

Mandatory Patient Safety Reporting Requirements for Licensed Health Care Facilities

(Revised)

Patient Safety Initiative

**Health Care Quality Assessment
New Jersey Department of Health and Senior Services**



October 27, 2008

Table of Contents

- I.** Procedures for Mandatory Reporting of Serious Preventable Adverse Events by Licensed Health Care Facilities
- II.** Instructions for Completing the Serious Preventable Adverse Event Report Form
- III.** FORM-Report of Serious Preventable Adverse Event in a New Jersey Licensed Health Care Facility
- IV.** Instructions for Completing the Serious Preventable Adverse Event Root Cause Analysis (RCA) Form
- V.** FORM-Report of Serious Preventable Adverse Event in a New Jersey Licensed Health Care Facility: Root Cause Analysis (RCA)

Appendix: 5 Rules of Causation

Chapter I: Procedures for Mandatory Reporting of Serious Preventable Adverse Events by Licensed Health Care Facilities

Mandatory Reporting of Serious Preventable Adverse Events

The Patient Safety Act (N.J.P.L. 2004, c.9) requires every health care facility licensed by the Department of Health and Senior Services to report every serious preventable adverse event, defined as an adverse event that is preventable and results in a patient death, loss of a body part, disability, or loss of bodily function lasting for more than seven days or still present at the time of discharge. Preventable event means an event that could have been anticipated and prepared against, but occurs because of an error or other system failure. Rules implementing this legislation were adopted in March 2008 and set up a time frame for the implementation of the reporting process for different types of licensed health care facilities (N.J.A.C. 8:43E-10).

Note: Other types of reportable events, including physical plant and operational interruptions, communicable diseases, and alleged criminal activities, are not covered by the Patient Safety Act and must continue to be reported according to existing procedures previously established by the Department.

Facilities Required to Report

On an interim basis, prior to adoption of rule amendments, a new reporting process was implemented on February 1, 2005 for all general hospitals licensed pursuant to N.J.A.C. 8:43G based on reporting requirements dated December 6, 2004. The reporting requirements were revised effective January 1, 2007. With the adoption of the rules, all ambulatory surgery centers licensed pursuant to N.J.A.C. 8:43A are required to implement the mandatory reporting process for serious adverse event on October 1, 2008. All special and psychiatric hospitals licensed pursuant to N.J.A.C. 8:43G and comprehensive rehabilitation hospitals licensed pursuant to N.J.A.C. 8:43H are required to implement the reporting process on April 1, 2008. General hospitals continue to report using the process initiated on February 1, 2005.

Mandatory Reporting Process and Time Lines

General, rehabilitation, psychiatric and special hospitals are required to report all serious preventable adverse events using the *Report of Serious Preventable Adverse Event in a New Jersey Licensed Health Care Facility Form*. Two versions of the form are available at www.NJ.gov/health/ps, the Department's patient safety web site. One version of the form is a computer-based form where event data can be entered and printed. The second version of the form is designed to be printed with the data entered by hand or typewriter. The Event Report Form is **due within five (5) business days** after the facility discovers the occurrence of the event.

The Report of Serious Preventable Adverse Event Root Cause Analysis (RCA) Form must be completed for each event subject to mandatory reporting and received by the Department **no later than 45 calendar days following the initial report to the Department**. Two versions of this form are also available at www.NJ.gov/health/ps, the Department's patient safety website.

The *Report of A Serious Preventable Adverse Event in A New Jersey Licensed Health Care Facility Form* should be faxed to the Department at (609) 984-7707. (Programming this fax number will prevent inaccurate transmission and protect confidentiality.) The *RCA Form* and any supporting documentation should be mailed in a confidential envelope to:

For Regular Mail:

Patient Safety Initiative
Health Care Quality Assessment
New Jersey Department of Health and
Senior Services
240 W. State St., PO Box 360
Trenton, NJ 08625-0360

For Special/Overnight Mail:

Patient Safety Initiative
Health Care Quality Assessment
New Jersey Department of Health and
Senior Services
240 W. State St., 11th Floor
Trenton, NJ 08608

The Patient Safety Initiative maintains a website to facilitate communication with hospitals at

www.NJ.gov/health/ps

A list of Frequently Asked Questions (FAQs) about the reporting system is posted and updated in response to questions from hospitals. As previously stated, reporting forms for both the initial Event Report and the RCA report may be downloaded from this site. The website also includes the New Jersey patient safety newsletters and additional information regarding the reporting system.

Additional Information

For additional information, please contact the Patient Safety Initiative at (609) 633-7759.

Chapter II: Instructions for Completing the Serious Preventable Adverse Event Report Form

The *Report of Serious Preventable Adverse Event in A New Jersey Licensed Health Care Facility Form* is to be completed and transmitted only by an authorized facility representative. Completed forms are to be FAXED to the Department at (609) 984-7707 within five (5) business days after the facility discovers the occurrence of the event. Department business days mean Monday – Friday except for State holidays.

In the event of objects erroneously retained after surgery, the hospital that discovers the retained object must report the event within five (5) business days. If the discovering facility is NOT the facility where the surgery that resulted in a retained object occurred, then the discovering facility shall NOT be responsible for performing the RCA. Additionally, the facility providing notification to the Department must also identify the facility where the retained object event occurred, if that information is known.

NOTE: A serious preventable adverse event is deemed *reported* to the Department only when the form is completed AND has been received by the Patient Safety Initiative. The Department will confirm receipt of the transmission by return fax. Updated versions of the form may be submitted if new information becomes available. Updated forms should include all information, indicating which fields are revised.

COMPLETING THE EVENT FORM

- Please type or print all information; please use no less than 10-point type.
- Revisions must be stated as such on the fax cover sheet. The Adverse Event Report Form must have the box marked “yes” that states, “Is this a revision of an earlier report to the Patient Safety Initiative for the same event?” and include the DHSS Report Number for that event. The DHSS Report Number is found on the Facility Notification Form that was faxed to the facility as the verification that the Department received and accepted the adverse event report.

NOTE: The Department anticipates that, to meet the reporting time frame, initial reports may be only partially completed and will be supplemented by updates.

SECTION A – GENERAL INFORMATION

1. Facility Identification

- List facility name, full address, and State of NJ Facility License Number.
- List the name, title, and contact information of the person completing the form.

2. Description of the Adverse Event

- Provide a short, narrative description of the adverse event including how the patient was immediately affected by the adverse event, and any diagnostic and therapeutic interventions done as a result of the event. For example, if the patient fell, the extent of the injury should be included, e.g., a laceration requiring 20 stitches or pain in the right hip and an x-ray revealed a fracture requiring surgery. The description should contain

enough information to determine whether the event meets the Patient Safety Act standard for reporting. However, the description should not be more than five or six sentences in length. A full narrative with a detailed event description is submitted in the RCA.

- List the date and time of the adverse event. NOTE: if the event involves a surgical procedure, indicate the time that the procedure began.
- List the date and time the adverse event was discovered by the hospital's professional/clinical staff. NOTE: This does NOT refer to when the risk manager or hospital administration was informed of the event.
- If the time of the event is unknown, list the time as "unknown."

3. How Was the Adverse Event Discovered?

- Check only one category.
- Indicate how the event was discovered. NOTE: This does NOT refer to how the hospital's administration was informed of the event.
- If "other" is checked, provide a brief description of how the event was discovered.

4. Patient Information

Provide the following information about the patient:

- Indicate whether the patient was admitted at the time of the adverse event (inpatient) or whether the patient was an outpatient at the time of the event. NOTE: Events occurring in the emergency department (ED) or same day surgery (SDS) are "outpatients," regardless of whether the patient was subsequently admitted.
- Indicate how the patient was admitted (Emergency Department, Direct Admission, Transfer from another acute care facility, or Transfer from a Long-Term Care Facility). If the event occurred when the patient was an outpatient, "Admission through" remains blank.
- List the patient's billing number, the unique identifier for each admission.
- List the patient's medical record number or other identification used by the facility.
- List the patient's name and full address, including the county of residence.
- List the patient's date of birth and gender.
- List the date of the patient's admission to the facility or date of the ambulatory encounter.
- List the patient's primary diagnosis.
- Complete both Race **and** Ethnicity items based on separate determinations using the following categories (adapted from U.S. Census 2000 specifications):

Race	Ethnicity
Caucasian: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.	Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central America, or other Spanish culture or origin.
Black or African American: A person having origins in any of the black racial groups of Africa.	Non-Hispanic or Latino
Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent.	
American Indian or Alaska Native: A person having origins in any of the original peoples of North and South America (including Central America) and who maintain tribal affiliation or community attachment.	
Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islanders.	

- If “other” is checked, provide a brief description of the race.

SECTION B – EVENT DETAILS

5. Types of Serious Preventable Adverse Events

Using the descriptions below, indicate the general classification and type of the serious preventable adverse event.

Check only **one** category.

A. Care management-related events include, but are not limited to:

1. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient/resident, wrong time, wrong rate, wrong preparation, wrong route of administration, etc.).
2. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.
3. Maternal death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge associated with labor or delivery in a low-risk pregnancy while in a health care facility.
4. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the health care facility.
5. Death or kernicterus associated with failure to identify and treat hyperbilirubinemia in a neonate while the neonate is a patient in a health care facility.

6. Stage III or IV pressure ulcers acquired after admission of the patient/resident to a health care facility. This does not include skin ulcers that develop as a result of an underlying vascular etiology, including arterial insufficiency, venous insufficiency and/or venous hypertension; or develop as a result of an underlying neuropathy, such as a diabetic neuropathy. Also excludes progression from Stage II to Stage III, if Stage II was recognized and documented upon admission.
 7. Patient death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with spinal manipulative therapy provided in a health care facility.
 8. Other patient/resident care management-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.
- B. Environmental events include, but are not limited to:
1. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with any shock while being cared for in a health care facility. Excludes events involving planned treatments, such as electric counter shock (heart stimulation).
 2. Any incident in which a line designated for oxygen or other gas to be delivered to a patient/resident contains the wrong gas or is contaminated by toxic substances and results in patient/resident death, loss of body part, disability or loss of bodily function lasting more than seven days or still present at discharge.
 3. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a burn incurred from any source while in a health care facility.
 4. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with a fall while in a health care facility.
 5. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with the use of restraints or bedrails while in a health care facility.
 6. Other environmentally-related adverse preventable events resulting in patient/resident death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.
- C. Product or device-related events include, but are not limited to:
1. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with use of generally detectable contaminated drugs, devices, or biologics provided by the health care facility, regardless of the source of contamination and/or product.
 2. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge, associated with use or function of a device in patient/resident care in which the device is used or functions other than as intended, including but not limited to catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
 3. Intravascular air embolism that occurs while the patient/resident is in the facility. However, this does not include deaths or disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

4. Patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days or still present at discharge associated with use of a new single-use device or a reprocessed single-use device in which the device is used or functions other than as intended. All events related to single-use devices should be reported in this category. Indicate whether the device was new or had been reprocessed.
 5. Other product or device-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.
- D. Surgery-related events (i.e., any invasive manual or operative methods including endoscopies, colonoscopies, cardiac catheterizations, and other invasive procedures) include but are not limited to:
1. Surgery initiated (whether or not completed) on the wrong body part.
 2. A surgical procedure (whether or not completed) intended for a different patient of the facility.
 3. A wrong surgical procedure initiated (whether or not completed) on a patient.
 4. Retention of a foreign object in a patient after surgery, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
 5. Intraoperative or postoperative (i.e., within twenty-four hours) coma, death or other serious preventable adverse event for an ASA Class I inpatient or for any ASA Class same day surgery patient or outpatient. Includes all patient deaths, comas or other serious preventable adverse events in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out.
 6. Other surgery-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.
- E. Patient/resident protection-related events include, but are not limited to:
1. Discharge of an infant to the wrong person, excluding patient/resident abductions.
 2. Any patient/resident death, loss of body part, disability, or loss of bodily function lasting more than seven days associated with patient/resident elopement.
 3. Patient/resident suicide or attempted suicide while in a health care facility. However, this does not include deaths or disability resulting from self-inflicted injuries that were the reason for admission to the health care facility.
 4. Other patient/resident protection-related adverse preventable event resulting in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven days or still present at the time of discharge not included within the definitions above.

6. For Medication Errors Only

- If 5.A.1 is checked, indicate the type of medication error.
- If “other” is checked, provide a short description of the medication error.
- List the brand name and/or generic name of the medication.

7. Where Was the Patient/Resident When the Event Occurred?

- Check only one location.
- Indicate the location of the patient when the event occurred.
- If “other” is checked, provide a short description of the location.

8. Immediate Corrective Action(s) Taken

- Describe the immediate treatment provided to the patient/resident in response to the event.
- Provide the immediate corrective action taken in response to the event. The description provided should include the specific procedures implemented, if any, to reduce the likelihood of recurrence of this event. For example, if the patient sustained a burn, you might state that the source of the burn, an electrocautery device, was removed from service immediately and all other such devices were checked by the biomedical department.
- List any additional reports provided to other organizations or agencies (e.g., equipment manufacturers, pharmaceutical manufacturers, and professional oversight boards) concerning this event.

**Chapter III: FORM-Report of Serious Preventable Adverse Event in
A New Jersey Licensed Health Care Facility**

See following page.

New Jersey Department of Health and Senior Services
REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT
IN A NEW JERSEY LICENSED HEALTH CARE FACILITY

NJDHSS INTERNAL USE ONLY

Report No. _____

This form must be completed for any serious preventable adverse event, which results in death or loss of a body part, or disability or loss of bodily function lasting more than seven (7) days or present at discharge. All information is protected based on the provisions of the Patient Safety Act [N.J.S.A. 26:2H-12.25(f)]

Is this a revision of an earlier report to the Patient Safety Initiative for the same event? <input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, give DHSS Report Number: _____	Facility Internal Tracking Number of this incident, if known: _____
--	--	---

SECTION A - GENERAL INFORMATION

1. FACILITY IDENTIFICATION

Facility Name: _____ Facility License No.: _____
 Facility Street Address: _____ County: _____
 City: _____ State: _____ Zip Code: _____
 Name of Person Submitting: _____ Telephone No.: _____
 Title or Position: _____ Fax No.: _____
 Email Address: _____

2. PLEASE SUPPLY A SIMPLE AND CLEAR DESCRIPTION OF THE EVENT OR SITUATION YOU ARE REPORTING:

Incident Information:

Incident Date: _____ Time: _____ AM PM
 Date Discovered: _____ Time: _____ AM PM

3. HOW WAS EVENT DISCOVERED? (Check only one)

- | | |
|--|--|
| <input type="checkbox"/> 1. Report by staff/physician | <input type="checkbox"/> 4. Assessment of patient/resident after event |
| <input type="checkbox"/> 2. Report by family/visitor | <input type="checkbox"/> 5. Review of chart/record |
| <input type="checkbox"/> 3. Report by patient/resident | <input type="checkbox"/> 6. Other: _____ |

4. PATIENT/RESIDENT INFORMATION

Inpatient or Outpatient
 Admission through: ED Direct Transfer from Acute Care General Hospital Transfer from LTC
 Patient/Resident Billing Number: _____
 Patient/Resident Name: _____ Medical Record No.: _____
 Street Address: _____ County: _____
 City: _____ State: _____ Zip Code: _____
 Date of Birth: _____ Gender: _____
 Admission Date or Date of Ambulatory Encounter: _____
 Primary Diagnosis: _____
 Race:
 Caucasian Amer. Indian/Alaskan Native Native Hawaiian/Pacific Islander Other: _____
 Black Asian Unable to Determine
 Ethnicity: Non-Hispanic/Unable to Determine Hispanic

New Jersey Department of Health and Senior Services
REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT
IN A NEW JERSEY LICENSED HEALTH CARE FACILITY
Continued

NJDHSS INTERNAL USE ONLY

Report No.

SECTION B - EVENT DETAILS

5. TYPES OF SERIOUS PREVENTABLE ADVERSE EVENTS (Check only one)

A. CARE MANAGEMENT EVENTS in a Health Care Facility

- 1. Patient/resident death/harm due to a medication error
- 2. Patient/resident death/harm due to a hemolytic reaction due to the administration of ABO-incompatible blood or blood products
- 3. Maternal death/harm due to labor/delivery in a low-risk pregnancy
- 4. Patient/resident death/harm due to hypoglycemia
- 5. Patient/resident death/harm due to failure to identify and treat hyperbilirubinemia in neonates
- 6. Stage 3 or 4 pressure ulcers acquired after admission
- 7. Patient/resident death/harm due to spinal manipulative therapy
- 8. Other event causing patient/resident death or harm that lasts seven days or is present at discharge

B. ENVIRONMENTAL EVENTS in a Health Care Facility

- 1. Patient/resident death/harm due to an electric shock
- 2. Any event in which a line designated for oxygen/other gas to be delivered to a patient/resident contains the wrong gas or is contaminated by toxic substances
- 3. Patient/resident death/harm due to a burn incurred from any source
- 4. Patient/resident death/harm due to a fall
- 5. Patient/resident death/harm due to the use of restraints or bedrails
- 6. Other event causing patient/resident death or harm that lasts seven days or is present at discharge

C. PRODUCT OR DEVICE EVENTS in a Health Care Facility

- 1. Patient/resident death/harm due to the use of contaminated drugs/devices/biologics
- 2. Patient/resident death/harm due to the use/function of a device in patient/resident care in which the device is used/functions other than as intended
- 3. Patient/resident death/harm due to intravascular air embolism
- 4. Patient/resident death/harm due to the use of a single-use device in which the device is used/functions other than as intended:
 - new single-use device
 - reprocessed single-use device
- 5. Other event causing patient/resident death or harm that lasts seven days or is present at discharge

D. SURGERY-RELATED EVENTS

- 1. Surgery performed on the wrong body part
- 2. Surgery performed on the wrong patient
- 3. Wrong surgical procedure performed on a patient
- 4. Retention of a foreign object in a patient after surgery or other procedure
- 5. Intraoperative or immediately post-operative coma or death in an ASA Class I inpatient or any ASA Class same day surgery patient or outpatient
- 6. Other event causing patient death or harm that lasts seven days or is present at discharge

E. PATIENT/RESIDENT PROTECTION EVENTS in a Health Care Facility

- 1. Infant discharged to the wrong person
- 2. Patient/resident death/harm due to patient elopement
- 3. Patient/resident suicide/attempted suicide
- 4. Other event causing patient/resident death or harm that lasts seven days or is present at discharge

New Jersey Department of Health and Senior Services
REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT
IN A NEW JERSEY LICENSED HEALTH CARE FACILITY
Continued

NJDHSS INTERNAL USE ONLY

Report No. _____

6. IF 5.A.1 WAS SELECTED, COMPLETE THIS SECTION:

What type of medication error occurred? *(Check all that apply)*

- Wrong Patient
- Wrong Drug
- Wrong Dose
- Wrong Route
- Wrong Frequency
- Wrong Time
- Omission
- Administration After Order Discontinued/Expired
- Wrong Diluent/Concentration/Dosage Form
- Monitoring Error

- Other: _____

Brand/Product Name (If Applicable): _____

Generic Name: _____

7. WHERE WAS THE PATIENT/RESIDENT WHEN THE EVENT OCCURRED? *(Check only one)*

- Patient/Resident Room
- Emergency Department
- Radiology
- Laboratory
- Operating Room
- Cardiac Catheterization Laboratory
- Labor and Delivery
- Nursery
- Recovery Room
- Rehabilitation Areas
- In Transit
- ICU / CCU / TCU
- Step Down Unit
- Telemetry Unit
- NICU
- Hallway or Other Common Area
- Other: _____

8. IMMEDIATE CORRECTIVE ACTION(S) TAKEN:

Chapter IV: Instructions for Completing the Serious Preventable Adverse Event Root Cause Analysis (RCA) Form

The *Report of Serious Preventable Adverse Event in A New Jersey Licensed Health Care Facility: Root Cause Analysis (RCA) Form* must be completed by the facility for each serious preventable adverse event reported to the Department. The completed *RCA form*, with any supporting documentation, must be received by the Department **no later than 45 calendar days following the date of submission of the initial report to the Department**. Information should be sent to:

For Regular Mail:

Patient Safety Initiative
Health Care Quality Assessment
New Jersey Department of Health and Senior Services
240 W. State St., PO Box 360
Trenton, NJ 08625-0360

For Special/Overnight Mail:

Patient Safety Initiative
Health Care Quality Assessment
New Jersey Department of Health and Senior Services
240 W. State St., 11th Floor
Trenton, NJ 08608

PURPOSE OF THE RCA

The purpose of the RCA is to uncover the factor(s) that led to and caused a serious preventable adverse event. It is not intended to assign blame to individuals or to organizations. Prior research has shown that most adverse events are due to systemic failures rather than intentional individual acts or professional incompetence. Only by determining the underlying systemic causes of an adverse event can an effective action plan be formulated to minimize the chances of reoccurrence.

The RCA and corrective action plan should draw on such resources as evidence-based medical literature, best-practices reports, Joint Commission Resources (a not-for-profit subsidiary of the Joint Commission), and other resources as appropriate.

RCA TEAM REQUIREMENTS

The RCA is to be performed by a multi-disciplinary team of the facility or the system. This may include nursing, pharmacy, medicine, physical therapy, respiratory therapy, central service, housekeeping, etc. Disciplines not directly involved in the event may also be included as they bring a fresh outlook to the analysis.

RCA PROCESS REQUIREMENTS

The RCA process consists of four components: Facts of the Event, Causality Statements, Action Plan, and Monitoring. All of these components must be included for the RCA to be considered acceptable. The components are defined as:

Facts of the Event

- a. The narrative should include the patient's admitting diagnosis, past medical history, pertinent hospital course (i.e., surgery, transfer to the ICU), medications, and any other factors that may have contributed to the occurrence of the event. It should provide the specific details of the adverse event and include the date, time, day of the week, location of the event, and how the patient was affected.
- b. The narrative should be succinct, clearly stated, and in chronological order. Identify all staff involved in the adverse event by title and function but do NOT use the actual

names of the staff. Give enough detail so that a person not familiar with the event can understand what happened. For example, the narrative should describe the direct cause of the event, i.e., the nurse gave the wrong medication.

- c. Indicate whether a similar event has occurred in the past three years in this facility. If yes, state when it occurred and describe what corrective actions, if any, were implemented.

Causality Statements

- a. Use the Facts of the Event to examine **why** the event occurred.
- b. Using the *Rules of Causation* guidelines that are attached (see Appendix), identify all the root causes of the event and the underlying procedural or systemic causes that contributed to the event's occurrence.
- c. The main objective in conducting a root cause analysis is to look at all procedural or systemic causes. For example, if a wrong medication is given by a nurse to a patient then the investigators must keep asking the question, "Why?"
 - Was the nurse working on a pediatric unit as a float nurse and has never had pediatric experience? Does the hospital have a policy that addresses the issues of supplying personnel for understaffed hospital units?
 - Was the nurse doing a double shift and was fatigued because there had been no coverage for breaks/meals and had not rested or had food for ten hours? Does the hospital have or did it follow its policy for personnel who work extra shifts?
 - Did the doctor write the order on the wrong patient because the computerized physician order entry (CPOE) did not require more than one patient identifier?
 - Did the pharmacy send the wrong medication because it is next to the correct medication on the shelf and the drug names are similar?
- d. The causality statement(s) connect these causes with the event. The format for a causality statement is: X (cause) increased the likelihood that Y (event) would occur.

Action Plan

- a. Describe the corrective actions that the facility will implement to prevent a similar incident from occurring in the future. These actions should be specific and address each cause listed (i.e., someone who is not a member of the RCA team should be able to understand what to do next).
- b. Describe the time frame for the implementation of each corrective action.

Monitoring

- a. Describe how each corrective action's effectiveness will be measured and monitored, i.e., how will the facility know whether the action was implemented? For example, if the action is rounding each hour, how will the facility know that this action is being carried out?

COMPLETING THE RCA FORM

- Please type or print all information; please use no less than 10-point type.
- DHSS Report Number must be on EACH page of the RCA report.
- Resubmissions must be labeled as such on the cover sheet and include the DHSS Report Number.

SECTION A – GENERAL INFORMATION

1. Facility Identification

- List facility name, full address, and State of NJ license number.
- List the name, title, and contact information of the person completing the form.

SECTION B – INCIDENT INFORMATION

2. Incident Date

- List the date and time of the event. Confirm information using the original event report.
- If the time of the event is unknown, list the time as “unknown.”
- List the patient/resident’s medical record number, billing number (if appropriate), and full name.

SECTION C – ROOT CAUSE ANALYSIS

3. Select Root Cause

- Indicate the root cause(s) of the event based on your analysis of the direct, procedural, and systemic causes of the adverse event (check all that apply).

4. What Were the Contributing Factors to the Event?

- Indicate the contributing factor(s) based on your analysis of the direct, procedural, and systemic causes of the adverse event (check all that apply).

5. Evaluate Impact of Event for Patient

- Review the impact of the event for the patient (check all that apply).

6. Describe Root Cause Analysis

- Provide a comprehensive description of the analysis process and findings. Describe the facts of the event, causality, action plan and monitoring as described under *RCA Process Requirements* on pages 1 and 2 of this chapter. Note any specific recommendations from the Patient Safety Committee.
- List any reports to other organizations or agencies (e.g., equipment manufacturers, pharmaceutical manufacturers and professional oversight boards) concerning this event.

**Chapter V: FORM-Report of Serious Preventable Adverse Event in A New Jersey
Licensed Health Care Facility: Root Cause Analysis (RCA)**

See following page.

**REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT
IN A NEW JERSEY LICENSED HEALTH CARE FACILITY:
ROOT CAUSE ANALYSIS (RCA)**

Report No. _____

This form must be completed for any serious preventable adverse event, which results in death or loss of a body part, or disability or loss of bodily function lasting more than seven (7) days or present at discharge. All information is protected based on the provisions of the Patient Safety Act [N.J.S.A. 26:2H-12.25(f)]

SECTION A - GENERAL INFORMATION

1. FACILITY IDENTIFICATION

Facility Name: _____ Facility License No.: _____
 Facility Street Address: _____ County: _____
 City: _____ State: _____ Zip Code: _____
 Name of Person Submitting: _____ Telephone No.: _____
 Title or Position: _____ Fax No.: _____
 Email Address: _____

SECTION B - INCIDENT INFORMATION

2. INCIDENT DATE: _____ Time: _____ AM PM
 Date Initial Report Sent to Patient Safety Initiative: _____ DHSS Report Number (Assigned by DHSS): _____
 Medical Record Number: _____ Patient/Resident Billing Number: _____
 Patient/Resident Name: _____

SECTION C - ROOT CAUSE ANALYSIS

3. SELECT ROOT CAUSE (Select all that apply):

- | | |
|--|--|
| <input type="checkbox"/> Behavioral assessment process | <input type="checkbox"/> Physical assessment process |
| <input type="checkbox"/> Patient identification process | <input type="checkbox"/> Patient observation procedures |
| <input type="checkbox"/> Care planning process | <input type="checkbox"/> Staffing levels |
| <input type="checkbox"/> Orientation & training of staff | <input type="checkbox"/> Competency assessment/credentialing |
| <input type="checkbox"/> Supervision of staff | <input type="checkbox"/> Communication with patient/family |
| <input type="checkbox"/> Communication among staff members | <input type="checkbox"/> Availability of information |
| <input type="checkbox"/> Adequacy of technical support | <input type="checkbox"/> Equipment maintenance/management |
| <input type="checkbox"/> Physical environment | <input type="checkbox"/> Security systems and processes |
| <input type="checkbox"/> Control of medications (Storage/access) | <input type="checkbox"/> Labeling of medications |
| <input type="checkbox"/> Other: _____ | |

New Jersey Department of Health and Senior Services
REPORT OF SERIOUS PREVENTABLE ADVERSE EVENT
IN A NEW JERSEY LICENSED HEALTH CARE FACILITY:
ROOT CAUSE ANALYSIS (RCA)
(Continued)

NJDHSS INTERNAL USE ONLY

Report No.

4. WHAT WERE THE CONTRIBUTING FACTORS TO EVENT (Select all that apply):

- | | |
|---|--|
| <input type="checkbox"/> Team factors | <input type="checkbox"/> Work environment |
| <input type="checkbox"/> Task factors | <input type="checkbox"/> Staff factors |
| <input type="checkbox"/> Patient characteristics | <input type="checkbox"/> Organizational/management |
| <input type="checkbox"/> Medical Device | <input type="checkbox"/> Medications |
| <input type="checkbox"/> Procedures | <input type="checkbox"/> Transportation |
| <input type="checkbox"/> Equipment | <input type="checkbox"/> Home Care |
| <input type="checkbox"/> Patient record documentation | <input type="checkbox"/> Imaging and X-rays |
| <input type="checkbox"/> Laboratory and diagnostics | <input type="checkbox"/> Other (Specify): |
-

5. EVALUATE IMPACT OF EVENT FOR PATIENT/RESIDENT (Select all that apply):

- | | |
|--|--|
| <input type="checkbox"/> Loss of limb(s) | <input type="checkbox"/> Additional patient monitoring in current location |
| <input type="checkbox"/> Loss of digit(s) | <input type="checkbox"/> Visit to Emergency Department |
| <input type="checkbox"/> Loss of body part(s) | <input type="checkbox"/> Hospital admission |
| <input type="checkbox"/> Loss of organ(s) | <input type="checkbox"/> Transfer to more intensive level of care |
| <input type="checkbox"/> Loss of sensory function(s) | <input type="checkbox"/> Increased length of stay |
| <input type="checkbox"/> Loss of bodily function(s) | <input type="checkbox"/> Minor surgery |
| <input type="checkbox"/> Disability - physical or mental impairment | <input type="checkbox"/> Major surgery |
| <input type="checkbox"/> Additional laboratory testing or diagnostic imaging | <input type="checkbox"/> System or processes delay care to a patient |
| <input type="checkbox"/> Other additional diagnostic testing | <input type="checkbox"/> To be determined |
| <input type="checkbox"/> Other (Specify): | <input type="checkbox"/> Death |
-

6. DESCRIBE ROOT CAUSE ANALYSIS:

(Attach the RCA.)

Appendix: 5 Rules of Causation

These 5 *Rules of Causation* are provided as a resource to assist the facility in conducting the Root Cause Analysis (RCA) of a Serious Preventable Adverse Event. In preparing the RCA, consider these principles.

Rule 1: Root Cause Statements must clearly indicate the “cause and effect” relationship.

When describing why an event has occurred, RCA statements should show the link between the root cause and the adverse outcome. Each link should be clear to both the RCA Team and others.

Examples: **WRONG:** A resident was fatigued.
 CORRECT: The level of the resident’s fatigue increased the likelihood that she misread the instructions, which led to incorrect tube insertion.

Rule 2: Negative descriptions should not be used in Root Cause Statements.

Negative descriptions are often a substitute for more accurate and clear descriptions. Words like *carelessness* and *complacency* are poor choices because they are broad, negative judgments that do little to describe the actual conditions or behaviors that led to the mishap.

Examples: **WRONG:** Poorly trained nurse.
 CORRECT: The level of the nurse’s training increased the likelihood that he misunderstood the IV Pump controls, which led to missing steps in the programming of dose and rate.

Rule 3: Each human error must have a preceding cause.

Many adverse events involve a set of events and errors. For each human error in the causal chain, there must be a corresponding cause. Similar to “Rule 1,” the links need to be clear and obvious to the RCA Team and others. It is the cause of the error, not the error itself, which leads to productive prevention.

Examples: **WRONG:** The lighting level was low.
 CORRECT: The level of lighting in the patient’s room increased the probability that the tripping hazard would not be seen, which led to the patient’s fall and....

Rule 4: Violations of procedure are not root causes; they must have a preceding cause.

Procedural violations are not directly manageable. Instead, it is the cause of the procedural violation that can be managed. The goal is to identify the positive and negative incentives that created the informal norm or accepted way of doing things.

Examples: **WRONG:** The pharmacy technician did not follow IV fluid mixing procedures.
 CORRECT: A lack of encouragement and oversight of pharmacy employees by Management created an informal atmosphere where missed training and bypassing procedures was acceptable practice.

Rule 5: *Failure to act is only causal when there was a pre-existing duty to act.*

The duty to act may arise from standards and guidelines for practice or other duties to provide patient care. The failure to act is judged on the duty to act at the time the error occurred.

Example: A doctor's failure to prescribe a cardiac medication after a myocardial infarction can only be causal if he/she was required by well-established guidelines to prescribe the medication in the first place.

These rules have been adapted from material provided by the: VA National Center for Patient Safety (www.patientsafety.gov).