



Corporate Medical Policy

Nonpayment for Serious Adverse Events

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Description of Procedure or Service

Adverse healthcare events are a leading cause of death and injury in the United States. A November 1999 report by the Institute of Medicine indicated that as many as 98,000 people die in hospitals each year as the result of medical errors. This would make medical errors the eighth leading cause of death in this country. Errors occur not only in hospitals but in other health care settings, such as physicians' offices, nursing homes, pharmacies, urgent care centers, and care delivered in the home. Unfortunately, very little data exist on the extent of the problem outside of hospitals.

The Institute of Medicine defines medical error as "the failure to complete a planned action as intended or the use of a wrong plan to achieve an aim." An adverse event is defined as "an injury caused by medical management rather than by the underlying disease or condition of the patient." Some adverse events are not preventable and they reflect the risk associated with treatment, such as a life-threatening allergic reaction to a drug when the patient had no known allergies to it. But, research clearly shows that the majority of medical errors can be prevented.

In 2002, the National Quality forum (NQF) published Serious Reportable Events in Healthcare: A Consensus Report, which outlined a list of adverse events that were "serious, largely preventable and of concern to both the public and health care providers." These events and subsequent revisions to the lists became known as "never events."

Principles for Nonpayment for Serious Adverse Events

The criteria used to determine whether events should be reported and analyzed to improve systems of care were not designed to determine whether payment should be made or withheld. The collection and analysis of serious adverse events serves a different purpose than identifying adverse events for which hospitals and other healthcare providers should not expect payment. Therefore, the adverse events reported to and analyzed by a Patient Safety Organization do not serve, by themselves, as appropriate guidance in determining a nonpayment policy.

Adapted from the American Hospital Association, the North Carolina Hospital Association (NCHA) recommends the following principles for use by hospitals in determining preventable adverse events for which full or partial nonpayment is appropriate. Any adverse event, including all of those identified by the National Quality forum, is potentially subject to full or partial nonpayment under these principles. The hospital should evaluate each occurrence of an adverse event to determine whether these principles apply to that particular occurrence.

1. The error event must be preventable. Hospitals should not be held accountable for something that could not be reasonably prevented by the hospital. A root cause analysis or comparable investigation may be required to determine preventability.

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2. **The error event must be within the control of the hospital.** Hospitals should not be held accountable for errors made by third parties, such as errors in the manufacture of drugs, devices or equipment, that occurred well before the materials reached the hospital. A root cause analysis or comparable investigation may be required to determine the source of the error. Hospitals should take reasonable steps to ensure that drugs, device, and equipment provided by third parties that are not regulated by government entities are safe and effective.

3. **The error event must be the result of a mistake made by the hospital.** The event must be the result of a mistake made by the hospital, hospital procedures not followed, and not something that could otherwise occur, as determined after careful and reasonable review of the error or event.

4. **The error or event must result in significant harm.** The list of events should be limited to those that yield very serious results.

5. **Non-payable event determinations should incorporate some element of case-by-case review and determination.** The source of some adverse events is clear, but most require further investigation and a root cause analysis or comparable investigation to determine the cause of the adverse event.

Each hospital must determine on its own exactly what its nonpayment policy will be and which adverse events meet the principles articulated in its policy. NCHA recognized that many hospitals already do not request payment for services related to adverse events that they could have prevented, and recommends that all hospitals adopt this policy. In implementing a nonpayment policy, a hospital should identify those services directly related to the adverse event, segregate the charges for those services to the extent feasible, and use its best efforts to make the appropriate adjustments with the payer and/or patient as soon as possible. Adjustments should be considered in the following situations:

- If an additional procedure is performed to correct an error in the previous procedure performed in the same facility (e.g., an object is retained during surgery), payment should not be expected for charges related to the additional procedure.
- If the adverse event results in a higher DRG payment, adjustments should be made to bill for the lower DRG.
- If a procedure is performed on the wrong patient or wrong body part, or the wrong surgical procedure is performed, payment should not be expected for the procedure in question.
- If the patient is readmitted because of an adverse event in the same facility, the hospital should not expect payment for services performed during readmission that are directly related to the event.
- If the adverse event results in an increased length of stay, level of care, or significant intervention, the hospital should identify to the extent feasible the charges associated with the additional care and make the appropriate adjustments.
- To the extent that a third party manufacturer or supplier has reimbursed a hospital for charges associated with a defective product, device, or drug, those charges should not be billed to the insurer.

If there are extenuating circumstances, or uncertainty that an adverse event preventable by a hospital actually occurred, determination of any payment adjustment should be made on a case-by-case basis.

This policy is intended to address payment expectation related to serious adverse events and is not intended to provide any guidance or recommendations related to compliance with existing or proposed Centers for Medicare and Medicaid (CMS) regulations or Joint Commission standards, nor should it be construed as evidence of or relevant to the standard of care in a particular case. This NCHA policy is a recommended guideline solely for payment and billing issues and does not establish a standard of care for hospitals.

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Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

Serious Reportable Events in Healthcare

The National Quality Forum endorsed a list of adverse events that are serious, largely preventable, and of concern to both the public and healthcare providers for the purpose of public accountability. This list does not capture all events that might possibly be useful to report. Rather, the items on the list are events that are of concern to both the public and healthcare professionals and providers; clearly identifiable and measurable (and thus feasible to include in a reporting system); and of a nature such that the risk of occurrence is significantly influenced by the policies and procedures of the healthcare organization.

1. 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 a foreign object in a patient after surgery or other procedure
 - e. intraoperative or immediately postoperative death in an ASA Class 1 patient
2. Product or Device Events
 - a. patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
 - b. 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
 - c. patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility
3. Patient Protection Events
 - a. infant discharged to the wrong person
 - b. patient death or serious disability associated with patient elopement (disappearance)
 - c. patient suicide, or attempted suicide, resulting in serious disability while being cared for in a healthcare facility
4. Care Management Events
 - a. 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)
 - b. patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
 - c. maternal death or serious disability association with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
 - d. patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility

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- e. death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubemia in neonates
 - f. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
 - g. patient death or serious disability due to spinal manipulative therapy
 - h. artificial insemination with the wrong donor sperm or wrong egg
5. Environmental Events
- a. patient death or serious disability associated with an electric shock while being cared for in a healthcare 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 contaminated by toxic substances
 - c. patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
 - d. patient death or serious disability associated with a fall while being cared for in a healthcare facility
 - e. patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility
6. Criminal Events
- a. any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
 - b. abduction of a patient of any age
 - c. sexual assault on a patient within or on the grounds of a healthcare facility
 - d. 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

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: no specific codes

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

North Carolina General Statute §131E-95

Medical Errors: The Scope of the Problem. Fact sheet, Publication No. AHRQ 00-P037. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/qual/errback.htm>

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National Quality Forum. Serious Reportable Events in Healthcare 2006 Update: A Consensus Report. www.qualityforum.org

Institute of Medicine. To Err is Human: Building a Safer Health system. November 1999. <http://www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf>

Centers for Medicare and Medicaid Services (CMS). Decision memo for wrong surgery performed on a patient (CAG-00401N). January 15, 2009. <http://www.cms.hhs.gov>

Policy Implementation/Update Information

4/27/09 New policy issued. BCBSNC has developed a set of principles for use by hospitals in determining preventable adverse events for which full or partial nonpayment is appropriate. The hospital should evaluate each occurrence of an adverse event to determine whether these principles apply to that particular occurrence.

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.