AHRQ Common Formats for Hospitals

Forms

Event ID: _____

Initial Report Date (HERF Q17): _____

Patient Safety Event Report:

HEALTHCARE EVENT REPORTING FORM (HERF)

Use this form to report either a patient safety event or unsafe condition. The term event includes both an incident that reaches the patient and a near miss that did not. Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. What is being reported? CHECK ONE:

a. ☐ **Incident:** A patient safety event that reached the patient, whether or not the patient was harmed.

b. ☐ **Near Miss:** A patient safety event that did not reach the patient.

c. ☐ **Unsafe Condition:** Any circumstance that increases the probability of a patient safety event.

2. Was there any evidence of harm to a patient at the time of this report? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

3. Event Discovery Date:

___ ___ / ___ ___ / ___ ___ ___ ___

MM DD YYYY

☐ Unknown

4. Event Discovery Time:

___ ___ ___ ___ HOURS

H H M M (MILITARY TIME)

☐ Unknown

5. Briefly describe the event that occurred or unsafe condition:

6. Briefly describe the location where the event occurred or where the unsafe condition exists:

7. Which of the following categories are associated with the event or unsafe condition? CHECK ALL THAT APPLY:

FOR EACH CATEGORY SELECTED BELOW, EXCEPT "OTHER", PLEASE COMPLETE THE CORRESPONDING CATEGORY-SPECIFIC FORM. ALL CATEGORIES INCLUDE REPORTING OF INCIDENTS. ANY CATEGORY WITH + ALSO INCLUDES REPORTING OF NEAR MISSES. ANY CATEGORY WITH * ALSO INCLUDES REPORTING OF UNSAFE CONDITIONS.

a. ☐ Blood or Blood Product*+
b. ☐ Device or Medical/Surgical Supply*+
c. ☐ Fall
d. ☐ Healthcare-associated Infection
e. ☐ Medication or Other Substance*+
f. ☐ Perinatal
g. ☐ Pressure Ulcer
h. ☐ Surgery or Anesthesia (includes invasive procedure)+
i. ☐ Other*+: **PLEASE SPECIFY** _____

Event ID: _____

Initial Report Date (HERF Q17): _____

PATIENT INFORMATION (COMPLETE ONLY IF INCIDENT):

Please complete the patient identifiers below. Additional patient information is captured on the Patient Information Form (PIF). (When reporting a perinatal incident that affected a mother and a neonate, please complete the patient identifiers below for the mother (Q8 – Q12) and the neonate (Q13 – Q16). Please also complete a separate PIF for the neonate involved.)

8. **How many patients did the incident reach?** _____ ENTER NUMBER

9. **Patient's Name:** _____ FIRST _____ MIDDLE _____ LAST

10. **Patient's Date of Birth:** __ __ / __ __ / __ __ __ __ MM DD YYYY

11. **Medical Record #:** _____

12. **Patient's Gender:** a. ☐ Male b. ☐ Female c. ☐ Unknown

NEONATAL PATIENT INFORMATION (COMPLETE ONLY FOR NEONATE AFFECTED BY PERINATAL INCIDENT):

13. **Patient's Name:** _____ FIRST _____ MIDDLE _____ LAST

14. **Patient's Date of Birth:** __ __ / __ __ / __ __ __ __ MM DD YYYY

15. **Medical Record #:** _____

16. **Patient's Gender:** a. ☐ Male b. ☐ Female c. ☐ Unknown

REPORT AND EVENT REPORTER INFORMATION

17. **Report Date:** __ __ / __ __ / __ __ __ __ MM DD YYYY

18. ☐ **Anonymous Reporter**

19. **Reporter's Name:** _____ FIRST _____ MIDDLE _____ LAST

20. **Telephone Number:** _____

21. **Email Address:** _____

22. **Reporter's Job or Position:** _____

Thank you for completing these questions.

Event ID: _____

Initial Report Date (HERF Q17): _____

Patient Safety Event Report:

PATIENT INFORMATION FORM (PIF)

Use this form only if you are reporting an incident. (When reporting a perinatal incident that affected a mother and a neonate, complete a PIF for the mother and a separate PIF for the neonate.) Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. At the time of the event what was the patient's age? CHECK ONE:

a. ☐ Neonate (0-28 days)
b. ☐ Infant (>28 days <1 year)
c. ☐ Child (1-12 years)
d. ☐ Adolescent (13-17 years)
e. ☐ Adult (18-64 years)
f. ☐ Mature adult (65-74 years)
g. ☐ Older adult (75-84 years)
h. ☐ Aged adult (85+ years)
i. ☐ Unknown

2. Is the patient's ethnicity Hispanic or Latino? CHECK ONE:

a. ☐ Hispanic or Latino
b. ☐ Not Hispanic or Latino
c. ☐ Unknown

3. What is the patient's race? CHECK ONE:

a. ☐ American Indian or Alaska Native
b. ☐ Asian
c. ☐ Black or African American
d. ☐ Native Hawaiian or Other Pacific Islander
e. ☐ White
f. ☐ More than one race
g. ☐ Unknown

4. Enter the patient's ICD-9-CM principal diagnosis code at discharge (if available):

ICD-9-CM CODE

5. After discovery of the incident, what was the extent of harm to the patient (i.e., extent to which the patient's functional ability is expected to be impaired subsequent to the incident and any attempts to minimize adverse consequences)? CHECK FIRST APPLICABLE:

AHRQ's Harm Scale

a. ☐ **Death:** Dead at time of assessment.
b. ☐ **Severe permanent harm:** Severe lifelong bodily or psychological injury or disfigurement that interferes significantly with functional ability or quality of life. Prognosis at time of assessment.
c. ☐ **Permanent harm:** Lifelong bodily or psychological injury or increased susceptibility to disease. Prognosis at time of assessment.
d. ☐ **Temporary harm:** Bodily or psychological injury, but likely not permanent. Prognosis at time of assessment.
e. ☐ **Additional treatment:** Injury limited to additional intervention during admission or encounter and/or increased length of stay, but no other injury. Treatment since discovery, and/or expected treatment in future as a direct result of event.
f. ☐ **Emotional distress or inconvenience:** Mild and transient anxiety or pain or physical discomfort, but without the need for additional treatment other than monitoring (such as by observation; physical examination; laboratory testing, including phlebotomy; and/or imaging studies). Distress/inconvenience since discovery, and/or expected in future as a direct result of event.
g. ☐ **No harm:** Event reached patient, but no harm was evident.
h. ☐ Unknown

6. Approximately when after discovery of the incident was harm assessed? CHECK ONE:

a. ☐ Within 24 hours
b. ☐ After 24 hours but before 3 days
c. ☐ Three days or later
d. ☐ Unknown

7. Was any intervention attempted in order to "rescue" the patient (i.e., to prevent, to minimize, or to reverse harm)? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

8. Which of the following interventions (rescue) were performed? CHECK ALL THAT APPLY:

a. ☐ Transfer, including transfer to a higher level care area within facility, transfer to another facility, or hospital admission (from outpatient)
b. ☐ Monitoring, including observation, physiological examination, laboratory testing, phlebotomy, and/or imaging studies
c. ☐ Medication therapy, including administration of antidote, change in pre-incident dose or route
d. ☐ Surgical intervention
e. ☐ Respiratory support (e.g., ventilation, tracheotomy)
f. ☐ Blood transfusion
g. ☐ Counseling or psychotherapy
h. ☐ Unknown
i. ☐ Other intervention: **PLEASE SPECIFY** _____

9. Did, or will, the incident result in an increased length of stay? CHECK ONE:

a. ☐ Yes
b. ☐ No (or not anticipated)
c. ☐ Unknown

10. After the discovery of the incident, was the patient, patient's family, or guardian notified? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**

Event ID: _____

Initial Report Date (HERF Q17): _____

Patient Safety Event Report:

SUMMARY OF INITIAL REPORT (SIR)

Use this form after all other forms applicable to this event (incident or near miss) or unsafe condition reported on the Healthcare Event Reporting Form (HERF) have been reviewed. Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. What is the date of this report?

__ __ / __ __ / __ __ __ __

MM DD YYYY

2. Where did the event occur, or, if an unsafe condition, where does it exist? (PLEASE REFER TO HERF QUESTION 6) CHECK ONE:

a. ☐ Inpatient general care area (e.g., medical/surgical unit)
b. ☐ Special care area (e.g., ICU, CCU, NICU)
c. ☐ Labor and delivery
d. ☐ Operating room or procedure area (e.g., cardiac catheter lab, endoscopy area), including PACU or recovery area
e. ☐ Radiology/imaging department, including onsite mobile units
f. ☐ Pharmacy
g. ☐ Laboratory, including pathology department and blood bank
h. ☐ Emergency department
i. ☐ Other area within the facility
j. ☐ Outpatient care area
k. ☐ Outside area (i.e., grounds of this facility)
l. ☐ Unknown
m. ☐ Other: **PLEASE SPECIFY** _____

3. Who reported the event or unsafe condition? (PLEASE REFER TO HERF QUESTION 18) CHECK ONE:

a. ☐ Healthcare professional
b. ☐ Healthcare worker, including liaison officer, patient transport/retrieval personnel, assistant/orderly, clerical/administrative personnel, domestic/hotel service personnel, interpreter/translator, technical/laboratory personnel, pastoral care personnel, or biomedical engineer
c. ☐ Emergency service personnel, including police officer, fire fighter, or other emergency service officer
d. ☐ Patient/relative/volunteer/caregiver/home assistant
e. ☐ Anonymous or unknown

4. What is the type of healthcare professional? CHECK ONE:

a. ☐ Doctor, dentist (including student)
b. ☐ Nurse, nurse practitioner, physician assistant (including student or trainee)
c. ☐ Pharmacist, pharmacy technician (including student)
d. ☐ Allied health personnel, paramedic

5. Please describe any additional details about the event or unsafe condition discovered after completion of the HERF:

_____

_____

_____

_____

IF UNSAFE CONDITION — STOP — This form is complete.

IF NEAR MISS, ANSWER QUESTIONS 6 - 12

IF INCIDENT, ANSWER QUESTIONS 7 - 13

6. What prevented the near miss from reaching the patient? CHECK ONE:

a. ☐ Fail-safe designed into the process and/or a safeguard worked effectively
b. ☐ Practitioner or staff who made the error noticed and recovered from the error (avoiding any possibility of it reaching the patient)
c. ☐ Spontaneous action by a practitioner or staff member (other than person making the error) prevented the event from reaching the patient
d. ☐ Action by the patient or patient's family member prevented the event from reaching the patient
e. ☐ Other
f. ☐ Unknown

7. Was the event associated with a handover/handoff? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

8. Are any contributing factors to the event known? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

9. What factor(s) contributed to the event? CHECK ALL THAT APPLY:

Environment

a. ☐ Culture of safety, management
b. ☐ Physical surroundings (e.g., lighting, noise)

Staff qualifications

c. ☐ Competence (e.g., qualifications, experience)
d. ☐ Training

Supervision/support

e. ☐ Clinical supervision
f. ☐ Managerial supervision

Policies and procedures, includes clinical protocols

g. ☐ Presence of policies
h. ☐ Clarity of policies

Equipment/device

i. ☐ Function
j. ☐ Design
k. ☐ Availability
l. ☐ Maintenance

Data

m. ☐ Availability
n. ☐ Accuracy
o. ☐ Legibility

Communication

p. ☐ Supervisor to staff
q. ☐ Among staff or team members
r. ☐ Staff to patient (or family)

Human factors

s. ☐ Fatigue
t. ☐ Stress
u. ☐ Inattention
v. ☐ Cognitive factors
w. ☐ Health issues

Other

x. ☐ Other: **PLEASE SPECIFY** _____

10. Was health information technology (HIT) implicated in this event? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

11. Was the event a National Quality Forum (NQF) Serious Reportable Event? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

ANSWER QUESTION 13

12. What was the applicable Serious Reportable Event? CHECK ONE:

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 I patient

Product or Device Events

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

Patient Protection Events

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

Care Management Events

l. ☐ 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)
m. ☐ Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
n. ☐ Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
o. ☐ Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
p. ☐ Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
q. ☐ Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
r. ☐ Patient death or serious disability due to spinal manipulative therapy
s. ☐ Artificial insemination with the wrong donor sperm or wrong egg

Environmental Events

t. ☐ Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
u. ☐ 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
v. ☐ Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
w. ☐ Patient death or serious disability associated with a fall while being cared for in a healthcare facility
x. ☐ Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

Criminal Events

y. ☐ Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
z. ☐ Abduction of a patient of any age
aa. ☐ Sexual assault on a patient within or on the grounds of a healthcare facility
bb. ☐ 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

IF NEAR MISS

This form is complete.

13. How preventable was the incident? CHECK ONE:

a. ☐ Almost certainly could have been prevented
b. ☐ Likely could have been prevented
c. ☐ Likely could not have been prevented
d. ☐ Almost certainly could not have been prevented
e. ☐ Provider does not make this determination by policy
f. ☐ Unknown

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**

Public reporting burden for the collection of information is estimated to average 15 minutes per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer, Attention: PRA, Paperwork Reduction Project (0935-0143), AHRQ, 540 Gaither Road, Room #5036, Rockville, MD 20850.

Event ID: _____

Initial Report Date (HERF Q17): _____

Patient Safety Event Report:

BLOOD OR BLOOD PRODUCT

Use this form to report any patient safety event or unsafe condition involving the processing and/or administration of blood or a blood product. This form is not intended for reporting blood or blood product collection and other processes prior to receipt of the product by the blood bank. If the event involves a device, please also complete the Device or Medical/Surgical Supply form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. What type of blood product was involved in the event? CHECK ONE:

a. ☐ Whole blood
b. ☐ Red blood cells
c. ☐ Platelets
d. ☐ Plasma
e. ☐ Cryoprecipitate
f. ☐ Granulocytes
g. ☐ Lymphocytes
h. ☐ Albumin
i. ☐ Factors (e.g., VII, VIII, IX, AT III)
j. ☐ IV immunoglobulin
k. ☐ RhIg
l. ☐ Other: **PLEASE SPECIFY** _____

2. What was the International Society of Blood Transfusion (ISBT) 8 digit product code for the product associated with this event?

ISBT PRODUCT CODE

IF UNSAFE CONDITION → STOP This form is complete.

3. Which of the following best describes the event? CHECK ONE:

a. ☐ Incorrect action (e.g., patient given blood of wrong ABO type)
b. ☐ Adverse reaction during or following administration without any apparent incorrect action
c. ☐ Unknown

→ STOP This form is complete.

4. What incorrect action was involved in administering the blood or blood product? CHECK ONE:

a. ☐ Incorrect patient
b. ☐ Incorrect ABO/Rh type
c. ☐ Incorrect product (e.g., giving heterologous blood product when autologous blood product should have been given)
d. ☐ Incorrect sequence of administration of products
e. ☐ Incorrect use of expired or unacceptably stored products

5. Was a two-person, three-way check documented? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

f. ☐ Incorrect volume (i.e., number of units or milliliters)

6. What was the volume? CHECK ONE:

a. ☐ Too much/too many
b. ☐ Too little/too few
c. ☐ Unknown

g. ☐ Incorrect IV fluid (i.e., administered product with incorrect IV fluid)
h. ☐ Incorrect timing (e.g., delay in administration)
i. ☐ Incorrect rate

7. Was the rate of administration: CHECK ONE:

a. ☐ Too fast
b. ☐ Too slow
c. ☐ Unknown

j. ☐ Unknown
k. ☐ Other: **PLEASE SPECIFY** _____

8. During which process was the event discovered (regardless of the stage when it originated)? CHECK ONE:

a. ☐ Product test or request
b. ☐ Sample collection
c. ☐ Sample handling
d. ☐ Sample receipt
e. ☐ Sample testing
f. ☐ Product storage
g. ☐ Available for issue
h. ☐ Product selection
i. ☐ Product manipulation
j. ☐ Request for pickup
k. ☐ Product issue
l. ☐ Product administration
m. ☐ Post-transfusion or administration
n. ☐ Unknown
o. ☐ Other: **PLEASE SPECIFY**

_____

9. During which process did the event originate (regardless of the stage when it was discovered)? CHECK ONE:

a. ☐ Product check-in
b. ☐ Product test or request
c. ☐ Sample collection
d. ☐ Sample handling
e. ☐ Sample receipt
f. ☐ Sample testing
g. ☐ Product storage
h. ☐ Available for issue
i. ☐ Product selection
j. ☐ Product manipulation
k. ☐ Request for pickup
l. ☐ Product issue
m. ☐ Product administration
n. ☐ Post-transfusion or administration
o. ☐ Unknown
p. ☐ Other: **PLEASE SPECIFY**

_____

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**

Public reporting burden for the collection of information is estimated to average 10 minutes per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer, Attention: PRA, Paperwork Reduction Project (0935-0143), AHRQ, 540 Gaither Road, Room #5036, Rockville, MD 20850.

Event ID: _____

Initial Report Date (HERF Q17): _____

Patient Safety Event Report:

DEVICE OR MEDICAL/SURGICAL SUPPLY

Use this form to report any patient safety event or unsafe condition involving a defect, failure, or incorrect use of a device. A device includes an implant, medical equipment, or medical/surgical supply (including disposable product). If the event involves a medication or other substance, please also complete the Medication or Other Substance form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. What type of device was involved in the event? CHECK ONE:

- a. ☐ Implantable device (e.g., device intended to be inserted into, and remain permanently in, tissue)
- b. ☐ Medical equipment (e.g., non-implantable device)
- c. ☐ Medical/surgical supply, including disposable product

2. At the time of the event, was the device placed within the patient's tissue? CHECK ONE:

- a. ☐ Yes
- b. ☐ No
- c. ☐ Unknown

3. Did the event result in the device being removed? CHECK ONE:

- a. ☐ Yes
- b. ☐ No
- c. ☐ Unknown

4. What is the name (brand or generic) of the device, product, or medical/surgical supply?

_____

5. What is the name of the manufacturer?

_____

6. Which of the following best describes the event or unsafe condition? CHECK ONE:

- a. ☐ Device failure

7. Which of the following best describes the device's involvement in the event? CHECK FIRST APPLICABLE:

- a. ☐ Device defect or failure directly impacted the patient (e.g., pacemaker)
- b. ☐ Device defect or failure was precursor to an event that reached the patient (e.g., infusion pump delivered an overdose)
- c. ☐ Device defect or failure created a near miss (e.g., instrument breaks immediately before use)
- d. ☐ Device defect or failure created an unsafe condition (e.g., device found to be defective during routine inspection or maintenance)
- e. ☐ Unknown

- b. ☐ Operator error

8. What type of operator error? CHECK ONE:

- a. ☐ Jury-rigging, creating a workaround, force-fitting, defeating fail-safe, etc.
- b. ☐ Selection or use of inappropriate device, including use of latex-containing product when patient was known to be allergic to latex
- c. ☐ Mis-setting, mis-programming, or otherwise misusing the device
- d. ☐ Unknown
- e. ☐ Other: **PLEASE SPECIFY** _____

- c. ☐ Combination or interaction of device failure and operator error
- d. ☐ Unknown

9. Did the event involve reuse of a device intended for single use (including use of a reprocessed single-use device)?
CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

10. Which of the following identifiers are known? CHECK ALL THAT APPLY:

a. ☐ Model number → **11. What is the model number?** _____

b. ☐ Serial number → **12. What is the serial number?** _____

c. ☐ Lot or batch number → **13. What is the lot or batch number?** _____

d. ☐ Other unique product identifier → **14. What is the type of other unique product identifier?** _____

15. What is the other unique product identifier? _____

e. ☐ Date of expiration → **16. What is the expiration date?** __ __/__ __/__ __ __ __
MM DD YYYY

f. ☐ "Unique Device Identifier" → **17. What is the "Unique Device Identifier" (UDI)?** _____

g. ☐ No identifiers known

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**
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Patient Safety Event Report:

FALL

Use this form to report details of a fall. For purposes of patient safety, a fall is a sudden, unintended, uncontrolled, downward displacement of a patient's body to the ground or other object. This definition includes unassisted falls and assisted falls (i.e., when a patient begins to fall and is assisted to the ground by another person). This definition excludes near falls (loss of balance that does not result in a fall) and falls resulting from a purposeful action or violent blow. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. Was the fall unassisted or assisted? CHECK ONE:

a. ☐ Unassisted
b. ☐ Assisted
c. ☐ Unknown

2. Was the fall observed? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

3. Who observed the fall? CHECK FIRST APPLICABLE:

a. ☐ Staff
b. ☐ Visitor, family, or another patient

4. Did the patient sustain a physical injury as a result of the fall? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

5. What type of injury was sustained? CHECK ONE; IF MORE THAN ONE, CHECK MOST SEVERE:

a. ☐ Dislocation
b. ☐ Fracture
c. ☐ Intracranial injury
d. ☐ Laceration requiring sutures
e. ☐ Other: **PLEASE SPECIFY** _____

6. Prior to the fall, what was the patient doing or trying to do? CHECK ONE:

a. ☐ Ambulating without assistance and without an assistive device or medical equipment
b. ☐ Ambulating with assistance and/or with an assistive device or medical equipment
c. ☐ Changing position (e.g., in bed, chair)
d. ☐ Dressing or undressing
e. ☐ Reaching for an item
f. ☐ Showering or bathing
g. ☐ Toileting-related activities
h. ☐ Transferring to or from bed, chair, etc.
i. ☐ Undergoing a diagnostic or therapeutic procedure
j. ☐ Unknown
k. ☐ Other: **PLEASE SPECIFY** _____

7. Prior to the fall, was a fall risk assessment performed? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

8. Was the patient determined to be at risk for a fall? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

9. What protocols/interventions were in place, or being used, to prevent falls for this patient? CHECK ALL THAT APPLY:

a. ☐ Assistive devices (e.g., wheelchair, commode, cane, crutches, scooter, walker)
b. ☐ Bed or chair alarm
c. ☐ Bed in low position
d. ☐ Call light/personal items within reach
e. ☐ Fall alert
f. ☐ Change in medication (e.g., timing or dosing of current medication)
g. ☐ Non-slip footwear
h. ☐ Patient and family education
i. ☐ Patient situated close to the nurses' station
j. ☐ Physical/occupational therapy
k. ☐ Siderails
l. ☐ Sitter
m. ☐ Toileting regimen
n. ☐ None
o. ☐ Unknown
p. ☐ Other: **PLEASE SPECIFY** _____

10. At time of the fall, was the patient on medication known to increase the risk for a fall? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

11. Was the medication considered to have contributed to the fall?
CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

Thank you for completing these questions.

Event ID: _____

Initial Report Date (HERF Q17): _____

Patient Safety Event Report:

HEALTHCARE-ASSOCIATED INFECTION

Use this form to report a healthcare-associated infection (HAI). An HAI is a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). It is acquired during the course of receiving treatment for other conditions within a healthcare setting. For an inpatient care location, there must be no evidence that the infection was present or incubating at the time of admission (except surgical site infection (SSI)). Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

The Centers for Disease Control and Prevention's National Health Safety Network (NHSN) gathers surveillance data on four major types of healthcare-associated infections: surgical site infections (SSI), central line-associated bloodstream infections (CLABSI), ventilator-associated pneumonias (VAP), and catheter-associated urinary tract infections (CAUTI). Although the Common Formats capture information on additional types of HAIs, we limit capture of further detail on HAIs to those tracked in the NHSN. Specific NHSN definitions are provided below.

Central line-associated bloodstream infection (CLABSI):	Primary bloodstream infection (BSI) in a patient that had a central line within the 48-hour period before the development of the BSI and that is not related to an infection at another site. http://www.cdc.gov/nhsn/PDFs/pscManual/4PSC_CLABScurrent.pdf
Ventilator-associated pneumonia (VAP):	Pneumonia (PNEU) that occurs in a patient who was intubated and ventilated at the time of, or within 48 hours before, the onset of the PNEU. http://www.cdc.gov/nhsn/PDFs/pscManual/6pscVAPcurrent.pdf
Catheter-associated urinary tract infection (CAUTI):	Urinary tract infection (UTI) that occurs in a patient who had an indwelling urinary catheter in place within the 48-hour period before the onset of the UTI. http://www.cdc.gov/nhsn/pdfs/pscManual/7pscCAUTIcurrent.pdf
Surgical site infection (SSI):	For full details please refer to http://www.cdc.gov/nhsn/PDFs/pscManual/9pscSSIcurrent.pdf

NOTE: There is no minimum period of time that the device must be in place in order for the infection to be considered device-associated.

1. Was the infection determined to be present or incubating on admission? CHECK ONE:

a. ☐ Yes – infection was determined to be present or incubating on admission → ANSWER QUESTION 2

b. ☐ No – infection developed during this admission

c. ☐ Unknown

→ ANSWER QUESTION 3

2. Which of the following best describes the infection? CHECK ONE:

a. ☐ Surgical site infection (SSI) in a patient operated on at this facility in the previous 30 days or, if an implant, in the previous year → ANSWER QUESTION 3

b. ☐ Community acquired infection that was determined to be present or incubating on admission with no treatment at any facility

c. ☐ Presumed HAI (other than SSI) that developed following a discharge from this facility

d. ☐ Presumed HAI (other than SSI) that developed following treatment at an outpatient site, operated by this facility

e. ☐ Presumed HAI that developed following treatment at another inpatient or outpatient facility

→ STOP This form is complete.

Event ID: _____

Initial Report Date (HERF Q17): _____

3. Was the person who determined the infection to be a healthcare-associated infection (HAI) a healthcare professional with specific training in infectious disease and/or infection control? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

4. What type of HAI is being reported? CHECK ONE:

a. ☐ Primary bloodstream infection (BSI)

5. Was it central line-associated (CLABSI)? CHECK ONE:

a. ☐ Yes → ANSWER QUESTION 10
b. ☐ No → STOP This form is complete.

b. ☐ Pneumonia

6. Was it a ventilator-associated pneumonia (VAP - i.e., the patient had a device to assist or control respiration continuously through a tracheostomy or by endotracheal intubation)? CHECK ONE:

a. ☐ Yes → ANSWER QUESTION 11
b. ☐ No → STOP This form is complete.

c. ☐ Urinary tract infection (UTI)

7. Was it catheter-associated (CAUTI)? CHECK ONE:

a. ☐ Yes → ANSWER QUESTION 12
b. ☐ No → STOP This form is complete.

d. ☐ Surgical site infection (SSI)

8. The SSI was classified as which of the following? CHECK FIRST APPLICABLE:

a. ☐ Organ/space
b. ☐ Deep incisional primary (DIP)
c. ☐ Deep incisional secondary (DIS)
d. ☐ Superficial incisional primary (SIP)
e. ☐ Superficial incisional secondary (SIS)
f. ☐ Unknown

→ STOP This form is complete.

PLEASE ALSO COMPLETE THE SURGERY OR ANESTHESIA FORM

e. ☐ Other type of infection (not involving surgical site) that developed during admission

9. Which other type of infection? CHECK ONE:

a. ☐ Bone or joint infection
b. ☐ Central nervous system infection
c. ☐ Cardiovascular system infection
d. ☐ Eye, ear, nose, throat, or mouth infection
e. ☐ Gastrointestinal system infection
f. ☐ Lower respiratory tract infection (other than pneumonia)
g. ☐ Reproductive tract infection
h. ☐ Skin or soft tissue infection
i. ☐ Systemic infection
j. ☐ Other: **PLEASE SPECIFY** _____

→ STOP This form is complete.

ONLY IF EVENT INVOLVED A **CLABSI**, ANSWER QUESTION **10**

10. Which type of central line? CHECK ONE:

a. ☐ Permanent (tunneled or implanted) central line
b. ☐ Temporary (non-tunneled) central line
c. ☐ Umbilical catheter

→ ANSWER QUESTION **14**

ONLY IF EVENT INVOLVED A **VAP**, ANSWER QUESTION **11**

11. The VAP was classified as which of the following? CHECK FIRST APPLICABLE:

a. ☐ Pneumonia in an immunocompromised patient determined by both clinical and laboratory criteria
b. ☐ Pneumonia with specific laboratory findings
c. ☐ Clinically defined pneumonia

→ ANSWER QUESTION **14**

ONLY IF EVENT INVOLVED A **CAUTI**, ANSWER QUESTIONS **12 - 13**

12. What was the urinary catheter status at the time of specimen collection that was the basis for diagnosis of CAUTI? CHECK ONE:

a. ☐ In place at the time of specimen collection
b. ☐ Removed within 48 hours prior to specimen collection

13. The CAUTI was classified as which of the following? CHECK ONE:

a. ☐ Symptomatic UTI
b. ☐ Asymptomatic bacteremic UTI

ONLY IF EVENT INVOLVED A **CLABSI, VAP, OR CAUTI**, ANSWER QUESTION **14**

14. At which inpatient location was the patient assigned when the specimen that met the infection criteria was collected, or when the first clinical evidence of CLABSI, VAP, or CAUTI appeared? If the infection developed within 48 hours of transfer from one location to one or more other locations within this facility, select the patient's first such inpatient location within the 48 hour period where the central line, urinary catheter, or ventilator was used. CHECK ONE:

a. ☐ Specialty care area (i.e., hematology/oncology ward, bone marrow transplant unit, solid organ transplant unit, inpatient dialysis unit, or long term acute care area)
b. ☐ Intensive care unit, including pediatric
c. ☐ Neonatal intensive care unit
d. ☐ Other location (e.g., surgical or medical ward)
e. ☐ Unknown

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**

Event ID: _____

Initial Report Date (HERF Q17): _____

Patient Safety Event Report:

MEDICATION OR OTHER SUBSTANCE

Use this form to report any patient safety event or unsafe condition involving a substance such as a medication, vaccine, nutrient, dietary supplement, medical gas, or contrast media. Do not complete this form if the event involves appropriateness of therapeutic choice or decision making (e.g., physician decision to prescribe medication despite known drug-drug interaction). If the event involves a device, please also complete the Device or Medical/Surgical Supply form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. What type of medication/substance was involved? CHECK ONE:

a. ☐ Medication

2. What type of medication? CHECK ONE:

a. ☐ Prescription or over-the-counter
b. ☐ Compounded preparation
c. ☐ Investigational drug
d. ☐ Unknown

3. Please list all ingredients:

_____

_____

_____

_____

b. ☐ Biological product

4. What type of biological product? CHECK ONE:

a. ☐ Vaccine
b. ☐ Other biological product (e.g., thrombolytic)

5. What was the lot number of the vaccine?

_____
LOT NUMBER

c. ☐ Nutritional product

6. What type of nutritional product? CHECK ONE:

a. ☐ Dietary supplement (other than vitamins or minerals)
b. ☐ Vitamins or minerals
c. ☐ Enteral nutritional product, including infant formula
d. ☐ Parenteral nutritional product
e. ☐ Other: **PLEASE SPECIFY**

_____

d. ☐ Expressed human breast milk

e. ☐ Medical gas (e.g., oxygen, nitrogen, nitrous oxide)

f. ☐ Contrast media

g. ☐ Radiopharmaceutical

h. ☐ Patient food (not suspected in drug-food interactions)

STOP This form is complete.

i. ☐ Other substance: **PLEASE SPECIFY**

_____

7. Which of the following best characterizes the event? CHECK ONE:

a. ☐ Incorrect action (process failure or error) (e.g., such as administering overdose or incorrect medication, and other medication errors)

b. ☐ Unsafe condition

→ ANSWER QUESTIONS 17 - 21

c. ☐ Adverse reaction in patient to the administered substance without any apparent incorrect action

d. ☐ Unknown

→ STOP This form is complete.

8. What was the incorrect action? CHECK ALL THAT APPLY:

a. ☐ Incorrect patient

b. ☐ Incorrect medication/substance

c. ☐ Incorrect dose(s)

9. Which best describes the incorrect dose(s)? CHECK ONE:

a. ☐ Overdose
b. ☐ Underdose
c. ☐ Missed or omitted dose
d. ☐ Extra dose
e. ☐ Unknown

d. ☐ Incorrect route of administration

e. ☐ Incorrect timing

10. Which best describes the incorrect timing? CHECK ONE:

a. ☐ Given too early
b. ☐ Given too late
c. ☐ Unknown

f. ☐ Incorrect rate

11. Which best describes the incorrect rate? CHECK ONE:

a. ☐ Too quickly
b. ☐ Too slowly
c. ☐ Unknown

g. ☐ Incorrect duration of administration or course of therapy

h. ☐ Incorrect dosage form (e.g., sustained release instead of immediate release)

i. ☐ Incorrect strength or concentration

12. Which best describes the incorrect strength or concentration? CHECK ONE:

a. ☐ Too high
b. ☐ Too low
c. ☐ Unknown

j. ☐ Incorrect preparation, including inappropriate cutting of tablets, error in compounding, mixing, etc.

k. ☐ Expired or deteriorated medication/substance

13. What was the expiration date? __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

l. ☐ Medication/substance that is known to be an allergen to the patient

14. Was there a documented history of allergies or sensitivities to the medication/substance administered? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

m. ☐ Medication/substance that is known to be contraindicated for the patient

15. What was the contraindication (potential or actual interaction)? CHECK ONE:

a. ☐ Drug-drug
b. ☐ Drug-food
c. ☐ Drug-disease
d. ☐ Other: **PLEASE SPECIFY** _____

n. ☐ Incorrect patient/family action (e.g., self-administration error)

o. ☐ Other: **PLEASE SPECIFY** _____

16. At what stage in the process did the event originate, regardless of the stage at which it was discovered?

CHECK ONE:

a. ☐ Purchasing
b. ☐ Storing
c. ☐ Prescribing/ordering
d. ☐ Transcribing
e. ☐ Preparing
f. ☐ Dispensing
g. ☐ Administering
h. ☐ Monitoring
i. ☐ Unknown
j. ☐ Other: **PLEASE SPECIFY** _____

QUESTIONS 17 - 23 DO NOT APPLY TO COMPOUNDED PREPARATION OR EXPRESSED HUMAN BREAST MILK

FOR AN INCIDENT, ANSWER QUESTIONS 17-23

FOR A NEAR MISS, ANSWER QUESTIONS 17-22

FOR AN UNSAFE CONDITION, ANSWER QUESTIONS 17-21

Please provide the following medication details for any medications or other substances directly involved in the event.

	17. Generic name or investigational drug name	18. Brand name (if known)	19. Manufacturer (if known)	20. Strength or concentration of product	21. Dosage form of product	22. Was this medication/ substance prescribed for this patient	23. Was this medication/ substance given to this patient?
1						a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No
2						a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No
3						a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No
4						a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No
5						a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No

IF THIS EVENT DID NOT INVOLVE AN INCORRECT ROUTE OF ADMINISTRATION — STOP — **This form is complete.**

IF THE EVENT INVOLVED AN INCORRECT ROUTE OF ADMINISTRATION, ANSWER QUESTIONS 24 - 25

24. What was the intended route of administration?
CHECK ONE:

- a. ☐ Cutaneous, topical application, including ointment, spray, patch
- b. ☐ Subcutaneous
- c. ☐ Ophthalmic
- d. ☐ Oral, including sublingual or buccal
- e. ☐ Otic
- f. ☐ Nasal
- g. ☐ Inhalation
- h. ☐ Intravenous
- i. ☐ Intramuscular
- j. ☐ Intrathecal
- k. ☐ Epidural
- l. ☐ Gastric
- m. ☐ Rectal
- n. ☐ Vaginal
- o. ☐ Unknown
- p. ☐ Other: **PLEASE SPECIFY** _____

25. What was the actual route of administration (attempted or completed)? CHECK ONE:

- a. ☐ Cutaneous, topical application, including ointment, spray, patch
- b. ☐ Subcutaneous
- c. ☐ Ophthalmic
- d. ☐ Oral, including sublingual or buccal
- e. ☐ Otic
- f. ☐ Nasal
- g. ☐ Inhalation
- h. ☐ Intravenous
- i. ☐ Intramuscular
- j. ☐ Intrathecal
- k. ☐ Epidural
- l. ☐ Gastric
- m. ☐ Rectal
- n. ☐ Vaginal
- o. ☐ Unknown
- p. ☐ Other: **PLEASE SPECIFY** _____

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**

Event ID: _____

Initial Report Date (HERF Q17): _____

Patient Safety Event Report:

PERINATAL

Use this form to report any patient safety event associated with the birthing process or intrauterine procedures that occur during the perinatal period to the mother, fetus(es), or neonate(s). The perinatal period extends from the 20th week of gestation through 4 weeks (28 days) postpartum. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

If a single event affected the mother, and/or fetus or neonate, use one perinatal event form. In the rare circumstance when a single event affects more than one neonate, fill out this form for the most severely affected neonate and note injury to other neonate(s) in the narrative.

1. Which of the following did the event involve? CHECK ONE:

a. ☐ Birthing process (labor and delivery)
b. ☐ Intrauterine procedure (prenatal)
c. ☐ Other
d. ☐ Unknown

STOP This form is complete.

2. Who was affected by the event? CHECK ONE:

a. ☐ Mother
b. ☐ Mother and fetus(es)
c. ☐ Mother and neonate

3. Was the mother a primipara? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

4. How many fetuses were in this pregnancy? ENTER NUMBER:

☐ NUMBER

COUNT FETUSES WHETHER OR NOT BORN ALIVE. IF A FETAL REDUCTION WAS PERFORMED, COUNT THE NUMBER AFTER SUCH REDUCTION.

5. Immediately prior to delivery, or at the time of the intrauterine procedure (prenatal), what was the best estimate of completed weeks of gestation? CHECK ONE:

a. ☐ 20-< 36 weeks
b. ☐ 36-< 38 weeks
c. ☐ 38-< 42 weeks
d. ☐ 42 weeks or more
e. ☐ Unknown

IF THIS EVENT INVOLVED THE BIRTHING PROCESS, ANSWER QUESTIONS 6 - 16

IF THIS EVENT INVOLVED AN INTRAUTERINE PROCEDURE, ANSWER QUESTIONS 14 - 16

6. What was the date of delivery? ___ ___ / ___ ___ / ___ ___ ___ ___

MM DD YYYY

7. Was labor induced or augmented? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

8. Which one? CHECK ONE:

a. ☐ Induced
b. ☐ Augmented

9. What was the final mode of delivery? CHECK ONE:

a. ☐ Vaginal delivery
b. ☐ Cesarean section
c. ☐ Unknown

10. Regardless of the final mode of delivery, was instrumentation used to assist vaginal (or attempted vaginal) delivery? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

11. What instrumentation was used? CHECK ONE:

a. ☐ Vacuum
b. ☐ Forceps
c. ☐ Vacuum followed by forceps

12. Number of live births:

ENTER NUMBER

13. What was the neonate's birthweight?

ENTER IN GRAMS

14. Which adverse outcome(s) did the mother sustain? CHECK ALL THAT APPLY:

a. ☐ Hemorrhage requiring transfusion
b. ☐ Eclampsia
c. ☐ Magnesium toxicity
d. ☐ Infection
e. ☐ Injury to body part or organ
f. ☐ Death
g. ☐ Neonate/fetal injury only
h. ☐ Other: **PLEASE SPECIFY** _____

15. Which of the following maternal infections? CHECK ONE:

a. ☐ Chorioamnionitis
b. ☐ Endometritis
c. ☐ Other: **PLEASE SPECIFY** _____

16. Which body part(s) or organ(s)? CHECK ALL THAT APPLY:

a. ☐ Uterine rupture
b. ☐ Third- or fourth-degree perineal laceration
c. ☐ Ureter
d. ☐ Bladder
e. ☐ Bowel
f. ☐ Other: **PLEASE SPECIFY** _____

ONLY IF EVENT AFFECTED A FETUS, ANSWER QUESTION 17

17. What adverse outcome did the fetus sustain? CHECK FIRST APPLICABLE:

a. ☐ Unexpected death
b. ☐ Injury

STOP This form is complete.

ONLY IF EVENT AFFECTED A NEONATE, ANSWER QUESTIONS 18 - 20

18. What was the 5-minute Apgar score?

APGAR SCORE

19. Which adverse outcome(s) did the neonate sustain? CHECK ALL THAT APPLY:

a. ☐ Birth trauma as listed under ICD-9-CM 767
b. ☐ Five-minute Apgar < 7 and birthweight > 2500 grams
c. ☐ Anoxic or hypoxic encephalopathy
d. ☐ Seizure(s)
e. ☐ Infection (e.g., group B strep)
f. ☐ Unexpected death
g. ☐ Other: **PLEASE SPECIFY** _____

20. Which birth trauma? CHECK ONE:

a. ☐ Subdural or cerebral hemorrhage
b. ☐ Injury to brachial plexus
c. ☐ Other: **PLEASE SPECIFY** _____

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**

Event ID: _____

Initial Report Date (HERF Q17): _____

Patient Safety Event Report:

PRESSURE ULCER

Use this form to report a pressure ulcer or suspected Deep Tissue Injury that was 1) not present on admission (i.e., newly-developed), or 2) worsened during the patient's stay. Report only an event that occurred prior to patient discharge. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

Stage 1:	Intact skin with non-blanchable redness of a localized area, usually over a bony prominence.
Stage 2:	Partial-thickness tissue loss of dermis presenting as a shallow open ulcer with a red/pink wound bed, without slough.
Stage 3:	Full-thickness tissue loss. Subcutaneous fat may be visible but bone, tendon, or muscle are not exposed.
Stage 4:	Full-thickness tissue loss with exposed bone, tendon, or muscle.
Unstageable:	Full-thickness tissue loss in which the base of the ulcer is covered by slough and/or eschar in the wound bed.
Suspected Deep Tissue Injury:	Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear.

1. What was the most advanced stage of the pressure ulcer or suspected Deep Tissue Injury being reported? CHECK ONE:

- a. ☐ Stage 1
- b. ☐ Stage 2

→ STOP This form is complete.

- c. ☐ Suspected Deep Tissue Injury

→ GO TO QUESTION 2

- d. ☐ Stage 3
- e. ☐ Stage 4
- f. ☐ Unstageable

→ GO TO QUESTION 3

- g. ☐ Mucosal ulcer only (no skin involvement)
- h. ☐ Unknown

→ STOP This form is complete.

2. What was the status of the suspected Deep Tissue Injury on admission? CHECK ONE:

- a. ☐ Present as suspected Deep Tissue Injury

→ STOP This form is complete.

- b. ☐ Present as a Stage 1 pressure ulcer
- c. ☐ Not present
- d. ☐ Unknown

→ GO TO QUESTION 4

3. What was the status of the Stage 3, 4, or unstageable pressure ulcer on admission? CHECK ONE:

- a. ☐ Not present
- b. ☐ Stage 1
- c. ☐ Stage 2

→ GO TO QUESTION 4

- d. ☐ Suspected Deep Tissue Injury
- e. ☐ Stage 3
- f. ☐ Stage 4
- g. ☐ Unstageable

→ STOP This form is complete.

- h. ☐ Unknown

→ GO TO QUESTION 4

4. On admission to this facility, was a skin inspection documented? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

5. When was the first pressure ulcer risk assessment performed? CHECK ONE:

a. ☐ On admission (within 24 hours)
b. ☐ Not on admission, but done prior to the discovery of a newly-developed, or advancement of an existing, pressure ulcer
c. ☐ Not on admission, but done after discovery of a newly-developed, or advancement of an existing, pressure ulcer
d. ☐ No risk assessment performed
e. ☐ Unknown

6. What type of risk assessment was performed? CHECK FIRST APPLICABLE:

a. ☐ Formal assessment (e.g., Braden, Braden Q (pediatric version), Norton, Waterlow)
b. ☐ Clinical assessment
c. ☐ Unknown

7. As a result of the assessment, was the patient documented to be at increased risk for pressure ulcer? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

8. Was any preventive intervention implemented? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

9. What intervention(s) was used? CHECK ALL THAT APPLY:

a. ☐ Pressure redistribution device
b. ☐ Repositioning
c. ☐ Nutritional support
d. ☐ Other: **PLEASE SPECIFY**

_____

10. Was the use of a device or appliance involved in the development or advancement of the pressure ulcer? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

11. What was the type of device or appliance? CHECK ONE:

a. ☐ Anti-embolic device
b. ☐ Intraoperative positioning device
c. ☐ Orthopedic appliance (e.g., cast, splint, orthotic)
d. ☐ Oxygen delivery device (e.g., nasal prongs, oxygen mask)
e. ☐ Tube
f. ☐ Other: **PLEASE SPECIFY**

_____

12. What was the type of tube? CHECK ONE:

a. ☐ Endotracheal
b. ☐ Gastrostomy
c. ☐ Nasogastric
d. ☐ Tracheostomy
e. ☐ Indwelling urinary catheter
f. ☐ Other: **PLEASE SPECIFY**

_____

13. During the patient's stay at this facility, did the patient develop a secondary morbidity (e.g., osteomyelitis or sepsis)? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

14. Was the secondary morbidity attributed to the presence of the pressure ulcer or suspected Deep Tissue Injury? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

Thank you for completing these questions.

Event ID: _____

Initial Report Date (HERF Q17): _____

Patient Safety Event Report:

SURGERY OR ANESTHESIA

Use this form to report an event involving a surgical or other invasive procedure (e.g., colonoscopy), or the administration of anesthesia. Do not complete this form if the event involved the removal of organs from brain-dead patients (ASA Class 6) or handling an organ after procurement. If the event involved an anesthetic device, please also complete the Device or Medical/Surgical Supply form. If the event involved an anesthetic, medical gas, medication, or other substance, please also complete the Medication or Other Substance form. If the event involved a healthcare-associated infection, please also complete the Healthcare-associated Infection form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and PSO use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. Describe briefly the procedure associated with this event:

_____

2. Enter ICD-9-CM procedure code associated with this event: _____

ICD-9-CM CODE

3. What was the patient's documented American Society of Anesthesiologists (ASA) Physical Classification System class? CHECK ONE:

a. ☐ Class 1
b. ☐ Class 2
c. ☐ Class 3
d. ☐ Class 4
e. ☐ Class 5
f. ☐ ASA classification was not documented

4. Was the procedure performed as an emergency? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

5. When was the event discovered? CHECK ONE:

a. ☐ Before anesthesia started (or no anesthesia used)
b. ☐ After anesthesia started, but before incision or start of procedure
c. ☐ After procedure started (incision) but before procedure ended (closure)
d. ☐ At closure, if surgical operation
e. ☐ After procedure ended, but before patient left operating room or other procedure area
f. ☐ During post-anesthesia care/recovery period
g. ☐ After post-anesthesia recovery, but before discharge
h. ☐ After patient was discharged
i. ☐ During anesthesia when no surgical operation or invasive procedure was performed
j. ☐ Unknown

6. What was the total length of the procedure (i.e., induction of anesthesia to the end of anesthesia)? CHECK ONE:

a. ☐ Less than 1 hour
b. ☐ Greater than or equal to 1 hour, but less than 3 hours
c. ☐ Greater than or equal to 3 hours, but less than 5 hours
d. ☐ Greater than or equal to 5 hours
e. ☐ Unknown

7. What type of anesthesia or sedation was used? CHECK FIRST APPLICABLE:

a. ☐ General anesthesia
b. ☐ Regional anesthesia (e.g., epidural, spinal, or peripheral nerve blocks)
c. ☐ Local or topical anesthesia
d. ☐ Sedation only

8. What was the level of sedation? CHECK ONE:

a. ☐ Deep sedation or analgesia
b. ☐ Moderate sedation or analgesia (conscious sedation)
c. ☐ Minimal sedation (anxiolysis)
d. ☐ No sedation (if regional, local, or topical anesthesia)
e. ☐ Unknown

e. ☐ None

ANSWER QUESTION 11

9. Who administered (or, if the event occurred prior to administration of anesthesia, person who was scheduled to administer) the anesthesia? CHECK ONE:

a. ☐ Anesthesiologist
b. ☐ Certified Registered Nurse Anesthetist
c. ☐ Other healthcare professional
d. ☐ Unknown

10. Was there supervision by an anesthesiologist? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

11. What was the medical or surgical specialty of the provider who performed the procedure? CHECK ONE:

SELECT THE SPECIALTY OF THE PROVIDER OR TEAM THAT PERFORMED THE PROCEDURE. IF THE PROCEDURE WAS NOT STARTED, SELECT THE SPECIALTY OF THE PROVIDER WHO WAS SCHEDULED TO PERFORM THE PROCEDURE.

a. ☐ Anesthesiology
b. ☐ Cardiology
c. ☐ Colorectal surgery
d. ☐ Dentistry, including oral surgery
e. ☐ Dermatology
f. ☐ Emergency medicine
g. ☐ Family medicine
h. ☐ Gastroenterology
i. ☐ General surgery
j. ☐ Internal medicine
k. ☐ Neurological surgery
l. ☐ Obstetrics/Gynecology
m. ☐ Ophthalmology
n. ☐ Orthopedic surgery
o. ☐ Otolaryngology
p. ☐ Pediatrics
q. ☐ Pediatric surgery
r. ☐ Plastic surgery
s. ☐ Podiatry
t. ☐ Pulmonology
u. ☐ Radiology, including vascular and interventional
v. ☐ Thoracic surgery
w. ☐ Urology
x. ☐ Vascular surgery
y. ☐ Other: **PLEASE SPECIFY** _____

12. What best describes the event? CHECK ONE:

a. ☐ Surgical event → ANSWER QUESTION 15

b. ☐ Anesthesia event → ANSWER QUESTION 24

c. ☐ Major complication that could be associated with either surgery or anesthesia → ANSWER QUESTION 13

13. Which of the following major complications occurred? CHECK ONE:

a. ☐ Cardiac or circulatory event

b. ☐ Central nervous system event

c. ☐ Renal failure, impairment, or insufficiency

d. ☐ Respiratory failure, requiring unplanned respiratory support, within 24 hours after the procedure

e. ☐ Other: **PLEASE SPECIFY** _____

14. Which of the following best describes the respiratory support provided? CHECK ONE:

a. ☐ Prolonged ventilator support

b. ☐ Re-institution of ventilator following discontinuation

c. ☐ Other: **PLEASE SPECIFY** _____

IF MAJOR COMPLICATION → STOP This form is complete.

15. Was the surgical event an unintentionally retained object? CHECK ONE:

a. ☐ Yes

b. ☐ No → ANSWER QUESTION 21

16. What type of object was retained? CHECK ONE:

a. ☐ Sponge

b. ☐ Needle

c. ☐ Towel

d. ☐ Whole instrument (e.g., clamp)

e. ☐ Instrument fragment

f. ☐ Other: **PLEASE SPECIFY** _____

17. Was a count performed for the type of object that was retained? CHECK ONE:

a. ☐ Yes

18. After counting, what was the reported count status? CHECK ONE:

a. ☐ Incorrect (unreconciled) count → ANSWER QUESTION 19

b. ☐ Correct (reconciled) count → STOP This form is complete.

b. ☐ No, object "countable"
c. ☐ No, object not "countable" (e.g., broken piece retained)
d. ☐ Unknown

→ STOP This form is complete.

19. Was an x-ray obtained before the end of the procedure to detect the retained object? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

20. Was the retained object radiopaque (i.e., detectable by x-ray)? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

IF RETAINED OBJECT → STOP This form is complete.

21. Which of the following best characterizes the surgical event? CHECK ONE:

a. ☐ Surgical site infection → ALSO COMPLETE THE HEALTHCARE-ASSOCIATED INFECTION FORM

b. ☐ Bleeding requiring return to the operating room

c. ☐ Burn and/or operating room fire

22. Which of the following occurred? CHECK ONE:

a. ☐ Burn
b. ☐ Operating room fire
c. ☐ Both

d. ☐ Incorrect surgical or invasive procedure

23. What was incorrect about the surgical or invasive procedure? CHECK FIRST APPLICABLE:

a. ☐ Incorrect patient
b. ☐ Incorrect side
c. ☐ Incorrect site
d. ☐ Incorrect procedure
e. ☐ Incorrect implant by mistake
f. ☐ Incorrect implant because correct implant was not available
g. ☐ Other: PLEASE SPECIFY _____

e. ☐ Iatrogenic pneumothorax
f. ☐ Unintended laceration or puncture
g. ☐ Dehiscence, flap or wound failure or disruption, or graft failure
h. ☐ Unintended blockage, obstruction, or ligation
i. ☐ Unplanned removal of organ
j. ☐ Air embolus
k. ☐ Other: PLEASE SPECIFY _____

IF SURGICAL EVENT → STOP This form is complete.

24. If the event involved anesthesia, which of the following best characterizes the event? CHECK ONE:

a. ☐ Dental injury
b. ☐ Ocular injury
c. ☐ Peripheral nerve injury
d. ☐ Awareness (during anesthesia)
e. ☐ Malignant hyperthermia
f. ☐ Problem with anesthetic, medical gas, medication, or other substance → **ALSO COMPLETE THE MEDICATION OR OTHER SUBSTANCE FORM**
g. ☐ Problem with device used in the delivery of anesthesia → **ALSO COMPLETE THE DEVICE OR MEDICAL/SURGICAL SUPPLY FORM**
h. ☐ Difficulty managing airway

25. Which of the following best characterizes the airway management problem? CHECK ONE:

a. ☐ Difficulty during tracheal intubation
b. ☐ Difficulty maintaining airway during procedure
c. ☐ Esophageal intubation
d. ☐ Re-intubation, following extubation, in the operating or recovery room
e. ☐ Other: **PLEASE SPECIFY** _____

i. ☐ Other: **PLEASE SPECIFY**
_____

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**

AHRQ Common Formats for Skilled Nursing Facilities

Forms

Event ID: _____

Initial Report Date (HERF Q12): _____

Patient Safety Event Report – Skilled Nursing Facility:

HEALTHCARE EVENT REPORTING FORM (HERF)

Use this form to report either a patient safety event or unsafe condition. The term event includes both an incident that reached the patient/resident and a near miss that did not. Highlighted fields are collected for local facility and Patient Safety Organization (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. What is being reported? check one:

a. ☐ **Incident:** A patient safety event that reached the patient/resident, whether or not the patient/resident was harmed.

b. ☐ **Near Miss:** A patient safety event that did not reach the patient/resident.

c. ☐ **Unsafe Condition:** Any circumstance that increases the probability of a patient safety event.

2. Event Discovery Date:

___ ___ / ___ ___ / ___ ___ ___ ___

MM DD YYYY

3. Event Discovery Time: ___ ___ ___ ___ HOURS

☐ Unknown

H H M M

(MILITARY TIME)

4. Briefly describe the event that occurred or unsafe condition:

5. Briefly describe the location where the event occurred or where the unsafe condition exists:

6. Which of the following categories are associated with the event or unsafe condition? CHECK ALL THAT APPLY:

FOR EACH CATEGORY SELECTED BELOW, EXCEPT ABUSE OR NEGLECT, ACCIDENT, ELOPEMENT OR "OTHER", PLEASE COMPLETE THE CORRESPONDING CATEGORY-SPECIFIC FORM. ALL CATEGORIES INCLUDE REPORTING OF INCIDENTS. ANY CATEGORY WITH + ALSO INCLUDES REPORTING OF NEAR MISSES. ANY CATEGORY WITH * ALSO INCLUDES REPORTING OF UNSAFE CONDITIONS.

a. ☐ Abuse or Neglect

b. ☐ Accident (e.g., scalding, choking, and/or restraint related)

c. ☐ **Device or Supply, Including Health Information Technology (HIT)*+**

d. ☐ Elopement

e. ☐ **Fall**

f. ☐ **Healthcare-associated Infection**

g. ☐ **Medication or Other Substance*+**

h. ☐ **Pressure Ulcer**

i. ☐ Other*+: **PLEASE SPECIFY** _____

Event ID: _____

Initial Report Date (HERF Q12): _____

PATIENT INFORMATION (COMPLETE ONLY IF INCIDENT):

Please complete the patient/resident identifiers below.

7. **Patient's/Resident's Name:** _____ (FIRST) _____ (MIDDLE) _____ (LAST)

8. **Patient's/Resident's Date of Birth:** ___ ___ / ___ ___ / ___ ___ ___ ___ (MM / DD / YYYY)

9. **Medical Record #:** _____ (ENTER NUMBER)

10. **Patient's/Resident's Gender:** a. ☐ Male b. ☐ Female c. ☐ Unknown

11. **How many patients/residents did the incident reach?** _____ (ENTER NUMBER)

REPORT AND EVENT REPORTER INFORMATION

12. **Report Date:** ___ ___ / ___ ___ / ___ ___ ___ ___ (MM / DD / YYYY) 13. ☐ **Anonymous Reporter**

14. **Reporter's Name:** _____ (FIRST) _____ (MIDDLE) _____ (LAST)

15. **Telephone Number:** _____ 16. **Email Address:** _____

17. **Reporter's Job or Position:** _____

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**

Public reporting burden for the collection of information is estimated to average 10 minutes per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer, Attention: PRA, Paperwork Reduction Project (0935-0143), AHRQ, 540 Gaither Road, Room #5036, Rockville, MD 20850.

Event ID: _____

Initial Report Date (HERF Q12): _____

Patient Safety Event Report – Skilled Nursing Facility:

PATIENT INFORMATION FORM (PIF)

Use this form only if you are reporting an incident. Highlighted fields are collected for local facility and Patient Safety Organization (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. At the time of the event what was the patient's/resident's age? CHECK ONE:

a. ☐ Infant or neonate (<1 year of age)
b. ☐ Child (1-12 years)
c. ☐ Adolescent (13-17 years)
d. ☐ Adult (18-64 years)
e. ☐ Mature adult (65-74 years)
f. ☐ Older adult (75-84 years)
g. ☐ Aged adult (85+ years)
h. ☐ Unknown

2. Is the patient's/resident's ethnicity Hispanic or Latino? CHECK ONE:

a. ☐ Hispanic or Latino
b. ☐ Not Hispanic or Latino
c. ☐ Unknown

3. What is the patient's/resident's race? CHECK ONE:

a. ☐ American Indian or Alaska Native
b. ☐ Asian
c. ☐ Black or African American
d. ☐ Native Hawaiian or Other Pacific Islander
e. ☐ White
f. ☐ More than one race
g. ☐ Unknown

4. Was any intervention attempted in order to "rescue" the patient/resident (i.e., to prevent, to minimize, or to reverse harm)? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

5. Which of the following interventions (rescue) were performed? CHECK ALL THAT APPLY:

a. ☐ Transfer, including transfer to a higher level care area within facility, transfer to another facility, or admission to hospital
b. ☐ Monitoring, including observation, physiological examination, laboratory testing, phlebotomy, and/or imaging studies
c. ☐ Medication therapy, including administration of antidote, change in pre-incident dose or route
d. ☐ Surgical/procedural intervention
e. ☐ Respiratory support (e.g., ventilation, tracheotomy)
f. ☐ Counseling or psychotherapy
g. ☐ Unknown
h. ☐ Other intervention: **PLEASE SPECIFY** _____

6. After discovery of the incident, and any subsequent intervention, what was the extent of harm to the patient/resident (i.e., extent to which the patient's/resident's functional ability is expected to be impaired subsequent to the incident and any attempts to minimize adverse consequences)? CHECK FIRST APPLICABLE:

AHRQ Harm Scale

a. ☐ **Death:** Dead at time of assessment.

b. ☐ **Severe permanent harm:** Severe lifelong bodily or psychological injury or disfigurement that interferes significantly with functional ability or quality of life. Prognosis at time of assessment.

c. ☐ **Permanent harm:** Lifelong bodily or psychological injury or increased susceptibility to disease. Prognosis at time of assessment.

d. ☐ **Temporary harm:** Bodily or psychological injury, but likely not permanent. Prognosis at time of assessment.

e. ☐ **Additional treatment:** Injury limited to additional intervention during admission or encounter and/or increased length of stay, but no other injury. Treatment since discovery, and/or expected treatment in future as a direct result of event.

f. ☐ **Emotional distress or inconvenience:** Mild and transient anxiety or pain or physical discomfort, but without the need for additional treatment other than monitoring (such as by observation; physical examination; laboratory testing, including phlebotomy; and/or imaging studies). Distress/inconvenience since discovery, and/or expected in future as a direct result of event.

g. ☐ **No harm:** Event reached patient/resident but no harm was evident.

h. ☐ Unknown

7. Approximately when after discovery of the incident was harm assessed? CHECK ONE:

a. ☐ Within 24 hours

b. ☐ After 24 hours but before 3 days

c. ☐ Three days or later

d. ☐ Unknown

8. After the discovery of the incident, was the patient/resident, patient's/resident's family, or guardian notified? CHECK ONE:

a. ☐ Yes

b. ☐ No

c. ☐ Unknown

Thank you for completing these questions.

Event ID: _____

Initial Report Date (HERF Q12): _____

Patient Safety Event Report – Skilled Nursing Facility:

SUMMARY OF INITIAL REPORT (SIR)

Use this form after all other forms applicable to this event (incident or near miss) or unsafe condition reported on the Healthcare Event Reporting Form (HERF) have been reviewed. Highlighted fields are collected for local facility and Patient Safety Organization (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. What is the date of this report?

__ __ / __ __ / __ __ __ __
MM DD YYYY

2. Where did the event occur, or, if an unsafe condition, where does it exist? (PLEASE REFER TO HERF QUESTION 5) CHECK ONE:

a. ☐ Patient/resident room
b. ☐ Toileting, bathing, showering room
c. ☐ Indoor activity area (e.g., TV room, gym)
d. ☐ Dining room
e. ☐ Pharmacy
f. ☐ Nursing station
g. ☐ Treatment or procedure room (e.g., physical therapy)
h. ☐ Other area within the facility
i. ☐ Outside area (i.e., grounds of this facility)
j. ☐ Unknown
k. ☐ Other: **PLEASE SPECIFY** _____

3. Who reported the event or unsafe condition? (PLEASE REFER TO HERF QUESTION 17) CHECK ONE:

a. ☐ Healthcare professional
b. ☐ Healthcare worker, including liaison officer, patient transport/retrieval personnel, assistant/orderly, clerical/administrative personnel, domestic/hotel service personnel, interpreter/translator, technical/laboratory personnel, pastoral care personnel, or biomedical engineer
c. ☐ Emergency service personnel, including police officer, fire fighter, or other emergency service officer
d. ☐ Patient/resident, relative, volunteer, caregiver, or homecare assistant
e. ☐ Unknown
f. ☐ Other: **PLEASE SPECIFY**
_____

4. What is the type of healthcare professional? CHECK ONE:

a. ☐ Doctor or dentist (including student)
b. ☐ Nurse, nurse practitioner, or physician assistant (including student or trainee)
c. ☐ Pharmacist or pharmacy technician (including student)
d. ☐ Allied health personnel, paramedic

5. Please describe any additional details about the event or unsafe condition discovered after completion of the HERF:

_____

_____

_____

_____

IF UNSAFE CONDITION — STOP — This form is complete.

IF NEAR MISS, ANSWER QUESTIONS 6 - 9

IF INCIDENT, ANSWER QUESTIONS 7 - 10

6. What prevented the near miss from reaching the patient/resident? CHECK ONE:

a. ☐ Fail-safe designed into the process and/or a safeguard worked effectively
b. ☐ Practitioner or staff member who made the error noticed and recovered from the error (avoiding any possibility of it reaching the patient/resident)
c. ☐ Spontaneous action by a practitioner or staff member (other than person making the error) prevented the event from reaching the patient/resident
d. ☐ Action by the patient/resident or family member prevented the event from reaching the patient/resident
e. ☐ Other
f. ☐ Unknown

7. Was the event associated with a handover/handoff? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

8. Are any contributing factors to the event known? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

9. What factor(s) contributed to the event? CHECK ALL THAT APPLY:

Environment

a. ☐ Culture of safety, management
b. ☐ Physical surroundings (e.g., lighting, noise)

Staff qualifications

c. ☐ Competence (e.g., qualifications, experience)
d. ☐ Training

Supervision/support

e. ☐ Clinical supervision
f. ☐ Managerial supervision

Policies and procedures, includes clinical protocols

g. ☐ Presence of policies
h. ☐ Clarity of policies

Data

i. ☐ Availability
j. ☐ Accuracy
k. ☐ Legibility

Communication

l. ☐ Supervisor to staff
m. ☐ Among staff or team members
n. ☐ Staff to patient/resident (or family)

Human factors

o. ☐ Fatigue
p. ☐ Stress
q. ☐ Inattention
r. ☐ Cognitive factors
s. ☐ Health issues

Other

t. ☐ Other: **PLEASE SPECIFY** _____

IF NEAR MISS — STOP — This form is complete.

10. How preventable was the incident? CHECK ONE:

a. ☐ Almost certainly could have been prevented
b. ☐ Likely could have been prevented
c. ☐ Likely could not have been prevented
d. ☐ Almost certainly could not have been prevented
e. ☐ Provider does not make this determination by policy
f. ☐ Unknown

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**

Event ID: _____

Initial Report Date (HERF Q12): _____

Patient Safety Event Report – Skilled Nursing Facility:

DEVICE OR SUPPLY, INCLUDING HEALTH INFORMATION TECHNOLOGY (HIT)

Use this form to report any patient safety event or unsafe condition involving a defect, failure, or incorrect use of a device, including an HIT device. A device includes an implant, medical equipment, or medical/surgical supply (including disposable product). An HIT device includes hardware or software that is used to electronically create, maintain, analyze, store, receive, or otherwise aid in the diagnosis, cure, mitigation, treatment, or prevention of disease, and that is not an integral part of (1) an implantable device or (2) an item of medical equipment.

Do not complete this form to report a manufacturing quality control problem, device defect or failure, or potential unsafe condition discovered prior to market approval or, in the case of an HIT device, clinical deployment. If the event also involves a medication or other substance, please complete the Medication or Other Substance form in addition to this form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and Patient Safety Organization (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. Which of the following best describes the event or unsafe condition? CHECK ONE:

a. ☐ Device failure

2. Which of the following best describes the effect of the device failure? CHECK FIRST APPLICABLE:

a. ☐ Device defect or failure directly impacted the patient/resident (e.g., pacemaker)

b. ☐ Device defect or failure or HIT device problem was precursor to an event that reached the patient/resident (e.g., infusion pump delivered an overdose of a drug)

c. ☐ Device defect or failure or HIT device problem resulted in a near miss (e.g., instrument broke immediately before use, realization prior to procedure that HIT system had indicated wrong patient/resident)

d. ☐ Device defect or failure or HIT device problem created an unsafe condition (e.g., device found to be defective during routine inspection or maintenance)

e. ☐ Unknown

b. ☐ Use error

3. What type of use error? CHECK ONE:

a. ☐ Creating a workaround, force-fitting, defeating fail-safe

b. ☐ Inappropriate substitution or use of device, including an HIT device (e.g., use of latex-containing product when patient/resident was known to be allergic to latex)

c. ☐ Mis-setting, mis-programming, or otherwise misusing a device, including an HIT device

d. ☐ Error in entering or interpreting data (e.g., wrong selection from menu, transposition of numbers)

e. ☐ Unknown

f. ☐ Other: **PLEASE SPECIFY** _____

c. ☐ Combination or interaction of device failure and use error

d. ☐ Unknown

4. Was a device intended for single use reused in the incident (including use of a reprocessed single-use device)? CHECK ONE:

a. ☐ Yes

b. ☐ No

c. ☐ Unknown

5. What type of device was involved in the event? CHECK ONE:

a. ☐ Implantable device (i.e., device intended to be inserted into, and remain permanently in, tissue)

b. ☐ Medical equipment (e.g., walker, hearing aid)

c. ☐ Medical/surgical supply, including disposable product (e.g., incontinence supply)

d. ☐ HIT device

6. Did the event result in the device being removed? CHECK ONE:

a. ☐ Yes

b. ☐ No

c. ☐ Unknown

7. What is the name (brand or generic) of the device, product, software, or medical/surgical supply?

_____

8. What is the name of the manufacturer?

_____

9. Which of the following identifiers are known? CHECK ALL THAT APPLY:

a. ☐ Model number

10. What is the model number?

_____

b. ☐ Software/firmware version

11. What is the software/firmware version?

_____

c. ☐ Serial number

12. What is the serial number?

_____

d. ☐ Lot or batch number

13. What is the lot or batch number?

_____

e. ☐ Other unique product identifier

14. What is the type of other unique product identifier?

_____

15. What is the other unique product identifier?

_____

f. ☐ Date of expiration

16. What is the expiration date?

__ __/__ __/__ __ __ __

MM DD YYYY

g. ☐ Unique Device Identifier

17. What is the Unique Device Identifier (UDI)?

_____

h. ☐ No identifiers known

Event ID: _____

Initial Report Date (HERF Q12): _____

18. Did the event or unsafe condition involve a medication or other substance? CHECK ONE:

a. ☐ Yes → **ALSO COMPLETE THE MEDICATION OR OTHER SUBSTANCE FORM**
b. ☐ No
c. ☐ Unknown

IF THE EVENT DID NOT INVOLVE AN HIT DEVICE — STOP This form is complete.

IF THE EVENT INVOLVED AN HIT DEVICE, ANSWER QUESTIONS 19 - 25

19. Which of the following best characterizes the HIT device related to the event or unsafe condition? CHECK ONE:

a. ☐ Administrative/billing or practice management system

20. Which component of the administrative/billing system? CHECK ONE:

a. ☐ Master patient index
b. ☐ Registration/appointment scheduling system
c. ☐ Coding/billing system
d. ☐ Unknown
e. ☐ Other: **PLEASE SPECIFY** _____

b. ☐ Automated dispensing system

c. ☐ Electronic health record (EHR) or component of EHR

21. Which type or component of the EHR? CHECK ONE:

a. ☐ Computerized provider order entry (CPOE) system
b. ☐ Pharmacy system
c. ☐ Clinical documentation system (e.g., progress notes)
d. ☐ Clinical decision support (CDS) system
e. ☐ Unknown
f. ☐ Other: **PLEASE SPECIFY** _____

d. ☐ Human interface device (e.g., keyboard, mouse, touchscreen, speech recognition system, monitor/display, printer)

e. ☐ Laboratory information system (LIS), including microbiology and pathology systems

f. ☐ Radiology/diagnostic imaging system, including picture archiving and communications system (PACS)

g. ☐ Other: **PLEASE SPECIFY** _____

22. Which of the following describes the circumstances involving the HIT device in the event or unsafe condition?
CHECK ALL THAT APPLY:

a. ☐ Incompatibility between devices
b. ☐ Equipment/device function
c. ☐ Equipment/device maintenance
d. ☐ Hardware failure
e. ☐ Network failure
f. ☐ Ergonomics, including human/device interface issue
g. ☐ Output from device during use
h. ☐ Security, virus, or other malware issue
i. ☐ Unexpected software design issue
j. ☐ Other: **PLEASE SPECIFY**

_____

23. Which problem(s) resulted from the equipment/device function problem? CHECK ALL THAT APPLY:

a. ☐ Error in charting, communication, or display of orders, vital signs, or results
b. ☐ Loss of clinical data
c. ☐ Medication error - software related
d. ☐ System returns or stores wrong data for correctly selected patient/resident
e. ☐ Other: **PLEASE SPECIFY**

_____

24. Which ergonomics or human/device interface issue(s)?
CHECK ALL THAT APPLY:

a. ☐ Alert fatigue/alarm fatigue
b. ☐ Data entry (e.g., selection of wrong patient/resident or wrong provider using HIT device)
c. ☐ Hardware location (e.g., awkward placement for use)
d. ☐ Information display
e. ☐ Other: **PLEASE SPECIFY**

_____

25. Which output problem(s)? CHECK ALL THAT APPLY:

a. ☐ Discrepancy between system data and printed, stored, or exported data
b. ☐ Image measurement/corruption issue
c. ☐ Image orientation incorrect
d. ☐ Incorrect or inadequate test results
e. ☐ Incorrect software programming calculations
f. ☐ Other: **PLEASE SPECIFY**

_____

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**
Public reporting burden for the collection of information is estimated to average 10 minutes per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: AHRQ Reports Clearance Officer, Attention: PRA, Paperwork Reduction Project (0935-0143), AHRQ, 540 Gaither Road, Room #5036, Rockville, MD 20850.

Event ID: _____

Initial Report Date (HERF Q12): _____

Patient Safety Event Report – Skilled Nursing Facility:

FALL

Use this form to report details of a fall. For purposes of patient/resident safety, a fall is a sudden, unintended, uncontrolled, downward displacement of a patient's/resident's body to the ground or other object (e.g., sink, table, surrounding furniture). This definition includes unassisted falls and assisted falls (i.e., when a patient/resident begins to fall and is assisted to the ground by another person). This definition excludes near falls (loss of balance that does not result in a fall) and falls resulting from a purposeful action or violent blow. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and Patient Safety Organization (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. Was the fall unassisted or assisted? CHECK ONE:

a. ☐ Unassisted
b. ☐ Assisted
c. ☐ Unknown

2. Was the fall observed? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

3. Who observed the fall? CHECK FIRST APPLICABLE:

a. ☐ Staff
b. ☐ Visitor, family, or another patient/resident

4. Did the patient/resident sustain a physical injury as a result of the fall? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

5. What type of injury was sustained? CHECK ONE; IF MORE THAN ONE, CHECK MOST SEVERE:

a. ☐ Dislocation
b. ☐ Fracture
c. ☐ Intracranial injury
d. ☐ Laceration requiring sutures
e. ☐ Skin tear/avulsion or significant bruising
f. ☐ Other: **PLEASE SPECIFY** _____

6. Prior to the fall, what was the patient/resident doing or trying to do? CHECK ONE:

a. ☐ Ambulating without assistance and without an assistive device or medical equipment
b. ☐ Ambulating with assistance and/or with an assistive device or medical equipment
c. ☐ Changing position (e.g., in bed, chair)
d. ☐ Dressing or undressing
e. ☐ Engaging in recreational activities (e.g., games, physical conditioning)
f. ☐ Reaching for an item
g. ☐ Showering or bathing
h. ☐ Toileting
i. ☐ Transferring to or from bed, chair, etc.
j. ☐ Unknown
k. ☐ Other: **PLEASE SPECIFY** _____

7. Prior to the fall, was a fall risk assessment performed? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

8. Was the patient/resident determined to be at increased risk for a fall? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

9. Prior to the fall, were any of the following risk factors present? CHECK ALL THAT APPLY:

a. ☐ History of previous fall
b. ☐ Prosthesis or specialty/prescription shoe
c. ☐ Sensory impairment (vision, hearing, balance, etc.)
d. ☐ None
e. ☐ Unknown
f. ☐ Other: **PLEASE SPECIFY** _____

10. What protocols/interventions were in place, or being used, to prevent falls for this patient/resident? CHECK ALL THAT APPLY:

a. ☐ Assistive device (e.g., wheelchair, commode, cane, crutches, scooter, walker)
b. ☐ Bed or chair alarm
c. ☐ Bed in low position
d. ☐ Call light/personal items within reach
e. ☐ Change in medication (e.g., timing or dosing of current medication)
f. ☐ Fall alert
g. ☐ Floor mats
h. ☐ Non-slip footwear
i. ☐ Patient/resident and family education
j. ☐ Patient/resident situated close to the nurses' station
k. ☐ Physical/occupational therapy
l. ☐ Siderails
m. ☐ Sitter
n. ☐ Supplemental, environmental, or area lighting (when usual facility lighting is considered insufficient)
o. ☐ Toileting regimen
p. ☐ Visible identification of patient/resident as being at risk for fall (e.g., Falling Star)
q. ☐ None
r. ☐ Unknown
s. ☐ Other: **PLEASE SPECIFY** _____

11. At time of the fall, was the patient/resident on medication known to increase the risk of fall? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

12. Was the medication considered to have contributed to the fall? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

13. Did restraints, bedrails, or other physical device contribute to the fall? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**
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Event ID: _____

Initial Report Date (HERF Q6): _____

Patient Safety Event Report – Skilled Nursing Facility:

SNF

HEALTHCARE-ASSOCIATED INFECTION

Use this form to report a healthcare-associated infection (HAI). An HAI is a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). It is acquired during the course of receiving treatment for other conditions within a healthcare setting. There must be no evidence that the infection was present or incubating at the time of admission. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and Patient Safety Organizations (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. Was the infection determined to be present or incubating on admission (i.e., signs and/or symptoms for diagnosis within the first 48 hours of admission)? CHECK ONE:

a. ☐ Yes - infection was determined to be present or incubating on admission → STOP This form is complete.

b. ☐ No - infection developed during this stay

c. ☐ Unknown

2. What type of HAI is being reported? CHECK ONE:

a. ☐ Urinary tract infection

3. Was it a catheter-associated urinary tract infection (CAUTI)? CHECK ONE:

a. ☐ Yes → ANSWER QUESTION 18

b. ☐ No

c. ☐ Unknown

→ STOP This form is complete.

b. ☐ Pneumonia

4. Was the patient on a ventilator at the time of the event? CHECK ONE:

a. ☐ Yes

b. ☐ No

c. ☐ Unknown

→ STOP This form is complete.

c. ☐ Primary bloodstream infection

5. Was it a central line-associated bloodstream infection (CLABSI)? CHECK ONE:

a. ☐ Yes → ANSWER QUESTION 7

b. ☐ No

c. ☐ Unknown

→ STOP This form is complete.

d. ☐ Clostridium difficile infection (CDI) → STOP This form is complete.

e. ☐ Other type of infection that developed during admission → ANSWER QUESTION 6

Event ID: _____

Initial Report Date (HERF Q6): _____

6. Which other type of infection? CHECK ONE:

- a. ☐ Bone or joint infection
- b. ☐ Central nervous system infection
- c. ☐ Cardiovascular system infection
- d. ☐ Eye, ear, nose, throat, or mouth infection
- e. ☐ Gastrointestinal system infection - non-CDI
- f. ☐ Lower respiratory tract infection (other than pneumonia)
- g. ☐ Reproductive tract infection
- h. ☐ Skin or soft tissue infection
- i. ☐ Systemic infection
- j. ☐ Other: **PLEASE SPECIFY** _____

→ STOP This form is complete.

ONLY IF EVENT INVOLVED A CLABSI, ANSWER QUESTIONS 7 - 17

7. Was there a positive blood culture? CHECK ONE:

- a. ☐ Yes
- b. ☐ No
- c. ☐ Unknown

→ STOP This form is complete.

8. At the time the blood specimen yielding the positive culture was collected, what was the patient's/resident's status with respect to a central line? CHECK ONE:

- a. ☐ In place at the time of specimen collection
- b. ☐ Removed within 48 hours prior to specimen collection

→ **9. Which of the following were in place or removed within 48 hours prior to specimen collection?** CHECK ALL THAT APPLY:

- a. ☐ Temporary central line, including PICC
- b. ☐ Permanent central line
- c. ☐ Unknown

- c. ☐ Removed >48 hours prior to specimen collection
- d. ☐ Unknown

→ STOP This form is complete.

10. Did the patient/resident have both peripheral and central IV lines in place at the time of the event? CHECK ONE:

- a. ☐ Yes
- b. ☐ No
- c. ☐ Unknown

→ **11. Is the bloodstream infection clearly attributable to the peripheral line?** CHECK ONE:

- a. ☐ Yes → STOP This form is complete.
- b. ☐ No
- c. ☐ Unknown

Event ID: _____

Initial Report Date (HERF Q6): _____

12. Was the positive blood culture related to an infection at another site? CHECK ONE:

a. ☐ Yes → STOP This form is complete.

b. ☐ No

c. ☐ Unknown

13. Was the blood culture positive for a recognized pathogen (e.g., S. aureus, Enterococcus, E. coli, Pseudomonas, Klebsiella, Candida)? CHECK ONE:

a. ☐ Yes → STOP This form is complete.

b. ☐ No

c. ☐ Unknown

14. Were two or more cultures drawn on separate occasions within two days of each other positive for a common skin contaminant (e.g., S. epidermidis)? CHECK ONE:

a. ☐ Yes

b. ☐ No

c. ☐ Unknown → STOP This form is complete.

15. At the time of the event, which of the following signs and symptoms were present? CHECK ALL THAT APPLY:

a. ☐ Fever (>38 degrees C core)

b. ☐ Chills

c. ☐ Hypotension → STOP This form is complete.

d. ☐ None → IF AGE ≤1, ANSWER QUESTION 16, IF AGE 65 ANSWER QUESTION 17, OTHERWISE → STOP This form is complete.

16. At the time of the event, which of the following signs and symptoms were present? CHECK ALL THAT APPLY:

a. ☐ Hypothermia (<36 degrees C core)

b. ☐ Apnea

c. ☐ Bradycardia

d. ☐ None → STOP This form is complete.

17. At the time of the event, which of the following signs and symptoms were present? CHECK ALL THAT APPLY:

a. ☐ Hypothermia (<36 degrees C core)

b. ☐ New mental status change

c. ☐ None

ONLY IF EVENT INVOLVED A CAUTI, ANSWER QUESTIONS 18 - 27

18. Was the diagnosis of urinary tract infection (UTI) confirmed by a positive urine culture? CHECK ONE:

a. ☐ Yes

b. ☐ No - urine culture negative

c. ☐ No - urine culture not done → STOP This form is complete.

19. At the time of the event what was the patient's/resident's age? CHECK ONE:

a. ☐ >1 year of age

b. ☐ ≤1 year of age

20. At the time the urine specimen yielding the positive culture was collected, what was the patient's/resident's status with respect to an indwelling urinary catheter? CHECK ONE:

a. ☐ Catheter was in place at time of the urine specimen collection

21. At the time of the event, which, if any, of the following signs and/or symptoms were present with no other recognized cause? CHECK ALL THAT APPLY:

a. ☐ Fever >38 degree C core (if patient less than 65 years of age)
b. ☐ Suprapubic tenderness
c. ☐ Costovertebral angle (CVA) pain or tenderness
d. ☐ None
e. ☐ Unknown

GO TO QUESTION 25

b. ☐ Catheter had been in place but was removed within 48 hours prior to the urine specimen collection

22. At the time of the event, which, if any, of the following signs and/or symptoms were present with no other recognized cause? CHECK ALL THAT APPLY:

a. ☐ Fever >38 degrees C core (if patient less than 65 years of age)
b. ☐ Suprapubic tenderness
c. ☐ Costovertebral angle (CVA) pain or tenderness
d. ☐ Urgency
e. ☐ Frequency
f. ☐ Dysuria
g. ☐ None
h. ☐ Unknown

GO TO QUESTION 25

c. ☐ Catheter had been in place but was removed >48 hours prior to the urine specimen collection

d. ☐ Patient/resident had not had an indwelling urinary catheter during stay

e. ☐ Unknown

STOP This form is complete.

23. At the time the urine specimen yielding the positive culture was collected, what was the patient's/resident's status with respect to an indwelling urinary catheter? CHECK ONE:

a. ☐ Catheter was in place at time of the urine specimen collection

b. ☐ Catheter had been in place but was removed within 48 hours prior to the urine specimen collection

→ **24. At the time of the event, which, if any, of the following signs and/or symptoms were present with no other recognized cause?** CHECK ALL THAT APPLY:

a. ☐ Fever >38 degrees C core
b. ☐ Hypothermia (< 36 degrees C core)
c. ☐ Apnea
d. ☐ Bradycardia
e. ☐ Dysuria
f. ☐ Lethargy
g. ☐ Vomiting
h. ☐ None
i. ☐ Unknown

c. ☐ Catheter had been in place but was removed >48 hours prior to the urine specimen collection

d. ☐ Patient/resident had not had an indwelling urinary catheter during stay

e. ☐ Unknown

→ **STOP** This form is complete.

25. What were the specific results of the positive urine culture? CHECK FIRST APPLICABLE:

a. ☐ $\geq 10^5$ colony-forming units (CFU)/ml with no more than 2 species of uropathogen organisms

→ IF PATIENT/RESIDENT HAD NO UTI SYMPTOMS, ANSWER QUESTION 27, OTHERWISE **STOP** This form is complete.

b. ☐ $\geq 10^3$ and 10^5 CFU/ml with no more than 2 species of uropathogen microorganisms

→ **26. Did the patient/resident have any of the following urinalysis results?** CHECK ALL THAT APPLY:

a. ☐ Postive dipstick for leukocyte esterase and/or nitrate
b. ☐ Pyuria (urine specimen with ≥10 white blood cells (WBC)/mm^3 or ≥WBC/high power field of unspun urine)
c. ☐ Microorganisms seen on gram stain of unspun urine
d. ☐ None

→ **STOP** This form is complete.

c. ☐ More than two species of uropathogen organisms

d. ☐ Fewer than $\geq 10^3$ CFU/ml of uropathogen organisms

e. ☐ Unknown

→ **STOP** This form is complete.

27. Did the patient/resident have a positive blood culture with at least one matching uropathogenic microorganism [e.g., Gram-negative bacilli, Staphylococcus, yeasts, beta-hemolytic Streptococcus, Enterococcus, G. vaginalis, Aerococcus urinae, Corynebacterium (urease positive)] to the urine culture? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

Thank you for completing these questions.

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Event ID: _____

Initial Report Date (HERF Q12): _____

Patient Safety Event Report – Skilled Nursing Facility:

MEDICATION OR OTHER SUBSTANCE

Use this form to report any patient safety event or unsafe condition involving a substance such as a medication, vaccine, nutrient, dietary supplement, medical gas, or contrast media. Do not complete this form if the event involves appropriateness of therapeutic choice or decision making (e.g., physician decision to prescribe medication despite known drug-drug interaction). If the event involves a device, please also complete the Device or Supply Including Health Information Technology (HIT) form. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Highlighted fields are collected for local facility and Patient Safety Organization (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

1. What type of medication/substance was involved? CHECK ONE:

a. ☐ Medication

2. What type of medication? CHECK ONE:

a. ☐ Prescription or over-the-counter
b. ☐ Compounded preparation
c. ☐ Investigational drug
d. ☐ Unknown

3. Please list all ingredients:

_____

_____

_____

_____

b. ☐ Biological product

4. What type of biological product? CHECK ONE:

a. ☐ Vaccine
b. ☐ Other biological product (e.g., erythropoietin)

5. What was the lot number of the vaccine?

LOT NUMBER

c. ☐ Nutritional product

6. What type of nutritional product? CHECK ONE:

a. ☐ Dietary supplement (other than vitamins or minerals)
b. ☐ Vitamins or minerals
c. ☐ Enteral nutritional product, including infant formula
d. ☐ Parenteral nutritional product
e. ☐ Other: **PLEASE SPECIFY**

_____

d. ☐ Medical gas (e.g., oxygen, nitrogen, nitrous oxide)

e. ☐ Patient/resident food (not suspected in drug-food interactions)

STOP This form is complete.

f. ☐ Other substance: **PLEASE SPECIFY**

_____

7. Which of the following best characterizes the event or unsafe condition? CHECK ONE:

a. ☐ Incorrect action (process failure or error) (e.g., such as administering overdose or incorrect medication)

b. ☐ Unsafe condition

→ ANSWER QUESTIONS 17 - 21

c. ☐ Adverse reaction in patient/resident to the administered substance without any apparent incorrect action

d. ☐ Unknown

→ STOP This form is complete.

8. What was the incorrect action? CHECK ALL THAT APPLY:

a. ☐ Incorrect patient/resident

b. ☐ Incorrect medication/substance

c. ☐ Incorrect dose(s)

9. Which best describes the incorrect dose(s)? CHECK ONE:

a. ☐ Overdose
b. ☐ Underdose
c. ☐ Missed or omitted dose
d. ☐ Extra dose
e. ☐ Unknown

d. ☐ Incorrect route of administration

e. ☐ Incorrect timing

10. Which best describes the incorrect timing? CHECK ONE:

a. ☐ Too early
b. ☐ Too late
c. ☐ Unknown

f. ☐ Incorrect rate

11. Which best describes the incorrect rate? CHECK ONE:

a. ☐ Too quickly
b. ☐ Too slowly
c. ☐ Unknown

g. ☐ Incorrect duration of administration or course of therapy

h. ☐ Incorrect dosage form (e.g., sustained release instead of immediate release)

i. ☐ Incorrect strength or concentration

12. Which best describes the incorrect strength or concentration? CHECK ONE:

a. ☐ Too high
b. ☐ Too low
c. ☐ Unknown

j. ☐ Incorrect preparation, including inappropriate cutting of tablets, error in compounding, mixing, etc.

k. ☐ Expired or deteriorated medication/substance

13. What was the expiration date? __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

l. ☐ Medication/substance that is known to be an allergen to the patient/resident

14. Was there a documented history of allergies or sensitivities to the medication/substance administered? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

m. ☐ Medication/substance that is known to be contraindicated for the patient/resident

15. What was the contraindication (potential or actual interaction)? CHECK ONE:

a. ☐ Drug-drug
b. ☐ Drug-food
c. ☐ Drug-disease
d. ☐ Other: **PLEASE SPECIFY** _____

n. ☐ Incorrect patient/resident/family action (e.g., self-administration error)

o. ☐ Other: **PLEASE SPECIFY** _____

16. At what stage in the process did the event originate, regardless of the stage at which it was discovered?

CHECK ONE:

a. ☐ Purchasing
b. ☐ Storing
c. ☐ Prescribing/ordering
d. ☐ Transcribing
e. ☐ Preparing
f. ☐ Dispensing
g. ☐ Administering
h. ☐ Monitoring
i. ☐ Unknown
j. ☐ Other: **PLEASE SPECIFY** _____

QUESTIONS 17 - 23 DO NOT APPLY TO COMPOUNDED PREPARATION

FOR AN INCIDENT, ANSWER QUESTIONS 17-23

FOR A NEAR MISS, ANSWER QUESTIONS 17-22

FOR AN UNSAFE CONDITION, ANSWER QUESTIONS 17-21

Please provide the following medication details for any medications or other substances directly involved in the event or unsafe condition.

	17. Generic name or investigational drug name	18. Brand name (if known)	19. Manufacturer (if known)	20. Strength or concentration of product	21. Dosage form of product	22. Was this medication/ substance prescribed for this patient /resident?	23. Was this medication/ substance given to this patient /resident?
1						a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No
2						a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No
3						a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No
4						a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No
5						a. ☐ Yes b. ☐ No	a. ☐ Yes b. ☐ No

IF THIS EVENT DID NOT INVOLVE AN INCORRECT ROUTE OF ADMINISTRATION

STOP This form is complete.

IF THE EVENT INVOLVED AN INCORRECT ROUTE OF ADMINISTRATION, ANSWER QUESTIONS 24 - 25

24. What was the intended route of administration? CHECK ONE:

- a. ☐ Cutaneous, topical application, including ointment, spray, patch
- b. ☐ Subcutaneous
- c. ☐ Ophthalmic
- d. ☐ Oral, including sublingual or buccal
- e. ☐ Otic
- f. ☐ Nasal
- g. ☐ Inhalation
- h. ☐ Intravenous
- i. ☐ Intramuscular
- j. ☐ Gastric
- k. ☐ Rectal
- l. ☐ Vaginal
- m. ☐ Unknown
- n. ☐ Other: **PLEASE SPECIFY** _____

25. What was the actual route of administration (attempted or completed)? CHECK ONE:

- a. ☐ Cutaneous, topical application, including ointment, spray, patch
- b. ☐ Subcutaneous
- c. ☐ Ophthalmic
- d. ☐ Oral, including sublingual or buccal
- e. ☐ Otic
- f. ☐ Nasal
- g. ☐ Inhalation
- h. ☐ Intravenous
- i. ☐ Intramuscular
- j. ☐ Gastric
- k. ☐ Rectal
- l. ☐ Vaginal
- m. ☐ Unknown
- n. ☐ Other: **PLEASE SPECIFY** _____

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**

Event ID: _____

Initial Report Date (HERF Q12): _____

Patient Safety Event Report – Skilled Nursing Facility:

PRESSURE ULCER

Use this form to report a pressure ulcer or suspected deep tissue injury that was 1) not present on admission (i.e., newly-developed) or 2) worsened during the patient's/resident's stay. Report only an event that occurred prior to patient/resident discharge. Narrative detail can be captured on the Healthcare Event Reporting Form (HERF). Exclude arterial or venous ulcers and diabetic foot ulcers. Highlighted fields are collected for local facility and Patient Safety Organization (PSO) use. This information will not be forwarded to the Network of Patient Safety Databases (NPSD).

Note: For staging information refer to the MDS 3.0 Training Materials located on the Centers for Medicare & Medicaid Services website: (https://www.cms.gov/NursingHomeQualityInits/45_NHQIMDS30TrainingMaterials.asp).

1. What was the most advanced stage of the pressure ulcer being reported? CHECK ONE:

- a. ☐ Stage 1
- b. ☐ Stage 2

→ STOP This form is complete.

- c. ☐ Stage 3
- d. ☐ Stage 4

→ GO TO QUESTION 3

- e. ☐ Unstageable (any type)

→ GO TO QUESTION 2

- f. ☐ Mucosal, arterial, or venous ulcer or diabetic foot ulcer
- g. ☐ Unknown

→ STOP This form is complete.

2. What was the type of the unstageable pressure ulcer? CHECK ONE:

- a. ☐ Not stageable due to non-removable dressing/device
- b. ☐ Not stageable due to coverage of wound bed by slough and/or eschar
- c. ☐ Not stageable related to suspected deep tissue injury
- d. ☐ Unknown

3. What was the status on admission of the Stage 3, 4, or unstageable pressure ulcer? CHECK ONE:

- a. ☐ Not present
- b. ☐ Stage 1
- c. ☐ Stage 2

→ GO TO QUESTION 4

- d. ☐ Stage 3
- e. ☐ Stage 4
- f. ☐ Unstageable

→ STOP This form is complete.

- g. ☐ Unknown

→ GO TO QUESTION 4

4. On admission to this facility, was a skin inspection documented? CHECK ONE:

- a. ☐ Yes
- b. ☐ No
- c. ☐ Unknown

5. When was the first pressure ulcer risk assessment performed? CHECK ONE:

- a. ☐ On admission (within 24 hours)
- b. ☐ Not on admission, but done prior to the discovery of a newly-developed, or advancement of an existing, pressure ulcer
- c. ☐ Not on admission, but done after discovery of a newly-developed, or advancement of an existing, pressure ulcer
- d. ☐ No risk assessment performed
- e. ☐ Unknown

6. What type of risk assessment was performed? CHECK FIRST APPLICABLE:

- a. ☐ Formal assessment (e.g., Braden, Braden Q (pediatric version), Norton, Waterlow)
- b. ☐ Clinical assessment
- c. ☐ Unknown

7. As a result of the assessment, was the patient/resident documented to be at increased risk for pressure ulcer? CHECK ONE:

- a. ☐ Yes
- b. ☐ No
- c. ☐ Unknown

8. Was any preventive intervention implemented? CHECK ONE:

- a. ☐ Yes
- b. ☐ No
- c. ☐ Unknown

9. What intervention(s) was used? CHECK ALL THAT APPLY:

- a. ☐ Pressure redistribution device
- b. ☐ Repositioning
- c. ☐ Nutritional support
- d. ☐ Other: **PLEASE SPECIFY** _____

10. Was the use of a device or appliance involved in the development or advancement of the pressure ulcer? CHECK ONE:

- a. ☐ Yes
- b. ☐ No
- c. ☐ Unknown

11. What was the type of device or appliance? CHECK ONE:

- a. ☐ Anti-embolic device
- b. ☐ Intraoperative positioning device
- c. ☐ Orthopedic appliance (e.g., cast, splint, orthotic)
- d. ☐ Oxygen delivery device (e.g., nasal prongs, oxygen mask)
- e. ☐ Restraints
- f. ☐ Tube
- g. ☐ Other: **PLEASE SPECIFY** _____

12. What type of tube? CHECK ONE:

- a. ☐ Endotracheal
- b. ☐ Gastrostomy
- c. ☐ Nasogastric
- d. ☐ Tracheostomy
- e. ☐ Indwelling urinary catheter
- f. ☐ Other: **PLEASE SPECIFY** _____

13. During the patient's/resident's stay at this facility, did the patient/resident develop a secondary morbidity (e.g., osteomyelitis or sepsis)? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

14. Was the secondary morbidity attributed to the presence of the pressure ulcer? CHECK ONE:

a. ☐ Yes
b. ☐ No
c. ☐ Unknown

Thank you for completing these questions.

OMB No. 0935-0143 **Exp. Date 8/31/2011**

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