

**MEDICAL ERRORS: SERIOUS REPORTABLE EVENTS/
HOSPITAL ACQUIRED CONDITIONS**

Effective Date: December 4, 2019

Review Dates: 6/06, 6/07, 10/07, 10/08, 10/09, 10/10,
10/11, 10/12, 10/13, 11/14, 11/15, 11/16, 11/17, 11/18,
11/19, 11/20, 11/21, 11/22, 11/23, 11/24

Date Of Origin: June 14, 2006

Status: Current

*Note: formerly known as the “Never Events / Medical Errors” policy.***I. POLICY/CRITERIA**

Applicability

- This policy is applicable to services provided in any recognized healthcare setting, including but not limited to hospitals, surgical centers, non-acute care facilities, physicians’ offices, infusion centers, and the home.

Who is required to report?

- The acute care inpatient facility is responsible for reporting Hospital Acquired Conditions (HACs) as defined by CMS (Appendix 2) to Priority Health within 48 hours of the event.
- Priority Health will monitor Serious Reportable Events (SREs)/HACs (Appendix 1 & 2) through case management, member complaints, claims review, and other channels.
- Reporting can be as follows:
Customer Service: (800) 942-0954
Provider Helpline: (800) 942-4765
RN Care Manager, Quality Concerns: (616) 355-3234
Email: QCC@PriorityHealth.com

What is the review process?

- When Priority Health identifies a case either through its surveillance systems or when a facility or provider reports a case, it will be investigated as outlined in the *Management of Clinical, Service and Confidential Concerns policy (Ref #1812)*.

Present on Admission (POA) Indicators

- Priority Health follows CMS guidelines for reporting POA indicators. Applicable facilities are required to submit POA indicators for all product lines.
- The POA indicator requirement applies to all **inpatient acute care hospitals with the following exceptions:**
 1. Critical Access Hospitals (CAHs)
 2. Long-term Care Hospitals (LTCHs)
 3. Maryland Waiver Hospitals
 4. Cancer Hospitals

5. Children's Inpatient Facilities
6. Rural Health Clinics
7. Federally Qualified Health Centers
8. Religious Non-Medical Health Care Institutions
9. Inpatient Psychiatric Hospitals
10. Inpatient Rehabilitation Facilities
11. Veterans Administration/Department of Defense Hospitals

http://www.cms.hhs.gov/HospitalAcqCond/03_AffectedHospitals.asp#TopOfPage

What is the appeals process?

- Plan decisions regarding clinical reviews or payment for SREs/HACs is subject to appeal and external peer specialty review. Please refer to the provider contract.

Payment Review and Determination

This policy follows the basic philosophy that “payment will not be made for medical errors,” but recognizes that many variables can impact payment determination in any specific case, including:

- The timing of the occurrence of the SRE/HAC, within the patient’s episode of care;
- The specific roles as well as clinical and procedural requirements of the providers involved in the patient’s episode of care (e.g. surgeons, anesthesiologists, hospital-based physicians and nursing staff, etc.);
- Patient behavior.

Given the actual occurrence of an SRE/HAC and the subsequent determination by Quality Review that one or more providers shared accountability leading to the occurrence of the event, a *Payment Review and Determination* shall be made by the Plan, based on the findings of the Quality Review and with input from the affected providers. The Payment Review and Determination shall be made consistent with the intent of this Policy and with recognition of the variables noted above. It may result in the following actions:

- Full Denial of Payment
- Partial Denial of Payment - Based on DRG assignment reflecting the Present on Admission indicators.

Payment of inpatient claims under a DRG arrangement will reflect the adjusted DRG weight reflective of the Present on Admission Indicators, which may result in a reduced DRG weight. Alternative payment arrangements may require other considerations.*

*Percent of Charge Arrangement -- Where it is determined that payment will be made following standard DRG grouping process, reflective of the present on

Admission (POA) indicators on the claim, the total billed charge amount will be reduced by an **Adjustment Factor** based on the relationship of the MS-DRG weight of the adjusted vs. initial DRG assigned. It is expected that the Adjustment Factor will be a value less than or equal to 1.00. For example:

$$\frac{\text{Adjusted MS-DRG Weight (identifying conditions NOT present on admission)}}{\text{Initial MS-DRG Weight (as if conditions WERE present on admission)}} = \text{Adjustment Factor}$$

Where an event occurs in a setting other than acute inpatient, payment adjustments will be determined consistent with the intent of this policy and with consideration of adjustment methods practiced by CMS or commercial payers.

Examples

Scenario	An infant is discharged from an acute care hospital to the wrong parents.
Quality review	Facility did not follow its policy on discharge of newborns.
Did harm occur?	Yes.
Reasonably avoided?	Yes.
Corrective action plan	Required
Payment withhold	Full withhold of facility payment; no withhold of physician payment.
Reporting required	No, unless or until listed by CMS

Scenario	Wrong side surgery in an ambulatory surgical center
Quality review	Provider and facility staff did not follow the prescribed pre-surgical checklist.
Did harm occur?	Yes.
Reasonably avoided?	Yes.
Corrective action plan	Required
Payment withhold	Full withhold of facility, surgeon, and anesthesiologist reimbursement.
Reported required	No, unless or until listed by CMS

Scenario	Patient fell out of bed
Quality review	Guard rails were raised when patient crawled out of bed
Did harm occur?	Yes.
Reasonably avoided?	No, all precautions taken, procedure followed.
Corrective action plan	None.
Payment withhold	None.
Reporting requirement	Yes, if resulting in patient injury, because listed by CMS.

Scenario	Post-operative mediastinitis
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Quality review	Provider and facility staff did not follow the prescribed pre-surgical checklist; post-operative antibiotics missed
Did harm occur?	Yes.
Reasonably avoided?	Yes.
Corrective action plan	Required
Payment withhold	Partial withhold of facility reimbursement.
Reporting requirement	Yes, because listed by CMS

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the [Priority Health Provider Manual](#).

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** *For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.*

IV. DESCRIPTION

The National Quality Forum (NQF), a nonprofit national coalition of physicians, hospitals, businesses and policy-makers, has identified 28 events as occurrences that should never happen in a hospital and can be prevented, thus labeled “never events” or serious reportable events (SREs) (see references). They include surgical events such as performing the wrong surgical procedure, product or device events such as contaminated drugs or devices, and criminal events such as abduction of a patient. The complete list of SREs is attached in Appendix 1.

Concurrently, the Center for Medicare and Medicaid Services (CMS) has published a list of hospital-acquired conditions (HACs) for which additional payments are withheld if the condition was not present on admission (POA). The Medicare list is included in Appendix 2 and can also be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions.html. There is incomplete alignment between the NQF’s SREs and the CMS HAC policy, but it is anticipated that with the future expansion of the Medicare list there will be better alignment.

The intent of this policy is to implement a strategy to monitor for a safe environment for medical services that minimizes avoidable risks to patients. For consistency with CMS and other payors, this policy requires CMS HACs (Appendix 2) be reported to Priority Health by the facility. In addition, Priority Health will monitor facilities and identify possible SREs (Appendix 1) that are not included in the CMS policy. In both circumstances, Priority Health will initiate a quality review (consistent with Priority Health policy *Management of Clinical, Service and Confidential Concerns policy (Ref #1812)* in voluntary collaboration with the provider(s). Where indicated, Priority Health will request a corrective action plan.

The further intent of this policy is to hold the patient and payer/employer financially harmless for the event and its sequelae. If patient harm occurs, and upon quality review as outlined in the policy, the facility and/or provider could have reasonably avoided said harms, then Priority Health may withhold payment for part or all services related to the event and its sequelae.

ICD-10 Diagnosis Codes:

Please see: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html

Present on Admission Indicator

Indicator	Description
Y	Diagnosis was present at time of inpatient admission.
N	Diagnosis was not present at time of inpatient admission.
U	Documentation insufficient to determine if condition was present at the time of inpatient admission.
W	Clinically undetermined. Provider unable to clinically determine whether the condition was present at the time of inpatient admission.
1	Exempt from POA reporting. This code is the equivalent of a blank on the UB-04.

VI. REFERENCES

1. CMS Improves Patient Safety for Medicare and Medicaid by Addressing Never Events
<https://www.cms.gov/newsroom/fact-sheets/cms-improves-patient-safety-medicare-and-medicaid-addressing-never-events>
2. CMS Hospital Acquired Conditions @
https://www.cms.gov/medicare/payment/fee-for-service-providers/hospital-acquired-conditions-hac?redirect=/HospitalAcqCond/03_AffectedHospitals.asp#TopOfPage (Retrieved September 26, 2024) (Appendix 2)
3. National Quality Forum (NQF), Serious Reportable Events In Healthcare—2011 Update: A Consensus Report, Washington, DC: NQF; 2011
4. National Quality Forum List of SREs @
http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx (Retrieved August 3, 2023) (Appendix 1)

Appendix 1 – List of Serious Reportable Events

source: National Quality Forum website, accessed 10/8/2014, 9/30/2015, 10/11/2016 & 10/17/2017, 10/2/2019, 9/14/2020, 9/1/2021, 8/31/2022, 9/14/2023

http://www.qualityforum.org/Topics/SREs/List_of_SREs.aspx

1. SURGICAL OR INVASIVE PROCEDURE EVENTS

1A. Surgery or other invasive procedure performed on the wrong site

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

1B. Surgery or other invasive procedure performed on the wrong patient

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

1C. Wrong surgical or other invasive procedure performed on a patient

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

1E. Intraoperative or immediately postoperative/post procedure death in an ASA Class 1 patient

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices

2. PRODUCT OR DEVICE EVENTS

2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the healthcare setting

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

2C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a healthcare setting

Applicable in: hospitals, outpatient/office-based surgery centers, long-term care/skilled nursing facilities

3. PATIENT PROTECTION EVENTS

3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

3B. Patient death or serious injury associated with patient elopement (disappearance)

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

3C. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a healthcare setting

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

4. CARE MANAGEMENT EVENTS

4A. Patient death or serious injury 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)

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

4B. Patient death or serious injury associated with unsafe administration of blood products

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare setting

Applicable in: hospitals, outpatient/office-based surgery centers

4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy

Applicable in: hospitals, outpatient/office-based surgery centers

4E. Patient death or serious injury associated with a fall while being cared for in a healthcare setting

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a healthcare setting

Applicable in: hospitals, outpatient/office-based surgery centers, long-term care/skilled nursing facilities

4G. Artificial insemination with the wrong donor sperm or wrong egg

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices

4H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

4I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

5. ENVIRONMENTAL EVENTS

5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a healthcare setting

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

5C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a healthcare setting

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a healthcare setting

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

6. RADIOLOGIC EVENTS

6A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices

7. POTENTIAL CRIMINAL EVENTS

7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

7B. Abduction of a patient/resident of any age

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a healthcare setting

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

7D. Death or serious 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 setting

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, long-term care/skilled nursing facilities

Appendix 2 – Medicare Hospital-Acquired Conditions HAC List
For coding please see: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/icd10_hacs.html

SELECTED HAC
Foreign Object Retained After Surgery
Air Embolism
Blood Incompatibility
Pressure Ulcer Stages III & IV
Falls and Trauma: <ul style="list-style-type: none"> • Fracture • Dislocation • Intracranial Injury • Crushing Injury • Burn • Other Injuries
Catheter-Associated Urinary Tract Infection (UTI)
Vascular Catheter-Associated Infection
Manifestations of Poor Glycemic Control <ul style="list-style-type: none"> • Diabetic Ketoacidosis • Nonketotic Hyperosmolar Coma • Hypoglycemic Coma • Secondary Diabetes with Ketoacidosis • Secondary Diabetes with Hyperosmolarity
Surgical Site Infection, Mediastinitis, Following Coronary Artery Bypass Graft (CABG)
Surgical Site Infection Following Certain Orthopedic Procedures <ul style="list-style-type: none"> • Spine • Neck • Shoulder • Elbow
Surgical Site Infection Following Bariatric Surgery for Obesity <ul style="list-style-type: none"> • Laparoscopic Gastric Bypass • Gastroenterostomy • Laparoscopic Gastric Restrictive Surgery
Surgical Site Infection Following Cardiac Implantable Electronic Device (CIED)
Deep Vein Thrombosis and Pulmonary Embolism Following Certain Orthopedic Procedures <ul style="list-style-type: none"> • Total Knee Replacement • Hip Replacement
Iatrogenic Pneumothorax with Venous Catheterization

For More Information

The HAC & POA web page at <http://www.cms.hhs.gov/HospitalAcqCond/> provides further information, including links to the law, regulations, change requests (CRs), and educational resources, including presentations, MLN articles, and fact sheets.

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