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ELIMINATING SERIOUS, PREVENTABLE, AND COSTLY MEDICAL ERRORS - NEVER EVENTS

OVERVIEW:

As part of its ongoing effort to pay for better care, not just more services and higher costs, the Centers for Medicare & Medicaid Services (CMS) today announced that it is investigating ways that Medicare can help to reduce or eliminate the occurrence of "never events" – serious and costly errors in the provision of health care services that should never happen. "Never events," like surgery on the wrong body part or mismatched blood transfusion, cause serious injury or death to beneficiaries, and result in increased costs to the Medicare program to treat the consequences of the error.

BACKGROUND:

According to the National Quality Forum (NQF), "never events" are errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a health care facility.

The criteria for "never events" are listed in Appendix 1. Examples of "never events" include surgery on the wrong body part; foreign body left in a patient after surgery; mismatched blood transfusion; major medication error; severe "pressure ulcer" acquired in the hospital; and preventable post-operative deaths. NQF's full list is included in Appendix 2. NQF developed this list with support from CMS.

While the exact number of "never events" is not known, they result in many deaths and additional health care costs. In 1999, the Institute of Medicine (IOM) estimated that as many as 98,000 deaths a year were attributable to medical errors, and recommended that error-related deaths be decreased by 50 percent over five years. A second study concluded that "never events" add significantly to Medicare hospital payments, ranging from an average of an additional $700 per case to treat decubitus ulcers to $9,000 per case to treat postoperative sepsis. Another study, reviewing 18 types of medical events, concluded that medical errors may account for 2.4 million extra hospital days, $9.3 billion in excess charges (for all payers), and 32,600 deaths.

Some states have enacted legislation requiring reporting of incidents on the NQF list. For example, in 2003, the Minnesota legislature, with strong support from the state hospital association, was the first to pass a statute requiring mandatory reporting of "never events".

The Minnesota law requires hospitals to report the NQF's 27 "never events" to the Minnesota Hospital Association's web-based Patient Safety Registry. The law requires hospitals to investigate each event, report its underlying cause, and take corrective action to prevent similar events. In addition, the Minnesota Department of Health publishesan annual report and provides a forum for hospitals to share reported information across the state and to learn from one another.

During the first year of Minnesota 's mandatory reporting program, 30 hospitals reported 99 events that resulted in 20 deaths and four serious disabilities. In the second year, 47 hospitals reported 106 events that resulted in 12 deaths and nine serious injuries. These included 53 surgical events, and 39 patient care management events. A more detailed listing of the most recent Minnesota findings is attached as Appendix 3.

In 2004, New Jersey enacted a law requiring hospitals to report serious, preventable adverse events to the state and to patients' families, and Connecticut adopted a mix of 36 NQF and state-specific reportable events for hospitals and outpatient surgical facilities. An Illinois law passed in 2005 will require hospitals and ambulatory surgery centers to report 24 "never events" beginning in 2008. Several other states have considered or are currently considering never event reporting laws.

Questions have been raised about whether such mandatory reporting leads to accurate estimates, because of the continued potential for underreporting of "never events." Even with incomplete estimates, it is clear that, while there has been improvement in some areas of quality and safety since the IOM report, our health care system still has not reached the IOM's goal of a 50 percent reduction in the number of deaths due to medical errors. Consequently, working with provider associations and other public and private groups, the Centers for Medicare & Medicaid Services is taking further steps to prevent "never events."

NEXT STEPS:

From its beginning, the Medicare program has generally paid for services under fee-for-service payment systems, without regard to quality, outcomes, or overall costs of care. In the past several years, CMS has been working with provider groups to identify quality standards that can be a basis for public reporting and payment. This includes the efforts of the Hospital Quality Alliance, which has developed an expanding set of quality measures. As a result of the Medicare Modernization Act and the Deficit Reduction Act, hospitals that publicly report these quality measures receive higher Medicare payment updates. In addition, CMS has launched a number of demonstrations aimed at improving quality of care, including by tying payment to quality. These include the Physician Group Practice Demonstration, the Premier Hospital Quality Incentive Demonstration, the Health Care Quality Demonstration, and the Care Management Performance Demonstration. As the results of these demonstrations become available, CMS expects to work with Congress on legislation that would support adjusting payments based on quality and efficiency of care.

Clearly, paying for "never events" is not consistent with the goals of these Medicare payment reforms. Reducing or eliminating payments for "never events" means more

resources can be directed toward preventing these events rather than paying more when they occur. The Deficit Reduction Act represents a first step in this direction, allowing CMS, beginning in FY 2008, to begin to adjust payments for hospital-acquired infections. CMS is interested in working with our partners and Congress to build on this initial step to more broadly address the persistence of "never events."

In particular, CMS is reviewing its administrative authority to reduce payments for "never events," and to provide more reliable information to the public about when they occur. CMS will also work with Congress on further legislative steps to reduce or eliminate these payments. CMS intends to partner with hospitals and other healthcare organizations in these efforts.

APPENDIX 1

CRITERIA FOR INCLUSION ON THE NEVER EVENT LIST

To be included on NQF's list of "never events", an event had to have been characterized as:

- Unambiguous—clearly identifiable and measurable, and thus feasible to include in a reporting system;
- Usually preventable—recognizing that some events are not always avoidable, given the complexity of health care;
- Serious—resulting in death or loss of a body part, disability, or more than transient loss of a body function; and
- Any of the following:
    - Adverse and/or,
    - Indicative of a problem in a health care facility's safety systems and/or,
    - Important for public credibility or public accountability.

APPENDIX 2

CURRENT NATIONAL QUALITY FORUM LIST OF "NEVER EVENTS"

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

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