HealthyMass Serious Reportable Events Task Force
POLICY GUIDELINES

Contents

1. Policy Statement

The *HealthyMass* Task Force, recognizing the Commonwealth's role as a purchaser of health services and a steward of public health, is committed to improving patient safety and maximizing quality of care for all citizens of Massachusetts. The Task Force believes that a uniform policy regarding reimbursement for costs associated with serious reportable events will focus attention on preventable errors and ensure that changes are made to improve patient safety.

Therefore, the Task Force has adopted the following policies and principles:

- State agencies and their contractors will not pay for costs associated with certain serious reportable health care events;
- Providers of these services are not permitted to bill members for the costs associated with these events;
- The Task Force will consult with providers, health insurance plans, and consumer representatives in implementing this policy;
- The Task Force will periodically review and recommend changes to the list of non-payable conditions;
- Wherever possible, payers and providers should utilize existing procedures when implementing the non-payment policy to minimize administrative burdens.

2. Policy Applicability

The *HealthyMass* non-payment policy applies to the twenty-eight serious reportable events ("SREs") that have been identified by the National Quality Forum ("NQF"). Additional specifications and definitions for these events are available in the NQF publication, *Serious Reportable Events in HealthCare – 2006 Update: A Consensus Report*

The non-payment policy will automatically apply to any additional events added to the NQF SRE list after the 2006 update.

The following providers are subject to the non-payment policy:

a) A hospital at which the event occurred, including any site covered by the hospital's license;
b) An ambulatory surgery center at which the event occurred;
c) The physician(s) performing the billable procedure during which the event occurred.

As the Medicare program has defined its own set of rules regarding payment for Hospital Acquired Conditions, including certain SREs, the policy guidelines may not be construed to prohibit a Medicare provider from submitting a claim for payment to the Medicare program.

3. Reimbursement Determination

Before a provider may charge or seek payment for services provided as the result of an SRE that occurs on premises covered by the provider's license, it must determine through a documented review process that the SRE:

(a) Was not preventable; and
(b) Was not within the provider's control; and
(c) Did not result from:
    i. a failure to follow the provider's policies and procedures; or
    ii. inadequate or non-existent provider policies and procedures; or
    iii. inadequate system design.

A failure to follow the provider's policies and procedures will include, but not be limited to, a failure to provide adequate training and supervision of staff. Providers must prepare a written report detailing the provider's findings. The report must describe the provider's procedure for completing the review and identify any changes that provider has made to policies or procedures as a result of the event.

4. Scope of No Charge Policy

Providers are prohibited from charging or seeking reimbursement from a payer or patient for services that are directly related to:

(a) the occurrence of the event;
(b) the correction or remediation of the event; or
(c) subsequent complications arising from the occurrence of the event.

Readmissions to the same hospital or follow-up care provided by the same provider or a provider owned by the same parent organization are not billable if the services meet the criteria specified above and occur within thirty days of the discovery of the event.

Providers that accept transferred patients previously injured by an SRE at another institution or under the care of another physician may bill and receive payment for all services provided.

Charges for services deemed non-billable by this policy are not billable to the patient, the patient's next of kin, the patient's representative, or any other payer.

The provider must waive any copayment or deductible due from the patient for the admission during which the SRE occurs.

5. Reporting to the Department of Public Health, Patients, and Payers

A. Initial Report

In accordance with the Department of Public Health's ("Department") SRE reporting and reimbursement regulations and related circular letters, within seven days of the discovery of an SRE, providers must report the occurrence of the event to the Department, and provide a copy of the report to any responsible third-party payer and the patient. The provider must also inform in writing the patient or the patient's representative(s) about the event and about the provider's SRE reimbursement policies and procedures.

Payers should establish written procedures for providers to notify payers of the occurrence of an event. The payer must accept as notification a copy of the incident report as filed with the Department. Payers must identify an individual who is primarily responsible for the implementation of these procedures.

When initiating reports regarding SREs, all parties should adhere to relevant statutes and regulations pertaining to the protection of personal health information.

B. Preventability Determination

In accordance with the Department's SRE reporting and reimbursement regulations and related circular letters, a provider shall complete a preventability determination of the SRE and file an updated SRE report with the Department no later than thirty days after the date of the initial SRE report. At a minimum, the preventability determination should include the following:

1. a narrative description of the SRE;
2. an analysis and identification of the root cause of the SRE;
3. an analysis of the preventability criteria;
4. a description of any corrective measures taken by the hospital following discovery of the SRE; and
5. whether the provider intends to charge or seek reimbursement for services provided by the hospital as a result of the SRE.

The provider will send a copy of the updated SRE report to the Department, the patient and any responsible third-party payer.

6. Non-Payment Policies

If the provider's review determines that the services related to the SRE are billable in whole or in part, the provider may request that the payer review the case and make payment. The payer will review the provider's evidence and reimbursement report and may decide to make full, partial, or no payment for the case.

Before submitting a bill for any episode during which an SRE occurred, providers must identify those charges directly related to an SRE by using the criteria noted in section four of this policy. In addition, the provider must identify related diagnosis and/or procedure codes. The provider must provide a copy of this review to the payer upon request.

As defined under the provisions of the contract between the payer and provider, the payer may request additional information which the payer deems necessary to facilitate further investigation or to carry out payment, credentialing, quality or other routine health plan functions.

Payers must issue billing guidelines to providers to instruct providers how to submit claims for these bills. Consistent with their own payment methods, payers should adopt policies and procedures to ensure that no payment is made for any services related to an SRE. Where possible, payers should leverage existing non-payment policies in use by other payers, such as the Medicare program. The policy must be specified in the contract with the provider or via other administrative means.

Providers may appeal payment determinations through review processes established pursuant to their contracting or regulatory arrangements with payers.

Appendix A: List of Serious Reportable Events[i]

Surgical Events

1. Surgery performed on the wrong body part
2. Surgery performed on the wrong patient
3. Wrong surgical procedure performed on a patient
4. Unintended retention of a foreign object in a patient after surgery or other procedure
5. Intraoperative or immediately post-operative death in an ASA Class 1 patient

Product or Device Events

6. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
7. 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
8. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

Patient Protection Events

9. Infant discharged to the wrong person
10. Patient death or serious disability associated with patient elopement (disappearance)
11. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility

Care Management Events

12. 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)
13. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
15. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
16. Death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates
17. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
18. Patient death or serious disability due to spinal manipulative therapy
19. Artificial insemination with the wrong donor sperm or wrong egg

Environmental Events

20. Patient death or serious disability associated with an electric shock or elective cardioversion while being cared for in a healthcare facility
21. 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

22. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
23. Patient death or serious disability associated with a fall while being cared for in a healthcare facility
24. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

Criminal Events

25. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
26. Abduction of a patient of any age
27. Sexual assault on a patient within or on the grounds of the healthcare facility
28. 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

[i] National Quality Forum, *Serious Reportable Events in Healthcare – 2006 Update;* The full report includes additional specifications and implementation guidance for each event.