Never Events, Adverse Events and SREs:
Implications for Nursing Facilities and Assisted Living Facilities
by

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It is well-known that the current Medicare model is on a collision course, and the projections are harsh. The cost of the program is substantially exceeding its funding. According to August 2008 testimony by Kerry Weems, Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), the Hospital Insurance Trust Fund will not be able to meet its obligations for full benefits to hospitals under Medicare Part A in just eleven years.[1] In addition, studies and media reports have also revealed the prevalence of errors in the delivery of healthcare. As a result of the convergence of the budgetary crunch and continuing efforts to improve transparency in health care and promote quality, CMS has embarked on identifying and denying reimbursement for "never events." While the current focus of "never events" is hospital-based, there are potential impacts to the long-term care community.

A "never event" is a serious, preventable condition that results from healthcare management; it's the event that never should have occurred. Section 203 of the Tax Relief and Health Care Act of 2006 defined the term as "an event that is listed and endorsed as a serious reportable event by the National Quality Forum (NFQ) as of November 16, 2006."[2] The National Quality Forum, a non-profit entity created in 1998, first published a list of serious reportable events (SREs) in 2002 and updated the list in 2006.[3] This list consists of six categories and 28 specific events. The six categories are surgical, product or device, patient protection, care management, environment, or criminal.[4]

Kerry Weems, CMS Acting Director, has testified numerous times before various Congressional Committees and has also delivered remarks before various other private

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[1] "The President's FY 2009 Budget Request," Testimony of Kerry Weems, Acting Administrator CMS Before the Subcommittee on Health (February 14, 2008). http://waysandmeans.house.gov/media/pdf/110/KWeems.pdf
[2] Tax Relief and Health Care Act of 2006, Sec. 201. OIG Study of Never Events. http://www.thomas.gov/cgi-bin/query/F?c109:1:./temp/~c1095299rO:e213251:
[3] Pursuant to the OIG Report of December 2008, the term "SRE" is preferred to the previously used "never event." See, "Adverse Events in Hospitals: Overview of Key Issues," Department of Health & Human Services, Office of the Inspector General, Daniel R. Levinson, Inspector General, OE-06-07-00470 (December 2008). http://www.oig.hhs.gov/oei/reports/oei-06-07-00470.pdf
See also, "Adverse Events in Hospitals: State Reporting Systems," Department of Health & Human Services, Office of the Inspector General, Daniel R. Levinson, Inspector General, OE-06-07-00471 (December 2008). http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf
[4] "Serious Reportable Events Transparency & Accountability are Critical to Reducing Medical Errors," National Quality Forum. http://www.qualityforum.org/projects/completed/sre/fact-sheet.asp

groups. His comments provide insight as to the direction of CMS actions. At the start of the Medicare system some 40 years ago, the system reimbursed providers for services rendered (fee–for-service) with little or no review of those services. Over the years, however, it became apparent that Medicare was paying for care and treatment without a review of the quality, effectiveness or cost of that care.

Legislative History

In an effort to address this issue, there have been a number of executive and legislative actions. The Deficit Reduction Act of 2005 (DRA) was passed by the House and Senate in December of 2005, and signed into law by President Bush on February 8, 2006.[5] Section 5001 of the DRA, entitled Hospital Quality Improvement, authorized the Secretary of the Department of Health & Human Services to select certain medical conditions that were 1) high cost, high volume or both; 2) resulted in a higher level of cost DRG (diagnostic related group) than when presented as secondary diagnosis; and/or 3) *could reasonably have been prevented* by the application of evidence based guidelines.

The Tax Relief and Health Care Act of 2006, Section 203, mandated that the Inspector General of the HHS conduct a study on hospital "never events." The study, to be completed within two years, was to report on the extent of never events impacting Medicare patients, the extent of Medicare or beneficiary expense for same and the processes for Medicare's detection and denial of claims. The Office of the Inspector General (OIG) released its findings of a national study of adverse event reporting in two reports to Congress issued in December 2008. These reports were the first in a series and released in compliance with the mandates of the Tax Relief and Health Care Act of 2006.[6] Although the mandate concerns adverse events *affecting Medicare recipients*, the underlying data of the reports did not make a distinction in categories of patients. A third report was issued which addressed a limited review of adverse events affecting Medicare recipients in two selected counties.[7] That study included only 278 beneficiaries.

Analysis of Adverse Event Reporting

Since the creation of the "never event" list, HHS and CMS have expanded the focus to include "adverse events." An "adverse event" is one which results in harm to a patient due to healthcare management, but is not necessarily serious in nature. The OIG Reports further defines the term as designating a negative clinical outcome which "does not imply an error, negligence or poor quality care."[8]

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[5] http://thomas.loc.gov/cgi-bin/query/F?c109:5:./temp/~c1099IMqyJ:e74364

[6] http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:h6111enr.txt.pdf

[7] "Adverse Events in Hospitals: Case Study of Incidence Among Medicare Recipients in Two Selected Counties," Department of Health & Human Services, Office of the Inspector General, Daniel R. Levinson, Inspector General, OEI-06-08-00220 (December 2008). http://www.oig.hhs.gov/oei/reports/oei-06-08-00220.pdf

[8] See, OIG Report on State Reporting Systems, *supra*, at p. 21.

The focus of the first report is on in-patient hospitalizations. In determining the scope of the first report, the OIG examined current CMS policies and expenditures. It also consulted with both CMS and the Agency for Healthcare Research and Quality (AHRQ). It found that the greatest percentage of Medicare costs were associated with in-patient hospitalizations. In 2007, the percentage was almost 30%.[9] Specifically, the Congressional Budget Office figures for 2007 were $125.7 billion for hospital in-patient care, $20.6 billion for skilled nursing facilities, and $9.6 billion for hospice care. The projections for 2017 are $210.0, $35.6 and $18.3 billion respectively.[10]

Another factor used in selecting the focus on in-patient hospitalizations is the incidence of adverse events. The OIG Report on Overview of Key Issues cited two recent studies that had similar results. The studies concluded that, on average, approximately 3% of all hospitalized patients experience an adverse event, and over 50% of those events are considered to be preventable.[11]

The report cites a number of sources, but relies on the input of identified stakeholders for context. The stakeholder interview respondents included representatives of 8 federal agencies, 4 state agencies (including the Georgia Department of Health and Human Services), ten professional associations, and 5 oversight or standard-setting organizations. Additional groups included patient advocacy groups, public policy groups, private payers, providers, researchers and service contractors.[12]

The Overview Report identified seven key issues:

Issue 1: Estimates of adverse event incidence vary widely and measurement is Difficult

The OIG conducted a national review of the reporting of adverse events in hospitals and found that the estimates vary widely and that measurement is difficult. According to the IOM[13] study in 1999, approximately 3% of hospitalized patients experienced some type of adverse event and up to 98,000 hospitalized patients die per year as a result of a medical error. There have not been any other large national studies, but there have been smaller studies.[14] The OIG Report on Overview of Key Issues included a review of six studies of general hospital or intensive care admissions that reported an incidence rate of adverse events between 2.9% and 20.2%. The studies with the lower recorded incidence rates included a greater number of clinical reviews of medical records (30,000 and 15,000), and the studies with the higher rates

[9] OIG Report on Overview of Key Issues, *supra,* at p. 2. Citing data contained within the Congressional Budget Office (CBO) "Fact Sheet for CBO's March 2007 Baseline: Medicare," March 7, 2007. http://www.cbo.gov/budget/factsheets/2007b/medicare.pdf

[10] Congressional Budget Office (CBO) "Fact Sheet for CBO's March 2007 Baseline: Medicare," March 7, 2007. http://www.cbo.gov/budget/factsheets/2007b/medicare.pdf

[11] OIG Report on Overview of Key Issues, *supra,* at p. 3.

[12] OIG Report on Overview of Key Issues, Appendix D.

[13] "To Err is Human: Building a Safer Health System," The Institute of Medicine, 1999.

[14] OIG Report on Overview of Key Issues, *supra*, at 11.

were observational studies with a significantly smaller pool (1,047 and 391).[15] One of the studies found that the risk for the occurrence of an adverse event increased by 6% for each day of hospitalization.[16] In the small study of intensive care patients, 45% of the adverse events were categorized as preventable.[17]

Some of the stakeholders interviewed as a part of the OIG Report on Overview of Key Issues concurred with the study results and stated that they project a 10% rate of medical problem of which half result in harm to the patient for an overall 5% rate of adverse event.[18] The elderly were found to have a greater risk of adverse event due to prevalence of pre-existing medical conditions, longer hospital stays and higher number of prescription medications.

Although there is a predicted 5% rate of adverse event, actual measurement is difficult due to the many methods of identifying an event. Patients present with past medical histories and assessments are often subjective. In addition, there are differences in the definitions of adverse events on the different lists. Those lists include the JCAOH List of Sentinel Events[19], the NQF List of Serious Reportable Events[20] and the CMS list of hospital-acquired conditions (HAC).[21]

Issue 2: Nonpayment policies are gaining prominence

In October of 2008, CMS initiated its policy of nonpayment for certain hospital-acquired conditions. As of this date, CMS will no longer provide reimbursement to hospitals for the listed conditions. The specific list of hospital-acquired conditions was first announced in April of 2008, and subsequently expanded in August of 2008 and again in December of 2008. It is expected that the list of non-covered conditions will expand. It is the contention of CMS that the nonpayment policy will cause hospitals to improve their policies and procedures so as to improve overall quality with a decrease in attendant costs due to error. Many providers, however, express concern that the nonpayment policy will increase hospital costs, decrease revenues, result in cost-shift, and limit care to certain populations.

The stakeholders expressed particular concern regarding the impact of nonpayment policies on the access of care to the elderly population. These patients may be deemed to be high-risk due to pre-existing conditions and co-morbidities, and higher rate of adverse events. As a result of their vulnerabilities and the cost of uncompensated care, there is a concern that there may be a limitation in the care provided to these patients.

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[15] OIG Report on Overview of Key Issues, *supra*, Appendix F.
[16] Id.
[17] Id.
[18] Id, at 11.
[19] http://www.jointcommission.org/SentinelEvents/Statistics/
[20] http://www.qualityforum.org/projects/completed/sre/fact-sheet.asp
[21] OIG Report on Overview of Key Issues, *supra*, at 13.

When care is provided, it will be incumbent upon hospitals to be more diligent in admission examinations. This will initially result in a greater cost to the hospital. Specific examples of concern include pressure ulcers and subclinical urinary tract infections. CMS contends that the additional costs will be compensated for by its adjustment to the rate of reimbursement for covered conditions.[22]

Private insurance carriers are following the nonpayment lead of CMS. The OIG Report on Overview of Key Issues identified a Minnesota state plan that has implemented the nonpayment policy for same 27 events on the NQF List of Serious Reportable Events. It also found "several other large national companies" that have plans to implement the nonpayment policy in the near future. These carriers were not identified.

Issue 3: Hospitals rely on staff to report adverse events

Hospitals rely on staff to report adverse events, however, there is general consensus that there is an under-reporting. The under-reporting is thought to be due to a combination of factors including the identification of what might be an adverse event, to a reluctance to expose a co-worker and time constraints.[23]

Issue 4: Hospitals report adverse events to oversight entities

There are numerous problems in the current reporting systems. Hospitals are required to report to various oversight entities and the reporting criteria differ and often overlap. As a result, hospitals may report different aspects of the same incident to several different entities. Reporting entities include state agencies, federal agencies such as the FDA and CDC, and oversight committees such as JCAOH.

The second OIG Report was devoted to a study of the state reporting systems across the country.[24] The survey found that only 26 states had implemented state reporting systems for adverse effects in hospitals. One additional state was in the process of implementing a system.[25] Although the system in South Carolina was implemented in 1976, and in Massachusetts in 1980, the bulk of the systems were not implemented until recently. The systems were found to have significant differences in the overall number of adverse events. In fact, the overall number of adverse events reported in 2006 ranged from a low of 6 in South Dakota to a high of 16,442 in New York. The Georgia system was implemented in 2003 and included 136 events in 2006.[26]

[22] OIG Report on Overview of Key Issues, *supra*, at 19.
[23] Id., at 21.
[24] "Adverse Events in Hospitals: State Reporting Systems," Department of Health & Human Services, Office of the Inspector General, Daniel R. Levinson, Inspector General, OE-06-07-00471 (December 2008). http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf

[25] Id, at 7.
[26] Id, at Appendix D.

The difference in the overall figures is not due to a higher incidence of adverse event from state to state. Rather, the difference is due to the significant variability in the classifications of reporting from state to state. Some states use the NFQ, others a modified NFQ and still others use state-determined criteria.[27] The OIG Report on the State Reporting Systems was complementary of most of the state systems, and found that the states with reporting systems tended to communicate with their hospitals in an effort to promote patient safety. However, due to the state-to-state reporting variability, the state reports could not be used for national purposes.

Despite the intense reporting required of hospitals, stakeholders expressed concern that there is a void in the reciprocal receipt of usable reporting from the agencies. What data is provided to the hospitals is either far too extensive, irrelevant, or too sparse. In its current state, what information is provided is simply not usable. The OIG Report on Overview of Key Issues found stakeholders to have little use for an inconsistent tally of events. Rather the stakeholders expressed an interest in uncovering the flaws in the delivery process that led to an adverse event.

Issue 5: Public disclosure has benefits but raises concerns

One of the key components of health care reform is transparency. Transparency refers to the dissemination of information to the public and the belief is that information in the hands of the patient/consumer will motivate improved quality. While the information may be of benefit to patients, the manner in which it is released may be confusing. Likewise, there are valid concerns regarding the release of information.

There is a concern that publication of a hospital's adverse event history may lead to an increase in malpractice litigation. Currently, peer review investigations are protected so as to promote open discussions among professionals. A voluntary release of the underlying facts of an incident may compromise those protections.

Patient confidentiality is also a concern. A never event is by definition a serious error and one that is likely to be reported in the community. The later reporting of the adverse event may inadvertently also identify the patient via the fact pattern.[28]

Issue 6: Hospitals may be slow to apply practices

The CMS nonpayment policy requires that an adverse event be "reasonably preventable" through the use of "readily available evidence-based guidelines." While there may not be agreement as to which events might be preventable, there is general agreement that adherence to best practice treatment guidelines can promote patient safety. Best practice treatment guidelines are being developed by a number of groups,

[27] Id.
[28] Id.

however, there is a general reluctance on the part of physicians to accept oversight of their professional judgment.[29]

The OIG Overview of Key Issues cited a 2007 study that found only 25% of hospitals followed all 27 of the NFQ guidelines. That same study found that only 13% of the hospitals followed the guidelines for infection control.[30] The New England Journal of Medicine, January 14, 2009, issue, published the results of a WHO study on the use of a surgical checklist on patient safety. While the use of a checklist has generally been accepted as beneficial, the study found the actual improvement in safety to be far more marked than expected. The use of a surgical checklist resulted in a 50% reduction in patient mortality rates, from 1.5% to 0.8%.[31]

Issue 7: Interviews and literature reveal strategies

The stakeholder interview and literature summaries concluded with the following recommendations:

- Assessing the desirability and feasibility of a national body to lead patient safety efforts
- Focus on hospital use of recommended practices and evidence-based clinical practice guidelines
- Establish methods for measuring the incidence of adverse events
- Expand use of electronic health records
- Monitor and analyze impact of policies to deny hospitals higher payment for admissions complicated by selected adverse events
- Improve the quality of adverse event reporting to outside entities[32]

Implementation of the Program

Limited Medicare funding combined with an interest in promoting patient safety led to the CMS accountability measures. The ultimate goal of the guidelines is to increase the quality of health care and provide value-based purchasing. Effective

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[29] See, Lerner, Maura and Josephine Marcotty, Minnesota hospitals strive for safety, but errors still increasing, Star Tribune (January 16, 2009); http://www.startribune.com/lifestyle/health/37687999.html?elr=KArksLckD8EQDUoaEyqyP4O:DW3ckUiD3aPc:_Yyc:aUnciatkEP7DhUsl

[30] OIG Report on Overview of Key Issues, *supra,* at p. 30.

[31] "A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population," New England Journal of Medicine (January 14, 2009). http://content.nejm.org/cgi/content/full/NEJMsa0810119?query=TOC; as referenced in http://www.time.com/time/health/article/0,8599,1871759,00.html.

[32] OIG Report on Overview of Key Issues, *supra,* at p. 32-33.

October 1, 2008, hospitals will be required to absorb the costs associated with adverse events known as hospital acquired conditions that affect Medicare recipients. Hospitals may also have to absorb the costs for Medicaid patients as the States were authorized to promulgate similar restrictions on Medicaid reimbursements. Private insurance carriers are likely to continue the trend.

In the short-term, the pressure on hospitals will be intense to minimize their potential exposure. Clearly, efforts to identify conditions present upon admission will be increased. In addition, there are concerns that there may be a reluctance to accept for elective care the more high-risk populations such as the elderly.

The effect of the adverse events regulations upon long-term care providers was not addressed by the OIG Reports on Adverse Events in Hospitals. Representatives from the long-term community are not readily identifiable in the list of consulted stakeholders. Reasonable inferences are that there may be an increase in the rate of certain conditions, such as pressure ulcers, being identified by a hospital as present on admission. Such a finding might reflect attention on the pre-hospitalization care. Similarly, it is unclear how the responsibility for the post-hospitalization care of a Medicare or Medicaid recipient that results from an adverse event will be funded. Typically, a patient will discharge to a skilled nursing facility for continuing care when complications have occurred. Will there be Medicare reimbursement to the skilled nursing facility or nursing home for the continuation of care that is denied to the hospital?

Finally, the number of conditions for which the CMS nonpayment policies apply has steadily increased since the list was first announced. It is likely that the number of conditions will continue to increase from the current twelve. It is also probable that the nonpayment policies will expand from hospitals to include other healthcare providers. In fact, the majority of the 28 serious reportable events on the NQF List are as applicable to skilled nursing facilities and nursing homes as to hospitals. Some of these events include a serious injury due to a medication error, hypoglycemia, a fall or improper use of restraints.

The Medicare program will be under continuing pressure to cut its costs while at the same time promoting an improved quality in the care provided to its recipients. While the current nonpayment policies apply only to hospitals, the potential for expansion of the policy is a trend to be closely monitored.

[LWC 1-21-09]

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SEC. 203. OIG STUDY OF NEVER EVENTS.

(a) Study-

(1) IN GENERAL- The Inspector General in the Department of Health and Human Services shall conduct a study on--

(A) incidences of never events for Medicare beneficiaries, including types of such events and payments by any party for such events;

(B) the extent to which the Medicare program paid, denied payment, or recouped payment for services furnished in connection with such events and the extent to which beneficiaries paid for such services; and

(C) the administrative processes of the Centers for Medicare & Medicaid Services to detect such events and to deny or recoup payments for services furnished in connection with such an event.

(2) CONDUCT OF STUDY- In conducting the study under paragraph (1), the Inspector General--

(A) shall audit a representative sample of claims and medical records of Medicare beneficiaries to identify never events and any payment (or recoupment) for services furnished in connection with such events;

(B) may request access to such claims and records from any Medicare contractor; and

(C) shall not release individually identifiable information or facility-specific information.

(b) Report- Not later than 2 years after the date of the enactment of this Act, the Inspector General shall submit a report to Congress on the study conducted under this section. Such report shall include recommendations for such legislation and administrative action, such as a noncoverage policy or denial of payments, as the Inspector General determines appropriate, including--

(1) recommendations on processes to identify never events and to deny or recoup payments for services furnished in connection with such events; and

(2) a recommendation on a potential process (or processes) for public disclosure of never events which--

(A) will ensure protection of patient privacy; and

(B) will permit the use of the disclosed information for a root cause analysis to inform the public and the medical community about safety issues involved.

(c) Funding- Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Inspector General of the Department of Health and Human Services $3,000,000 to carry out this section, to be available until January 1, 2010.

(d) Never Events Defined- For purposes of this section, the term `never event' means an event that is listed and endorsed as a serious reportable event by the National Quality Forum as of November 16, 2006.

NATIONAL QUALITY FORUM LIST OF SERIOUS REPORTABLE EVENTS [33]

The National Quality Forum (NQF) List of Serious Reportable Events is grouped into six categories: surgical, produ device, patient protection, care management, environmental, and criminal events. "Serious" describes an event res in death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at tim discharge.[42]
Surgical Events
A. Surgery performed on the wrong body part
B. Surgery performed on the wrong patient
C. Wrong surgical procedure performed on a patient
D. Unintended retention of foreign object in a patient after surgery or procedure
E. Intraoperative or immediately postoperative death
Product or Device Events
A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the health care f
B. Patient death or serious disability associated with use or function of a device in patient care in which the device is used or functions than as intended
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a health care facilit
Patient Protection Events
A. Infant discharged to the wrong person
B. Patient death or serious disability associated with patient elopement
C. Patient suicide, or attempted suicide, resulting in serious disability while being cared for in a health care facility
Care Management Events

[33] "Adverse Events in Hospitals: State Reporting Systems," Department of Health & Human Services, Office of the Inspector General, Daniel R. Levinson, Inspector General, OE-06-07-00471, Appendix B (December 2008). http://www.oig.hhs.gov/oei/reports/oei-06-07-00471.pdf

A. Patient death or serious disability associated with a medication error
B. Patient death or serious disability associated with a hemolytic reaction due to administration of ABO/HLA-incompatible blood or bloo products
C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a health care fa
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while patient is cared for in a health care
E. Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates
F. Stage III or IV pressure ulcers acquired after admission to a health care facility
G. Patient death or serious disability due to spinal manipulative therapy
H. Artificial insemination with the wrong donor sperm or wrong egg
Environmental Events
A. Patient death or serious disability associated with an electric shock while being cared for in a health care facility
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminate toxic substances
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a health care facility
D. Patient death or serious disability associated with fall while cared for in a health care facility
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health care facility
Criminal Events
A. Care provided by someone impersonating a health care provider
B. Abduction of a patient of any age
C. Sexual assault on a patient within or on the grounds of a health care facility

D. Death or significant injury resulting from a physical assault that occurs within or on the grounds of the facility

42 NQF, "Serious Reportable Events in Healthcare, 2006 Update," 2007, pp. vi and 6.