BACKGROUND
Preventable medical errors are a leading cause of death in the United States and result in more than $4.5 billion in additional health spending every year. In a bid to improve patient safety and curtail escalating health care costs, Medicare, Aetna, WellPoint and a number of other major insurers are moving to ban payments for “never events” – medical errors so egregious and obvious that they should never happen. Using publicly available information, this issue brief tracks the evolution of “never event” lists and their use by Medicare and private insurers.1

“NEVER EVENT” LISTS ENDORSED BY NATIONAL QUALITY FORUM & MEDICARE

National Quality Forum
In 2002, the National Quality Forum (NQF) published a report, Serious Reportable Events in Healthcare, which identified and endorsed as “never events” 27 preventable adverse health events of significant concern to the public and health care providers. In publishing the report, the NQF’s objective was to establish a consensus among health care stakeholders on what the specific “never events” are and define them in a manner that makes it clear what has to be reported. The list was part of a federally funded pilot project for “never event” reporting by hospitals nationwide. However, because the national program was not realized, the list has instead been adopted and implemented on a state-by-state basis. More recently, the list has been adopted by health plans to shape hospital payment policies. The list was last amended in November 2006 and now includes 28 “never events.” (APPENDIX A)

To be included in NQF’s list of “never events,” an event must be characterized as: 1) unambiguous - clearly identifiable and measurable, and thus feasible to include in a reporting system; 2) usually preventable - recognizing that some events are not always avoidable, given the complexity of health care; 3) serious - resulting in death or loss of a body part, disability, or more than transient loss of a body function; and, 4) either adverse, indicative of a problem in a health care facility’s safety systems, or important for public credibility or public accountability.

Nearly a dozen states require hospitals to report all or some of the NQF-endorsed “never events.” California adopted the list of 27 events in September 2006.2 Prompted by state laws requiring the reporting of errors, nearly 1,300 hospitals nationwide – and all hospitals in Pennsylvania, Minnesota and Massachusetts – have pledged not to charge for some or all of the “never events.”

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2 SB 1301 (Alquist, Chapter 647, Statutes of 2006) requires hospitals to report the events to DHS effective July 1, 2007. DHS is required to make the information readily available to consumers between Jan. 1, 2009 and Jan. 1, 2015.
Medicare
Section 5001(c) of the Deficit Reduction Act of 2005 (DRA), required CMS to select and adjust hospital payments for at least two conditions that a) are high cost or high volume or both, b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and, c) could reasonably have been prevented through the application of evidence-based guidelines by October 1, 2007.

CMS responded in August 2007 by adopting the final Medicare Inpatient Prospective Payment System (IPPS) rule for hospitals. IPPS identifies eight “never events” for which, beginning Oct. 1, 2008, Medicare will not provide additional payment to hospitals unless the events were present on admission.

“Never Events” selected by Medicare:
1. Serious Preventable Event — Object Left in Surgery
2. Serious Preventable Event — Air Embolism
3. Serious Preventable Event — Blood Incompatibility
4. Catheter-associated Urinary Tract Infections
5. Pressure Ulcers (Decubitus Ulcers)
6. Vascular Catheter-Associated Infection
7. Surgical Site Infection — Mediastinitis After Coronary Artery Bypass Graft (CABG) Surgery
8. Hospital-Acquired Injuries — Fractures, Dislocations, Intracranial Injury, Crushing Injury, Burn and Other Unspecified Effects of External Causes

In 2009, Medicare will add to its list hospital-acquired blood infections, blood clots in legs and lungs, and pneumonia acquired from a ventilator. Although Medicare’s list is shorter than NQF’s, it is considered broader. Medicare’s list currently includes urinary-tract infections and will include hospital-acquired blood infections and pneumonia whereas NQF’s list does not include any infections. Urinary-tract infections and hospital-acquired pneumonia are among the most common events and can add more than $10,000 to a hospital bill. Bloodstream infections can add more than $100,000 to a bill. Finally, Medicare’s list encompasses all pressure ulcers (bedsores) while NQF’s list covers only Stage 3 or 4 bedsores.

Medi-Cal
Medi-Cal has not adopted a formal policy of nonpayment for “never events.” However, a Medi-Cal managed care plan can deny payment for a “never event” based on its utilization management policy and procedures. For example, operation on the wrong limb is considered an unauthorized service ineligible for payment. However, surgery to correct the error would be authorized and reimbursable.

ADOPTION OF “NEVER EVENT” LISTS BY PRIVATE INSURERS
Nearly all “never events” are rare enough that refusing payments for them will not provide a big financial savings. The biggest potential for savings lies in adopting payment policies for the most common errors – infections. However, Aetna and Wellpoint have already adopted policies using NQF’s list, which does not include infections. On the other hand, UnitedHealth Group Inc., and Cigna Corp. are currently exploring policies similar to Medicare’s, which does include infections.
Aetna, Inc.,
As of January 2008, Aetna is stipulating in new hospital contracts and contracts up for renewal that it will no longer pay for or allow patients to be billed for any of the 28 NQF endorsed “never events.” In addition, Aetna’s new contracts incorporate language from the Leapfrog Group’s “Never Event” Policy and requires hospitals to: 1) report the events to at least one specified agency within 10 working days; 2) take action to prevent future events; 3) waive all costs related to the event, and, 4) apologize to the affected patient and family. ³ (APPENDIX B)

Blue Cross Blue Shield Association has indicated that its 39 member plans are looking to either adopt policies similar to Aetna’s or work with hospitals on reducing errors. The changes will be phased in over several years and will vary among all Blue plans.

Wellpoint, Inc.,
Wellpoint is taking a smaller scale approach in Virginia by stipulating only four errors from NQF’s list, including leaving a sponge or other object in a patient after a procedure and performing the wrong procedure. Wellpoint has indicated that it intends to extend its policy soon to plans in New England and in Georgia. However, based on available information, it is unclear whether Wellpoint is going to extend its policy covering only four errors or will incorporate more errors from the NQF list.

SUMMARY
The policy of requiring hospital disclosure of and not paying for serious and preventable medical errors is gaining momentum. More than a thousand hospitals nationwide have stepped forward on the issue and have agreed to waive costs for “never events.” However, there is inconsistency in the “never event” payment policies adopted by health plans, which have alternately adopted NQF’s or Medicare’s “never event lists.” The NQF and Medicare lists differ on a significant point: payment for hospital-acquired infections.

³ Leapfrog Group was launched by the Business Roundtable in 2000 and represents organizations (public and private employers) that purchase health care. The organization carries out its mission to improve the safety, quality, and affordability of health care by focusing on hospital safety.
The following NQF-endorsed list of “never events” has been adopted by a number of states and more recently health plans as the basis of public reporting and payment systems.

**Surgical Events**
- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure on a patient
- Retention of a foreign object in a patient after surgery or other procedure
- Intraoperative or immediately post-operative death in a normal health patient (defined as a Class 1 patient for purposes of the American Society of Anesthesiologists patient safety initiative)

**Product or Device Events**
- 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 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

**Patient Protection Events**
- Infant discharged to the wrong person
- Patient death or serious disability associated with patient elopement (disappearance) for more than four hours
- Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility

**Care Management Events**
- Patient death or serious disability associated with a medication error (e.g., error 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-incompatible blood or blood products
- Maternal death or serious disability associated with labor or delivery on a low-risk pregnancy while being cared for in a healthcare 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
- Artificial insemination with the wrong donor sperm or donor egg
Environmental Events
- Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
- 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 substances
- Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
- Patient death associated with a fall 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

Criminal Events
- 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 a healthcare facility
- 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 a healthcare facility
APPENDIX B

THE LEAPFROG GROUP
“NEVER EVENTS” POLICY STATEMENT

Sample Hospital Policy

On DATE, X Hospital agreed to the following policy on the issue of serious reportable events (“never events”, as defined by the National Quality Forum’s 2006 report):


- We will apologize to the patient and/or family affected by the never event
- We will report to at least one of the following agencies within 10 days of becoming aware that the never event has occurred:
  - The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), as consistent with their Sentinel Event policy
  - State reporting program for medical errors
  - Patient Safety Organization
- Perform a root cause analysis, per instructions from the chosen reporting agency, to identify the basic or causal factors that underlay the never event and to improve our systems and processes
- We will waive all costs directly related to a serious reportable event (“never event”) and will refrain from seeking reimbursement from the patient or a third party payer for costs related to it