF. ¹³⁶ Accordingly, though CMS asserts that its list of Never Events are reasonably preventable through evidence-based guidelines, some commentators have suggested that CMS abandoned, to a great deal, the consensus that the National Quality Forum (NQF) used as a framework to select the original list of Never Events. ¹³⁷

Notably, there are serious problems with the evidence-based guidelines that CMS advocates. ¹³⁸ As discussed in Section II, one of

¹³³ Clarke et al., *supra* note 107, at 395.

¹³⁴ *Cf.* Defontes et al., *supra* note 131 (addressing the problems of wrong anatomical site or wrong patient surgical procedures through an improved climate of communication among members on the surgical team).

¹³⁵ See generally Clarke et al., *supra* note 107.

¹³⁶ CMS focuses largely on the *costs* of care, which may not be synonymous with the *standard* of care. Accordingly, CMS selects events that have high costs over events that a hospital could truly prevent and could thereby improve the standard of care.

¹³⁷ See DerGurahian, *supra* note 88.

¹³⁸ Critics have pointed out numerous concerns with evidence-based guidelines in general. See generally Carter L. Williams, *Evidence-Based Medicine in the Law Beyond Clinical Practice Guidelines: What Effect Will EBM Have on the Standard of Care?*, 61 WASH. & LEE L. REV. 479 (2004). For example, evidence-based guidelines do not reflect common clinical experience, and advocate inconsistent legal standards. *Id.* at 500 (stating that the "current standard of care analysis is potentially inconsistent with the practice of evidence-based medicine"). Accordingly, CMS's second criteria for the selection a Never Event – that it be reasonably preventable through the application of evidence-based guidelines – does not necessarily reflect a widely approved standard in the medical profession. In other words, what CMS advocates as an evidence-based guideline may be contrary to medical standards of care. *Id.* Accordingly, a hospital that is faced with the possibility of a Never Event would

the DRA's requirements was that any HAC that CMS chose must "reasonably have been prevented through the application of evidence-based guidelines."¹³⁹

This is the case for three reasons. First, CMS often chose conditions that are not preventable. In other words, they are conditions that would occur even with proper medical care. Second, the HACs are often the result of ordinary medical *risks* and not, as was the case with the NQF list, the result of a medical *mistake*. Third, CMS advocates that hospitals adopt evidence-based guidelines (to avoid the occurrence of a HAC) that are often vague and inapplicable. As a result, CMS financially punishes a hospital for events that are beyond the hospital's control and for not following unrealistic, inapplicable guidelines. This section illustrates the effect of this change by analyzing two of the events chose by CMS – urinary tract infection and "Injuries Sustained from Falls."

1. Catheter-Associated Urinary Tract Infection (UTI)

At first glance, catheter-associated urinary tract infection (UTI) might seem like a strong candidate to be included as a Never Event – it affects a common necessity of hospitalization – the use of a catheter¹⁴⁰ – and is among the most common infections in acute and long-term care facilities¹⁴¹ -- affecting between six hundred thousand to one million patients a year.¹⁴² Of the original thirteen conditions it proposed, CMS believed that this condition best met the criteria for an HAC.¹⁴³ Further, catheters are among the most widely used devices in hospitals.¹⁴⁴ Moreover, the consequences of a UTI can be devastating, ranging from an additional day of hospital care to death.¹⁴⁵ Addition-

have two choices: institute a standard contrary to the medical standards of care (and thereby open itself up to tort litigation) or provide the patient proper care without hope for reimbursement.

¹³⁹ Deficit Reduction Act of 2005, *supra* note 62.

¹⁴⁰ An estimated twenty-five million indwelling urethral catheters sold in the United States annually. Sanjay Saint et al., *Are Physicians Aware of Which of Their Patients Have Indwelling Urinary Catheters?*, 109 AM. J. MED. 476, 476 (2000).

¹⁴¹ KENRAD E. NELSON & CAROLYN M. WILLIAMS, *INFECTIOUS DISEASE EPIDEMIOLOGY THEORY AND PRACTICE* 522 (2nd ed. 2007).

¹⁴² Heidi L. Wald & Andrew M. Kramer, *Nonpayment for Harms Resulting in Medical Care: Catheter-Associated Urinary Tract Infections*, 298 JAMA 2782, 2783 (2007).

¹⁴³ Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 24,719-24,720.

¹⁴⁴ *Id.*

¹⁴⁵ Saint et al., *supra* note 140, at 476.

ally, UTIs have a large financial impact – costing the health care system an estimated \$400 million annually.¹⁴⁶

However, CMS there are two main problems here. First, UTI is not an avoidable through proper care of the hospital staff, and second, it is often a medical *risk* of hospitalization. In fact, CMS admits that most clinicians and infectious disease control experts do not believe that catheter-associated UTIs are preventable.¹⁴⁷ Many of the contributing factors of UTI are outside the control of the hospital staff.¹⁴⁸ The risk of developing a catheter-associated UTI depends, in part, upon two several key factors, among them the duration of the catheter once in place, the patient's susceptibility to infection.¹⁴⁹ UTIs are generally considered unavoidable when a catheter is left in the patients for more than four days because of the buildup of bacteria.¹⁵⁰ Thus, patients who require intermediate or long-term use of catheters and/or are confined to a hospital bed have a baseline rate of acquiring a UTI.¹⁵¹

Additionally, CMS does not provide simple guidelines that would enable medical professionals to avoid UTIs. CMS instead relies largely upon evidence-based guidelines that were set by a twenty-eight-year-old CDC report.¹⁵² That report asserts prevention guidelines that presume that hospitals could avoid UTIs by properly managing an indwelling catheter,¹⁵³ by limiting the duration of catheter placements, and by only using catheters when necessary.¹⁵⁴ Proper management, according to that report, includes such actions as cathe-

¹⁴⁶ APIC, Guide to the Elimination of Catheter-Associated Urinary Tract Infections 32 (2008), http://www.apic.org/Content/NavigationMenu/PracticeGuidance/APICEliminationGuides/CAUTI_Guide_0609.pdf.

¹⁴⁷ Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. at 24,719.

¹⁴⁸ APIC, *supra* note 146, at 8.

¹⁴⁹ *Id.*

¹⁵⁰ Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. at 24,719.

¹⁵¹ Wald & Kramer, *supra* note 142.

¹⁵² The report that CDC relies upon is EDWARD S. WONG, CTRS. FOR DISEASE CONTROL & PREVENTION, DEP'T OF HEALTH & HUMAN SERVS., GUIDELINE FOR PREVENTION OF CATHETER-ASSOCIATED URINARY TRACT INFECTIONS (1981), *available at* http://www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html; *see* Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. 47,130, 47,203-47,204. (Aug. 22, 2007) (to be codified at 42 CFR pts. 411, 412, 413, and 489).

¹⁵³ *See id.* at 47,204.

¹⁵⁴ *Id.*

terizing only when necessary, emphasizing hand washing, and inserting catheter using aseptic technique and sterile equipment.¹⁵⁵

CMS reiterated these prevention guidelines in the 2008 Proposed Rule, stating “[t]he primary prevention intervention would be not using catheters or removing catheters as soon as possible”¹⁵⁶ However, as previously indicated, one of the major risk factors in the development of UTI is the presence of a catheter, which may be necessary to properly care for patients.¹⁵⁷ Despite this, CMS does not make any exception for patients requiring long-term catheter care, for which long-term catheter use is critical to the management of urinary elimination.¹⁵⁸

For example, consider the Intensive Care Unit, where patients are often immobile and unable to use the restroom. As stated above, in some contexts, the risk of a UTI is unavoidable, even with the use of proper sanitation, if the catheter is used at all.¹⁵⁹ Accordingly, the only way that the hospital could ensure that the patient in the example would not contract a catheter-associated UTI is to not use the device. The hospital thus has two choices: it can leave the patient alone, in increasing pain and discomfort; or administer proper care that necessarily carries with it a risk of infection. Thus, as a result of the Never Events Policy, some hospitals would provide proper treatment (by providing a catheter to a patient in need) and not be reimbursed.¹⁶⁰

Accordingly, one can see a markedly different standard in CMS’s adoption of UTI as a “Never Event.” A UTI is not avoidable; it is the result of a medical risk; and CMS does not adequately present guidelines to demonstrate how medical professionals could avert UTIs. In other words, whereas NQF chose conditions that were avoidable, the result of hospital mistakes, and avertable through the adoption of simple guidelines; CMS chose a condition that is common, unavoidable and the often, contracted despite proper hospital care.

¹⁵⁵ WONG, *supra* note 152.

¹⁵⁶ Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. at 47,203.

¹⁵⁷ APIC, *supra* note 146, at 8; see also Fred Bazzoli, *Cigna the Latest to Say It Won't Pay For Preventable Medical Errors*, HEALTHCARE FIN. NEWS, Apr. 21, 2008, <http://www.healthcarefinancenews.com/story.cms?id=7935>.

¹⁵⁸ See Wald & Kramer, *supra* note 142.

¹⁵⁹ Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 24,719.

¹⁶⁰ See Wald & Kramer, *supra* note 142.

2. Falls

One can further observe the insufficiency of CMS's standard for selecting Never Events by analyzing its adoption of trauma caused by falls from wheelchairs, chairs, beds, other furniture and commodes as an HAC.¹⁶¹

First, the event is not entirely avoidable. As in the case of catheter-associated UTIs, certain patients are much more susceptible to falls – the elderly perhaps most prominently.¹⁶² The incidence of falls and the severity of complications arising from a fall increase with age, increased disability, and functional impairment.¹⁶³ For instance, nearly one-third of people sixty-five years of age or older fall at least once per year,¹⁶⁴ a number that rises to fifty percent once people turn eighty years or older.¹⁶⁵ Among the elderly, falls were the second leading cause of death due to unintentional injuries in 1994.¹⁶⁶

Thus, it may not seem surprising that CMS was more hesitant to include falls as an HAC.¹⁶⁷ In its 2008 Proposed Rule, CMS plainly stated that falls may not be preventable and, as a result, did not initially propose adopting "trauma caused from falls" as an HAC.¹⁶⁸ But it still invited comments on the exclusion of falls as a HAC.¹⁶⁹ Notwithstanding its initial proposal, in its 2008 Final Rule, CMS adopted falls as an HAC.¹⁷⁰ CMS did not provide any compelling reason for its decision, stating generically that falls could be reduced through the application of evidence-based guidelines.¹⁷¹ CMS simply stated that falls should be reasonably avoidable by hospitals and presented no further support for the idea.¹⁷²

¹⁶¹ Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. 47,130, 47,214 (Aug. 22, 2007) (to be codified at 42 CFR pts. 411, 412, 413, and 489).

¹⁶² Letter from John Murphy, President, Am. Geriatrics Soc'y, to Kerry Weems, Acting Adm'r, Ctrs. for Medicare & Medicaid Servs. (Aug. 25, 2008), http://www.americangeriatrics.org/products/positionpapers/HAC_letter2008.pdf.

¹⁶³ Pekka Kannus et al., *Fall-Induced Injuries and Deaths Among Older Adults*, 281 JAMA 1895, 1895 (1999).

¹⁶⁴ *Id.*

¹⁶⁵ Letter from Murphy, *supra* note 162, at 3.

¹⁶⁶ Kannus et al., *supra* note 163.

¹⁶⁷ See Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 24,718.

¹⁶⁸ *Id.*

¹⁶⁹ *Id.* at 24,724-24,725.

¹⁷⁰ Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. 47,130, 47,214 (Aug. 22, 2007) (to be codified at 42 CFR pts. 411, 412, 413, and 489).

¹⁷¹ *Id.*

¹⁷² *Id.* at 47,214-47,215.

Second, falls are not the result of mistakes that the hospital workers make. While the number of falls can be reduced through the adoption of fall prevention, it is not a medical mistake that should “Never Happen.”¹⁷³ A 2008 article in the *New England Journal of Medicine* study compared two hospital staffs: one that adopted risk assessments and strategies for the prevention of falls and one that did not.¹⁷⁴ In the study, the staff that applied the fall-risk prevention strategies reduced the total number of falls by only eleven percent.¹⁷⁵ Put conversely, eighty-nine percent of the falls happened in spite of fall-reduction strategies.¹⁷⁶ In response to the *New England Journal of Medicine* study,¹⁷⁷ the President of the American Geriatrics Society predicted that no evidence-based intervention could reasonably prevent all falls in elderly patients.¹⁷⁸

A 1999 article from the *Journal of the American Medical Association* seems to confirm these findings, arguing that nationwide fall injuries would not have been reduced through a change of any hospitalization policy, short of favoring outpatient care.¹⁷⁹ In other words, even through the best care available, it may be impossible to completely prevent the elderly from suffering from falls in a hospital setting.

Third, CMS did not provide guidelines that would enable a hospital to avoid the event. Instead, CMS referred to a website that lists all the Patient Safety Indicators¹⁸⁰ as evidence-based guidelines that would help a hospital prevent falls,¹⁸¹ which does not mention fall reduction.¹⁸² These indicators directly contradict the CMS-given definition that evidence-based guidelines are “best practices for performing certain medical procedures or treatments.”¹⁸³ Accordingly, any hospital would likely find it difficult to reduce the occurrence of falls through the adoption of these contradictory guidelines.

¹⁷³ Mary E. Tinetti et al., *Effect of Dissemination of Evidence in Reducing Injuries From Falls*, 359 NEW ENG. J. MED. 252 (2008).

¹⁷⁴ *Id.* at 252.

¹⁷⁵ *Id.* at 258.

¹⁷⁶ *Id.*

¹⁷⁷ See Tinetti et al, *supra* note 173.

¹⁷⁸ Letter from Murphy, *supra* note 162, at 3.

¹⁷⁹ Kannus et al., *supra* note 163, at 1898.

¹⁸⁰ “Patient Safety Indicators (PSIs) are a set of measures that screen for adverse events that patients experience as a result of exposure to the health care system.” Agency for Health Care Research & Quality, U.S. Dep’t of Health & Human Servs., Patient Safety Indicators Fact Sheet (2006), <http://qualityindicators.ahrq.gov/downloads/psi/2006-Feb-PatientSafetyIndicators.pdf>.

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ Fisk, *supra* note 8.

Thus, one can see that CMS applied a low standard in its adoption of "trauma caused by falls" as a Never Event. Like catheter-associated UTI, CMS chooses an HAC that is unavoidable among certain patients; is not a medical mistake; and CMS does so without providing realistic guidelines on how to prevent or mitigate injuries caused from falls. Again, this standard is in stark contrast to the standard used to create the NQF list – events that are preventable; that result from medical mistakes; and that are avoidable through the adoption of simple guidelines.¹⁸⁴

3. Further Questions

Further, this Never Events policy raises other complicating issues that CMS never addresses.¹⁸⁵ Though it is intended to reduce costs, this policy could have the opposite effect – and actually *increase* the cost of care as hospitals spend additional costs on screening and on an undefined appeals process.¹⁸⁶ Other commentators suggest that this policy will force hospitals to engage in cost shifting and thus, will not reduce costs at all.¹⁸⁷ Instead of facing a financial punishment, hospitals will simply allocate unpaid costs of care from one patient through above-cost charges to other patient populations.¹⁸⁸

Additionally, hospitals will be forced to increase its resources towards screening. As previous indicated, CMS's policy is based upon the IPPS reimbursement billing system.¹⁸⁹ If the present-on-admission code is not present, CMS presumes that the condition was hospital-acquired and will not reimburse the hospital.¹⁹⁰ As a result, a hospital must ensure that it detects all preexisting conditions.¹⁹¹ As previously indicated, a hospital must screen an entering patient through the use of a doctor or a trained technician in order to receive reimbursement for treating a Never Event.¹⁹²

However, hospitals may be violating the law if they attempt to screen in an emergency. The Emergency Medical Treatment and Ac-

¹⁸⁴ See *supra* Part III.A.

¹⁸⁵ See generally Fisk, *supra* note 8.

¹⁸⁶ *Id.*

¹⁸⁷ Dobson et al., define cost shifting as "systematically higher prices (above cost) paid by one payer group to offset lower prices (below cost) paid by another." Allen Dobson et al., *The Cost-Shift Payment 'Hydraulic': Foundation, History, and Implications*, 25 HEALTH AFF. 22, 23 (2006).

¹⁸⁸ See *id.*

¹⁸⁹ See *supra* Section I.

¹⁹⁰ See *supra* Section I.

¹⁹¹ See *supra* Section I.

¹⁹² See *supra* Section I; see also James Schlett, *Medicare Won't Pay For Hospital-Acquired Injuries*, DAILY GAZETTE, Sept. 28, 2008, at C1.

tive Labor Act (EMTALA) forbids a hospital from delaying medical examination and treatment in the emergency department in order to obtain insurance information¹⁹³ or prior authorization for care.¹⁹⁴ This may present a unique challenge with regard to Never Events, where the screening is necessary to receive reimbursement – and thus an attempt to receive authorization for care.¹⁹⁵ As a result, a hospital may not be able to thoroughly detect for the presence of some Never Events for patients that it admits for care.¹⁹⁶

Consider an example where a man enters the emergency room complaining of chest pains. The physician quickly determines that the man is suffering from a heart attack and in need of emergency care. The man also exhibits many of the individual characteristics that make him more likely to be suffering from an early-stage pressure ulcer – a Never Event that is particularly hard to detect in early stages.¹⁹⁷ The

¹⁹³ The Emergency Medical Treatment and Active Labor Act ("EMTALA") 42 USCA 1395; see also PETER R. KONGSTVEDT, *MANAGED CARE: WHAT IS IT AND HOW IT WORKS* 83 (3d ed. 2008); see also Diana K. Quinn et al., *The Emergency Medical Treatment and Active Labor Act of 1985 and the Practice of Psychiatry*, 53 *PSYCHIATRY SERVICES* 1301, 1303 (2002) (providing a brief summary of the Emergency Medical Treatment and Active Labor Act of 1985).

¹⁹⁴ Gov. Accountability Office, *Emergency Care: EMTALA Implementation and Enforcement Issues* GAO-01-747 at 13 (June 22, 2001) (explaining that "the 1999 Special Advisory Bulletin [clarifying EMTALA issues] hospitals should not obtain prior authorization from an individual's insurance company before screening or stabilizing treatment begins.").

¹⁹⁵ For a description of the IPPS billing system, and the use of Present-On-Admission codes, see *supra* note 77 and accompanying text.

¹⁹⁶ Quinn et al., *supra* note 193, at 1301 (stating that "the intent of this legislation is not to punish physicians or hospitals but to protect patients and health care providers from economic, institutional and political pressures that might compromise health care providers' ability to evaluate and treat patients who are seeking emergency care").

¹⁹⁷ A pressure ulcer forms when an area of skin remains in one position for an extended period of time, due to the patient's inability to shift their body. Univ. of Md. Med. Ctr., *Pressure Ulcer - Overview* (2008), <http://www.umm.edu/ency/article/007071.htm>. There are five factors that make a person more susceptible to a pressure ulcer: immobility, inactivity, nutritional factors, fecal and urinary incontinence, and decreased sensory perception. Wound Care Info. Network, *Staging Pressure Ulcers* (2008), <http://www.medicaledu.com/staging.htm>. Hence, pressure ulcers often exist among obese patients, who are immobile, inactive, and have poor nutritional factors. Pressure ulcers exist in four separate stages, with symptoms ranging from "changes in . . . skin temperature" (phase one) to "full thickness skin loss with extensive destruction" (phase four). Wound Care Info. Network, *supra*. Thus, a patient with a phase I pressure ulcer could enter a hospital with an unidentified pressure ulcer and have no visible symptoms. CMS responds to this by stating, "by selecting this condition, we would provide hospitals the incentive to perform careful examination of the skin of patients on admission to identify [pressure] ulcers." Final Rule Regarding Changes to the Medicare Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. 47,203

physician is between a rock and a hard place. On one hand, she knows that if she does not thoroughly screen the man for a pressure ulcer, the hospital will not have the proper present-on-admission codes that it needs to receive reimbursement.¹⁹⁸ On the other hand, the patient is in need of emergency care for his heart, and further, the physician cannot delay treatment or else risk a violation of EMTALA for delaying treatment in order to obtain a form of "prior authorization for care."¹⁹⁹

The hospital's only line of defense would be to appeal. However, it is not clear that a hospital would even have the right to appeal a Never Event ruling, or how it would do so. CMS declined to specify any appeals process, only stating that current procedures allow providers to challenge denials of reimbursement.²⁰⁰ Accordingly, any hospitals that decide to appeal a denial in reimbursement may find themselves in a lengthy, undefined appeals process – a cost that could ultimately be passed on to its patients.

IV. RECOMMENDATIONS

This Section makes three recommendations. First, it suggests that CMS should revise the standard it uses when selecting future Never Events. Primarily, it should adopt a standard that is similar to the one used by the NQF. Second, this Section suggests that CMS should revise its current list of Never Events to those events that the NQF vetted. Doing so would reduce the number of HACs from ten to three and ensure that hospitals would have proper guidelines to avoid a Never Event. Third, CMS needs to change how it selects future Never Events.

First, CMS should revise the standard it uses when it selects future Never Events. As previously indicated, CMS's standard has inherent problems.²⁰¹ Accordingly, a hospital may find itself being denied reimbursement for a patient's unavoidable injuries caused by a

(Aug. 22, 2007).

¹⁹⁸ EMTALA, *supra* note 193; *see also* KONGSTVEDT, *supra* note 200. This is because the hospital will not have the proper present-on-admission coding. For a brief description of IPPS coding, and Present-on-Admission coding, *see* Linda Wilson, *POA Coding Challenges: Concern Grows over Quality of Documentation*, MODERN HEALTHCARE, June 2, 2008, at 10.

¹⁹⁹ "A violation of EMTALA can result in fines of up to \$50,000 per violation . . . and loss of Medicare reimbursement." Quinn et al., *supra* note 193, at 1301.

²⁰⁰ *See* Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems, 72 Fed. Reg. 47,130, 47,216 (Aug. 22, 2007) (to be codified at 42 CFR pts. 411, 412, 413, and 489).

²⁰¹ *See supra* Section III.

non-preventable condition and without guidance from CMS on how the hospital could improve in the care.

Instead, CMS should reevaluate how it selects future events to be included in the list. CMS should account for three factors: (1) the ability of the hospital to completely avoid the event; (2) the existence of true industry-wide evidence-based guidelines; and (3) the effect that event has upon the patient's life. For example, had CMS used this standard in selecting its original list, it would have selected "foreign object retained in the body following surgery" as a Never Event and not a "Catheter-Associated U.T.I." By adopting this standard, CMS would only choose events that were both truly avoidable and largely disabling to patients.

Second, CMS should limit its current list of Never Events to completely preventable medical errors that have been vetted through a NQF-like collaboration process.²⁰² In doing so, CMS should distinguish between those events that are truly preventable (or medical *mistakes*) and those that are complications of illness or hospital stays (or medical *risks*).²⁰³ Coincidentally, of the ten categories of HACs, the only events that are always preventable are all found on the NQF's list of Never Events. Practically speaking, this change would mean reducing the number of Never Events to three: leaving foreign objects in the body during surgery; failing to prevent air embolisms following surgery; and providing incompatible blood or blood products during care.²⁰⁴

CMS could better serve hospitals by adopting guidelines that accurately reflect the practices used in the medical profession.²⁰⁵ If CMS chooses to do this, it needs to carefully select guidelines that will enable hospitals, physicians, and medical care workers to completely avoid the Never Events. To facilitate this, CMS should follow the example set by the NQF, and seek a consensus from physicians, hospitals, and other healthcare providers, including "public and private purchasers; national, regional, state, and local groups representing consumers; accrediting bodies; supporting industries; and organizations involved in healthcare research or quality improvement."²⁰⁶

²⁰² Press Release, Nat'l Quality Forum, *supra* note 90.

²⁰³ For a workable definition of medical errors, see Wu et al., *supra* note 6.

²⁰⁴ This list intentionally excludes wrong-site surgery – a NQF condition that CMS proposed but ultimately could not fit into its payment codes.

²⁰⁵ Alternatively, CMS could abandon the requirement altogether. For a discussion on the problems with evidence-based guidelines, see *supra*, note 138.

²⁰⁶ NAT'L QUALITY FORUM SRE, *supra* note 45. As discussed above, some consider NQF's process to be the "gold standard" of health care measurement. See

CONCLUSION

In conclusion, Never Events policies represent an effort to reduce costs and medical errors, but ultimately raise many unanswered questions, as this Note has attempted to demonstrate.²⁰⁷ Although many groups have used the term "Never Events," the standard by which the events are selected has changed considerably over time. Whereas policy groups once used the term to mark the distinction between acceptable and unacceptable levels of hospital care, it has evolved into a government policy that punishes the occurrence of unavoidable events. In other words, while Never Events once referred to "events that should never happen," it now refers to events that are unavoidable hospital risks without guidance on how to improve in the future. Put simply, Never Events are now events that sometimes happen and cannot be avoided.

Further, a number of questions remain unanswered. For example, what ability does the hospital have to appeal a Never Event determination? How should a patient's unique characteristics affect a Never Events determination? (For example, the patient's age, mobility, etc.). How should a hospital improve its care in the future, so as to avoid a similar determination in the absence of appropriate evidence-based guidelines? Finally, how will EMTALA interact with physician's requirement to screen all patients on admission for a Never Event?

Ultimately, hospitals and patients will have to determine the answers to these questions. They will likely do so by paving the way through a costly appeals process and incurring a difficult financial burden that may ultimately increase, instead of reduce, costs. Accordingly, CMS should rethink this policy, and change the standard it uses in selecting Never Events. Until CMS does so, hospitals will likely find Never Events policies confusing, vague, difficult to implement, and ultimately, unhelpful to patient care.

