Patient Safety Reporting System

State of New Jersey
Department of Health

Facility User Guide
# Patient Safety Reporting Facility User Guide

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I. Introduction

New Jersey is committed to promoting patient safety and preventing serious preventable adverse events. In 2004, the New Jersey Patient Safety Act (P.L. 2004, c9) was signed into law. The statute was designed to improve patient safety in hospitals and other health care facilities by establishing a serious preventable adverse event reporting system. This site is designed to help health care facilities develop strong patient safety programs, collect and analyze aggregate data and fulfill the law’s mandatory reporting requirements.

Additional resources may be found on the Patient Safety website at: http://nj.gov/health/ps/. Program staff is also available to speak with you at: (609) 633-7759.

This document is a guide for facility users in using the Patient Safety Reporting System.

II. Logging In

Facility users will receive temporary access information from their Facility Admin User; Facility Admin Users will receive temporary access information from the Department of Health (DOH). All new users will use their temporary password to access the system for the first time. When the user accesses the system, they will be asked to create a secret word and reset their password. The secret word will be used if a user forgets their log in information.

After receiving your user name and temporary password, access the My New Jersey Network to register.

- Open a browser (internet) window.
- Enter the URL patientsafety.nj.gov
- Click on “Go To Register”
Enter all information using the user ID and password provided. The password provided is entered in the One time user authorization key box.

Click “Submit Registration.”
Fill in Section B to create a “myNewJersey” account.
- Enter the user ID provided.
- Enter a new password; this will be your permanent password.
- Click “Link Patient Safety Reporting to My Account” button.
A. **Established Users logging in through the My New Jersey Network**

After the one time registration process is complete, use the My New Jersey network to access the Patient Safety System.

- Open a browser (internet) window
- Enter the URL for the My New Jersey network: nj.gov
- Enter user name and password
- Click on “Log On”
- **NOTE:** The system will automatically log out in 2 hours from this point. Please make sure to keep track of time and save all entries. The 2 hours does not depend on actively using the system.
- Click on “DHSS Patient Safety Reporting System” link
B. Managing Facility User Information — Used by Facility Administrative User (Facility Admin) Only

Each facility will have a designated Facility Administrative User (Facility Admin).

- Facility Admin users will be created by DOH.
- The Facility Admin will be responsible for assigning users and user roles for their organization.
- Notification on event reports will be done via email to the Facility Admin. It is critical that the email addresses for Facility Admins are kept up-to-date in the system.
- Notifications will always be made to the Facility Admins even for event reports submitted by other users within their facility.

1. To View Existing Users:

   - Click on the “User Maintenance” link (see graphic above).
   - Click on the plus [+] symbol to show the facilities assigned to the user.
   - Click on the “View” link to display the user information.
2. To Edit User Information:
   - Click on the “Edit User Info” button (see graphic below).
   - Edit information and click “Update.”

![User Information](image)

3. To Delete User:
   The “Delete User” button will remove the user from the system. Use the “Return” button to return to the previous screen (see graphic above).

4. To Add New User:
   - Click on “User Maintenance.”
   - Select “Create New User” link.
   - Select the user roles. The majority of users will be assigned the roles of Report Reader (rptReader) and Report Writer (rptWriter).
     - **Report Reader**: User has access to read event report information for their assigned facility.
     - **Report Writer**: User has access to submit and edit event report information for their assigned facility.
     - **Facility Admin**: User receives automated event report correspondence for facility event reports; and manages other facility users.
   - Enter user name and email address.
   - Select one or more facilities for the user.
   - Click on “Create User” button.

Assigning the user will generate a user name and temporary password which the Facility Admin will communicate to the new user. The user will now need to go through the self registration process to gain access to the “myNewJersey network” and the application as described in Section II.
III. What to Report

The following events must be reported:

**Care Management**

- **Medication Error**
  Patient 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.

- **Wrong Blood Product**
  Patient 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.

- **Maternal Labor**
  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.

- **Hypoglycemia**
  Patient 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.

- **Neonate Hyperbilirubinemia**
  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.

- **Pressure Ulcers**
  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.

- **Spinal**
  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.

- **Other**
  Other patient 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.

**Environmental**

- **Electric Shock**
  Patient 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).

- **Wrong Gas**
  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.

- **Burn**
  Patient 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.

- **Fall**
  Patient 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.

- **Restraints**
  Patient 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.

- **Other**
  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.

**Product/Device**

- **Contaminated Drugs/Devices/Biologics**
  Patient 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.

- **Malfunction**
  Patient 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 (including new single-use device or a reprocessed single-use device) in patient/resident care in which the device is used or functions other than as intended. This includes and is not limited to catheters, drains, and other specialized tubes, infusion pumps, and ventilators. Indicate whether the device was new or had been reprocessed.

- **Air Embolism**
  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.

- **Other**
  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.
Patient Protection

- **Infant Discharge**
  Discharge of an infant to the wrong person, excluding patient/resident abductions.

- **Elopement**
  Any patient death, loss of body part, disability, or loss of bodily function lasting more than seven days associated with patient/resident elopement.

- **Suicide/Attempted Suicide**
  Patient 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.

- **Other**
  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.

Surgical

- **Wrong Site**
  Surgery initiated (whether or not completed) on the wrong body part.

- **Wrong Patient**
  A surgical procedure (whether or not completed) intended for a different patient of the facility.

- **Wrong Procedure**
  A wrong surgical procedure initiated (whether or not completed) on a patient.

- **Retained Foreign Object**
  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.

- **Intra/Post-Op Coma or Death**
  Intraoperative or postoperative (i.e., within 24 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.

- **Other**
  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.
IV. When to Report

- The initial event information must be reported to the State through the web-based registry within 5 business days of the event discovery date.
- An RCA must be prepared by the patient safety committee exploring the underlying causes and contributing factors to the event and must be submitted to DOH within forty-five (45) days from the date when the initial event report was submitted to DOH.
- What is the discovery date?
  - The discovery date is the date the facility first becomes aware of the occurrence of a reportable event. Example: a sponge is retained during a procedure (event date) but is not discovered until the patient returns to the emergency department two days later (discovery date).
  - The discovery date is not the date that risk management or administration becomes aware of the event, but the date that any person at the facility becomes aware of the occurrence.
V. System Navigation

Navigating around the system is accomplished by using the main menu found on many screens. The main menu is located on the top right of the screen.

After logging into the system, the home page will appear. Use the menu located on the top right of the screen to select the section of the system to enter. Each of these options will be explained in detail in later sections.

- **Add Event** – enter a new event report.
- **View Events** – provides a list of all events for a facility; a list of events by status (e.g. under review by DOH; needs additional information from facility).
- **Resources** – provides a list of resources consulted for event reports. Also contains information required to be entered for all of the types of events.
- **User Maintenance** – only available to Facility Admins.
Listing and Selecting Events – “View Events”

The View Events menu presents the events in the system. All events are listed for the current year with a status showing where the event is in the process. To select an event use the link under the VIEW column (see below).

Entering information into the boxes under the column heading will limit the list of events shown. In the screen displayed below, events are limited to 2010 and facilities that start with “test”. To list all events click on the “Clear” link in the VIEW column. This will remove all limitations on the list.

VI. Prior to Adding an Event

It is recommended that prior to entering a new event the user should check the Resources tab to understand the information required for the event type.

- Click on “Report Questions” under the Resources menu option.
Choose Initial Event or RCA tab for the questions pertaining to that section.
Use the drop down list to select the type of event.
Click on “View Initial Event Questions” to display the information required for the event type selected.

*DOH recommends that the initial event information and the RCA information be entered into a word processing document. This will allow the use of cut and paste to then transfer the information into the Patient Safety System. This will also speed the entry process into the system and help to alleviate the two hour time window for using the system for a given logon.
VII. How to Report an Event

Reporting of the event and RCA is categorized into four different steps within the system:

**STEP I: Initial Event Information Submission by Facility**
- Within **five (5) business days** of event discovery, the facility submits new event information. The new event information contains patient information, event information and event-specific information.
- DOH receives an automated email notification when the event is submitted.

**STEP II: Event Review by DOH**
- DOH is notified of event submission via email. DOH determines reportability.
- DOH selects reportability decision option generating an automatic email to Facility Admin User(s) describing the reportability decision and next steps.
- If the event is determined to be not reportable by DOH, the email message indicates reasons for non-reportability, the event is closed and no further action is required.
- If the event is determined to be reportable by DOH, the email message indicates the event is reportable and directs the facility to submit an RCA and generates a due date for submission of the RCA. The due date is 45 calendar days from event submission.
- If DOH requires more information for a decision, the email indicates that additional information is required by the facility. A link will be provided in the email to the patient safety system to access comments and edit the information that was previously provided.
- More information required:
  - The facility user resubmits event information to DOH.
  - DOH receives an automated email notification when the event is resubmitted.

**STEP III: RCA Submission by Facility Including Causality Statement and Action Plan**
- The facility user submits the RCA information within 45 days of initial event submission.
- DOH receives an automated email notification when the RCA is submitted.

**STEP IV: RCA Review by DOH**
- DOH reviews the RCA against review criteria.
- If the criteria are met, an automated notification is sent to the Facility Admin User(s) and the event is completed.
- If the criteria are not met, DOH provides comments in sections where additional information or clarification is needed.
- DOH sends a notification email to the Facility Admin User(s) stating that action is required by the facility. A link is provided for the facility user to edit the information that was submitted. The facility user will read the reviewer comments and make changes as appropriate.
- The facility user resubmits the RCA to DOH within 14 calendar days.
**A. Step I: Enter Initial Event Information**

Log-in to the system with user name and password. The main menu for the system is displayed.

- Select “Add Event” from the menu bar on the top right of the screen *(see graphic below)*.
- The list of Adverse Event Types will be displayed.
- Use the drop-down menu to select the Event Type. The Event Type cannot be changed after continuing to the next screen.
  - Click the “HERE” link to display a complete description of each event type.
  - Click the “Continue” button after the selection is made.
1. Patient Information

Fields are comprised of a combination of drop-down menus and text boxes.

- To complete a field with a drop-down menu, click on the arrow for that field, and then click on the appropriate selection.
- To complete a text box, type in the information.
- Use the scroll bar on the right to view the entire screen.
- All patient information fields are required, except Middle Name and Admitting ICD-9.
- County selection will only be used for New Jersey.
- Click on the question mark (?) button for additional information.
- Click the “Save/Next” button at the bottom of the screen to continue.

Note: The Patient Safety Reporting System times-out after 2 hours. If you do not complete the required fields and save the event information, the information that you have entered will be lost after two hours. The time is based on how long you have been in the “my NewJersey” network. If entering information and the screen is not complete, enter placeholder information (e.g. TBD) to be able to save the screen. You can then return to the same event report at a later time and update any information that was previously omitted.
2. Event Information

- Use the scroll bar on the right to view the entire screen.
- All information is required.
- Additional questions will be displayed based on the type of the event.
- Click the “Save/Next” button at the bottom of the screen to continue.

The Event Information screen follows on the next page:
### Event Classification: Care Management - Pressure Ulcers

#### Event Information

- **Event date:**
- **Enter Event Time in Military (e.g. 1500=3:00PM), if not known, enter ‘unknown’**
- **Discovery Time in Military (e.g. 0200=2:00AM)**

- **Date event discovered:**

**How was the event discovered?**
- **Please Select**

**In what unit did the event occur?**
- **Please Select**

**In what location did the event occur?**

<table>
<thead>
<tr>
<th>Location of injury (check at least one):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdomen</td>
</tr>
<tr>
<td>Ankle</td>
</tr>
<tr>
<td>Back/spine</td>
</tr>
<tr>
<td>Chest</td>
</tr>
<tr>
<td>Foot</td>
</tr>
<tr>
<td>Forearm</td>
</tr>
<tr>
<td>Hand</td>
</tr>
<tr>
<td>Head</td>
</tr>
<tr>
<td>Other:</td>
</tr>
</tbody>
</table>

**Severity of injury (check at least one):**
- Death
- Cast/Immobilization
- Increased length of stay is anticipated
- Minor injury

**Immediate clinical action(s) taken for patient:**

- **1000 Characters left**

**Immediate corrective action(s) to prevent future similar events:**

- **1000 Characters left**

**Location of pressure ulcer (check at least one):**
- Occipital | Heels |
| Sacrum | Other |
| Buttocks |

**Stage**
- **Please Select**

**Size of pressure ulcer:**

**Was this a device related pressure ulcer?**
- Yes
- No

**Was the patient or health care representative notified about the event within 24 hours of event discovery?**
- Yes
- No

*All Fields are Required*
3. **To Submit Event to DOH for Review:**

- The patient and event information is displayed for review. Click on the “Edit” button to change any of the information entered.
- Click on the “Submit Event” option in the Report Menu bar to send the event to DOH for review.
- DOH will be notified via email of the event submission.

![Image of Report Menu with options]

4. **To Save the Event and Not Submit to DOH**

To save the event and NOT submit the event to DOH, use the menu bar at the top of the screen to navigate away from the event. Select a main menu bar option such as “Home”.

![Image of Menu Options]

To return to the event at a later time use the “View Events” option as shown in this section.

When an event is selected, use the Report Menu to navigate the event. The red arrow in the Report Menu will indicate where the event report is in the process. In this example, Event Info would be the next step in the entry process.
B. Step II: Event Review by DOH

DOH will review the event information and determine the next action of the event report. The Facility Admin will be notified via email of the decision and next steps. Options for next steps include:

- No further reporting action needed for the State.
- Additional information is needed to determine reportability.
- RCA required.
- Explanation of information is needed.

1. Additional Information Needed for Review

If additional Information is needed, DOH will send an email with a description of the information needed. The facility can view the comments made about the event report and update the information before re-submitting the event to DOH.

- When entering the reporting system, under the Action Items heading on the home page, click on the Report Number link to display the event.

- Under each section there will be an indicator if comments were made for that section. The partial screen below shows how to access comments for the Event Information section.
- Click on the “Comments” link to view the reviewer’s comments.
2. **Submit RCA for Less Serious or Near Miss Event**

If the determination is made that an event is less serious or near miss than an RCA can be submitted for those events. The regulations require the facility’s patient safety committee to conduct annually at least one RCA for a less serious preventable adverse event or a near miss that is not subject to the mandatory reporting. Contact DOH to provide an RCA for these type of events. The steps for providing an RCA will be the same as for those events requiring an RCA.

3. **Explanation Needed for Event Report Without Changes**

DOH may request an explanation of some of the event report information. The facility will receive an email indicating that a further explanation is needed. The event report cannot be updated and the response to the email will be made in the system.

Events reports that need an explanation will be displayed on the home page when entering the system. See the screen displayed below:
• Click on “Respond” to enter a response and then send response to DOH:

• Enter a response.
• Click on “Save” to send the response to DOH.

NOTE: The event report is still being reviewed by DOH and cannot be updated.
C. Step III: RCA Submission by Facility including Causality Statement and Action Plan

If the DOH review of the initial event information determines that an RCA is required for the event, the facility will complete the RCA section of the event.

- To begin the RCA entry process, click on “View Events”.
- Use the drop down for Event Status to select “RCA – Facility Edit” for the event status column.
- Events requiring an RCA will be displayed.

- Click on “Detail” for the event to begin the RCA entry process.
- Screen displayed below is shown:

- Click on “General Info” to begin the RCA entry process. This first section of the RCA entry process may also be accessed from the Report Menu.
- The Report Menu can be used to select the specific section of the RCA to be completed at a later time. The Report Menu is shown below.
Report Menu

1. RCA: General Information
   - Complete all fields in this section – all fields are required.
   - Click on “Save/Next” to save the completed information and move to the next section.

2. RCA: Facts of the Event
   - Complete all fields in this section or enter “NA” if not applicable – all fields are required.
   - The RCA Facts of the Event screen can be saved when partially completed. However, all fields must be completed prior to submitting the event to DOH for review.
   - Click on “Save/Next” at the bottom of the screen to save the completed information and move to the next section.
If all fields are not completed and the RCA is submitted, an error message will be displayed as shown below. Return to the Facts of the Event screen to complete all entries.

**Invalid Submission**

- Please return to the RCA: Facts of the Event and complete all fields
- Enter 'NA' where not applicable
- Click [HERE](#) to return to the RCA: Facts of the Event

3. **RCA: Specific Questions**

- Complete all fields in this section — all fields are required.
- This screen contains questions based on the type of event being reported.
- Click on “Save/Next” to save the completed information and move to the next section.
### RCA Specific Questions

1. Pressure ulcer risk assessment (Braden) documented on admission and daily?  
   - [ ] Yes  
   - [ ] No

2. Skin inspection was documented on admission and daily?  
   - [ ] Yes  
   - [ ] No

3. Removal of devices such as stockings and splints were documented each shift?  
   - [ ] Yes  
   - [ ] No  
   - [ ] NA

4. Did staff use the documented care plan to assess risk and plan appropriate interventions?  
   - [ ] Yes  
   - [ ] No

5. Patient Characteristics (check at least one):  
   - [ ] Dialysis  
   - [ ] Smoker  
   - [ ] Sepsis  
   - [ ] Morbid obesity (BMI >=40)  
   - [ ] Kidney failure  
   - [ ] Peripheral vascular disease  
   - [ ] Clinically malnourished  
   - [ ] Heart failure  
   - [ ] Receiving palliative or comfort care  
   - [ ] Incontinent  
   - [ ] Respiratory failure  
   - [ ] History of previous pressure ulcer  
   - [ ] Diabetic  
   - [ ] Neurological/Neuromuscular condition

6. Patients with impaired sensory perception, mobility, and activity as defined by the Braden scale had the following interventions documented:  
   - Repositioning q 2hrs  
     - [ ] Yes  
     - [ ] No  
   - Heels off of bed  
     - [ ] Yes  
     - [ ] No  
   - Appropriate support surfaces (mattresses, chair cushions) for pressure redistribution  
     - [ ] Yes  
     - [ ] No

7. Patients with friction/shear risk as defined by the Braden scale had HOB 30 degrees or less documented (if medically contraindicated, there was an MD order and an alternative plan was documented to prevent shear injury)?  
   - [ ] Yes  
   - [ ] No

8. Did patient refuse repositioning?  
   - [ ] Yes  
   - [ ] No
4. **RCA: Root Cause/Causality Statement**
   - Select a single root cause and enter the corresponding causality statement.
     - More than one root cause can be associated with an RCA. Additional root causes can be added after completion of the first root cause and associated action plan(s) and monitoring.
   - When the entry for this screen is complete, click the “Save/Next” button to continue to the action plan for this root cause.

![RCA: Root Cause/Causality Statement](image)

- **1. Root Cause Categories:**
  - Behavioral assessment process
  - Patient identification process
  - Care planning process
  - Orientation and training of staff
  - Supervision of staff
  - Communication among staff members
  - Adequacy of technical support
  - Control of medications (Storage/access)
  - Physical assessment process
  - Patient observation procedures
  - Staffing levels
  - Competency assessment/credentialing
  - Communication with patient/family
  - Availability of information
  - Equipment maintenance/management
  - Security systems and processes
  - Labeling of medications
  - Physical environment
  - Other

- **If 'Other', please identify Root Cause**

- **2. Causality Statement:**
5. RCA: Action Plan

Multiple action plans can be entered for each root cause. How to enter additional action plans will be described in the next section. An action plan can only have one methodology specified. If an action plan involves more than one methodology (i.e. chart review and observational audits), each methodology should be entered as a separate action plan. This will allow for entry of multiple methodologies with corresponding goals and thresholds.

- The causality statement is displayed for reference.
- Click on the question mark “?” button for additional information.
- Complete all entries on the screen for the action plan.
- If more than one methodology is to be used, a separate action plan is required for each methodology.
  - See the next section for instructions on adding a new action plan.
- Click “Save/Next” at the bottom of the screen

6. Edit/Add Root Cause Findings

- To add an action plan for the root cause:
  - Click on the plus (+) symbol next to the root cause to display the action plan.
  - Select “Add Action Plan”.
  - Complete action plan fields for the new action plan.
  - Click “Save/Next”.

- To add an additional root cause finding:
  - Click on the “Add Root Cause” button.
  - Complete the steps for entering a root cause.
  - Complete the steps for entering an action plan(s) for the root cause. Each root cause must have at least one action plan associated with it.
7. RCA Additional Questions

- When the root cause and action plan entries are complete:
  - Click “Continue to RCA Additional Questions” to complete the RCA entry process.
  - Complete all fields in this section – all fields are required.
  - Click on “Save/Next” to save the completed information.

8. Submitting RCA to DOH for Review
Patient Safety Reporting Facility User Guide

- Prior to submission, any section of the RCA can be accessed by using the Report Menu options. Click on “Edit” to update that section of the RCA. Click “Save/Next” to save changes. This process is described in this section.
- To submit the RCA, click on the “Submit RCA” option as shown on the following screen.
- DOH will be notified that the RCA was submitted and ready for review.

**D. Step IV: RCA Review by DOH**

DOH will review the RCA information and determine the next action of the RCA process. The Facility Admin will be notified via email of the decision and next steps. There may be more than one cycle for the RCA review process if DOH needs additional information to accept the RCA as complete.

Options for next steps include:
- RCA Comments – additional information needed.
- Event Complete – No additional action needed.

If additional information is needed:
- When entering the reporting system, under Action Items on home page:
  - Click on the link under “Report Number” to display the event.

Under each section there will be an indicator if comments were made for that section.
- Click on the “Comments” link to view the reviewer’s comments.
- Click the “Edit” link to make changes to address the reviewer’s comments for that section.
- Save the changes and click on the “Submit Event” option to resend the RCA to DOH.
E. Providing Additional Documentation for Event and/or RCA

At any time during the event reporting process, additional documentation can be attached to the event/RCA. Documents must be attached to the event report based on the report number. The use of attachments applies to a single event/RCA. DOH must be contacted for each event/RCA that requires attachments.

- Contact DOH and provide the report number and request to add attachments.
- When DOH confirms that attachments can be made through an email or phone call then enter the Patient Safety System.
- Use the “View Events” menu option to access the event report.
- Enter the report number in the box under the Report Number heading.
- Click on “Detail” to access the event report.
An attachment option is available for the event/RCA as shown below.

- Click on “Upload Supporting Documentation” to attach documents to the event.

The next screen provides the ability to browse to the document.

- Click on the “Upload” button once the document is found.
- Multiple documents can be attached.
Report Menu: Return to Detail

Report Number: 2010-0056

Event Classification: Care Management - Medication Error

Upload File

<table>
<thead>
<tr>
<th>Delete</th>
<th>View Doc</th>
<th>Data Uploaded</th>
<th>File Name</th>
<th>Uploaded By</th>
</tr>
</thead>
</table>

No data to display
VIII. Event Tracking

In addition to the Action Items listed on the Home Screen, the progress of all event reports can be viewed by using the “View Events” option.

- Click on the “View Events” option from the main menu on the top of the screen.
- To access an event or RCA, click on the link in the View column for that event.
- To limit the list enter a report number in the box under the Report Number column.
- Use the drop down arrows to select Event Status or Event Type.

IX. Completed Events

When an event report and RCA has been determined to be complete, DOH will send an email notification that no further action is required. This completes the process for the event report and RCA.
X. Ad-Hoc Reports

Custom reports can be retrieved and saved in the system.

- To create custom reports use the View Events menu option.

This will display a default report which can be changed and saved for future use.

- To filter the information provided on the reports, use the entry box or drop-down for each column of data.
  - For example, the report below is limited to 2010 data.
To further define the filter, click on the key symbol to select the operation (equal to, greater than) for the filter.

<table>
<thead>
<tr>
<th>View</th>
<th>Report Year</th>
<th>Facility Name</th>
<th>Report Number</th>
<th>Event Status</th>
<th>Event Type</th>
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<tbody>
<tr>
<td>Clear</td>
<td>2010</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Detail</td>
<td>2010</td>
<td></td>
<td></td>
<td>Closed</td>
<td>Care Management - Medication Error</td>
</tr>
<tr>
<td>Detail</td>
<td>2010</td>
<td></td>
<td></td>
<td>Closed</td>
<td>Care Management - Wrong Blood Product</td>
</tr>
<tr>
<td>Detail</td>
<td>2010</td>
<td></td>
<td></td>
<td>Closed</td>
<td>Care Management - Maternal Labor</td>
</tr>
<tr>
<td>Detail</td>
<td>2010</td>
<td></td>
<td></td>
<td>RCA-DHSS Review</td>
<td>Care Management - Wrong Blood Product</td>
</tr>
<tr>
<td>Detail</td>
<td>2010</td>
<td>TEST FACILITY</td>
<td>20103010</td>
<td>Closed</td>
<td>Care Management - RCA-Facility Edit</td>
</tr>
<tr>
<td>Detail</td>
<td>2010</td>
<td>TEST FACILITY</td>
<td>20103010</td>
<td>RCA-Facility Edit</td>
<td>Care Management - RCA-DHSS Review</td>
</tr>
<tr>
<td>Detail</td>
<td>2010</td>
<td>TEST FACILITY</td>
<td>20103012</td>
<td>Environmental - Electric Shock</td>
<td></td>
</tr>
<tr>
<td>Detail</td>
<td>2010</td>
<td>TEST FACILITY</td>
<td>20103013</td>
<td>Event-DHSS Review</td>
<td>Care Management - Spinal</td>
</tr>
<tr>
<td>Detail</td>
<td>2010</td>
<td>TEST FACILITY</td>
<td>20103013</td>
<td>Event-DHSS Review</td>
<td>Care Management - Hypoglycemia</td>
</tr>
</tbody>
</table>

To remove or add columns, click on the “Show Customization Window” option to display a list of fields available to add to the report.

1. To add a column:
   - Click on the field desired and while holding down the mouse button, drag the field into the report.
     - The Admission Through field is being added to this report.
To remove a column:
- Click on the column name and drag it to the field chooser list.
  - The Facility Name column was removed from this report and now appears in the field chooser list.
3. To Save a Report:
   - Click on the “Save a Report” option.
   - Enter a name for the report and click “Save Report.”

4. Accessing Saved Reports
   - To access the report at a later time, click on the “Saved Reports” option.
   - A list of saved reports will be shown; click on the desired report to access.

5. Deleting Saved Reports
   - Use the delete button to remove the report from the saved reports.
   - Confirmation of the delete will be displayed
6. To Export Report Information

- To save the information in the report, use the “Export to Excel” option.
  - This will open a Windows download dialogue box.
- Click on “Save” and specify where to save the information.
XI. Frequently Asked Questions

General Questions

- What to Report?
- What is a preventable event?
- The event did not cause actual harm to the patient. Do I still need to report?
- Does this event need a report?
- What if our facility thinks the event is not-preventable?
- What if the event is rare and unusual?
- What types of events should be reported as Less Serious or Near Misses?
- How do I report events?
- When should I report?
- Where do I report suspected criminal activity?
- Where should I report interruption of services?
- Where do I report communicable and infectious diseases?

Specific Event Type Questions

- What if we discover a retained object left at another facility?
- What types of injury from falls should be reported?
- What types of pressure ulcers should be reported?
- What should I report under the Care Management Event “Other” category?
- What is considered “surgery”?
- What if the event is considered a complication of surgery or treatment?

Event Form Definition Questions

- How detailed should the Description of the Event be?
- What is the Event Date?
- What is the Event Time?
- What is Date Event Discovered?
- What is the Time Discovered?
- How was Event Discovered?
- What do the different Admission through choices mean?
- How do I determine Race and Ethnicity?
- What information is required for immediate clinical actions taken for the patient?
- What information is required for immediate corrective actions to prevent future similar events?
Responses to Questions

What to Report?

According to the Patient Safety Act (N.J.P.L. 2004, c.9) every health care facility licensed by the New Jersey Department of Health and Senior Services (Department) must report every serious preventable adverse event. The Act defines a serious preventable adverse event as an adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven (7) days or is still present at discharge. Some events do not need to meet a threshold of injury due to the potential serious nature of the event.

What is a preventable event?

A preventable event means an event that could have been anticipated and prepared against, but occurs because of an error or other system failure.

The event did not cause actual harm to the patient. Do I still need to report?

The following adverse events must be reported even if there is no harm to the patient:

- Intravascular air embolism
- Surgery/procedure/anesthesia performed on the wrong body part
- Surgery/procedure/anesthesia performed on the wrong patient
- Surgery/procedure/anesthesia performed on a patient
- Catheter placement in the wrong vessel
- Retention of a foreign object
- Discharge of an infant to the wrong person
- Attempted suicide

Does this event need a report?

- If the 5 day reporting deadline is approaching and you are uncertain whether an event meets the 7 day criteria for loss of bodily function or you are not sure if the disability will resolve before 7 days, report the event.
- If the issue resolves within 7 days, submit a revised report.

Click HERE to return to questions
What if our facility thinks the event is not-preventable?

In this situation, it is best to submit the initial event with justification of it not being preventable to the Patient Safety Reporting System and the Patient Safety staff will make the determination if it is not-preventable.

What if the event is rare and unusual?

A rare and unusual event is one that is so uncommon that complicated changes in policies and procedures may cause more problems for the health care system compared to the benefits. The event should be discussed with one of the clinical staff in the Patient Safety Reporting System and an RCA may be required.

What types of events should be reported as Less Serious Events or Near Misses?

In general, less serious events are adverse events which result in less serious injuries and can include:

- Minor lacerations and bruises.
- Less serious fractures such as:
  - single fractures of fingers, toes or ribs, that do not extend the patient’s length of stay, do not significantly impact function and do not require major intervention.
  - single compression fracture that requires only pain management for therapy, does not extend the length of stay, does not significantly impact function, and does not require major intervention.
- Near Misses

are occurrences that could have resulted in an adverse event but was prevented such as, medication errors which are identified before the wrong medication is given to the patient.

If the facility is uncertain regarding the need to report, contact the Patient Safety Reporting System.

How do I report events?


Click HERE to return to questions
When should I report?

- Event reports of all serious preventable adverse events are due within five (5) business days after the facility discovers the event.
- The Root Cause Analysis (RCA) is due within forty-five (45) calendar days after the facility sends the initial report of the event.

Where do I report suspected criminal activity?

A health facility should immediately report to the appropriate police authorities all criminal acts or potentially criminal acts that occur within a facility and pose a danger to the life or safety of patients or residents, employees, medical staff or members of the public present in the facility. These acts should also be reported to the Department’s Acute Care Survey Unit at 1-800-792-9770.

Do not report these acts to the Patient Safety Reporting System.

Where should I report interruption of services?

Unexpected physical plant and operational interruptions should be reported within three hours to the Department’s Acute Care Survey Unit at 1-800-792-9770.

Do not report these acts to the Patient Safety Reporting System.

Where do I report communicable and infectious diseases?

Communicable diseases should be reported in accordance with the requirements of N.J.A.C. 8:57-1 et seq.

Report these to the Department’s Communicable Disease Service at 609-826-5964 (regular business hours) or 609-392-2020 (holidays/off hours)

These events may also be reportable to the Patient Safety Reporting System. If the facility is uncertain regarding the need to report, contact the Patient Safety Reporting System.

Click HERE to return to questions
Specific Event Type Questions

What if we discover a retained object left at another facility?

- If a facility discovers a retained object as a result of a surgical or diagnostic procedure that occurred at its own facility, then the facility must report the event within 5 days and perform the RCA.

- If a facility discovers a retained object as a result of a surgical or diagnostic procedure that occurred at another facility, then the discovering facility must report the event within 5 days.
  - If the identity of the original facility is ascertainable:
    - The discovering facility must inform PSRS where the prior surgery occurred.
    - The discovering facility should advise the original facility regarding the retained object if consistent with facility policy.
    - The discovering facility is not responsible to perform an RCA.
    - The original facility (where the object was retained) must perform the RCA.

What types of injury from falls should be reported?

Any serious injury from a fall must be reported. Serious injuries may include but are not limited to the following:

- Intracranial bleed/injury of any severity.
- Fracture of the hip or other joints.
- Fractures of the leg or arm.
- Injuries which require prolonged hospitalization.
- Injuries which require significant physical therapy or rehabilitation.
- Injuries which significantly impact the patient’s ability to function.

If the facility is unsure if the injury meets severity criteria, they should contact the Patient Safety Reporting System for guidance.

Click HERE to return to questions
What types of pressure ulcers should be reported?

Stage III and IV pressure ulcers acquired after the admission of the patient/resident are reportable events.

- This excludes progression from Stage II to Stage III, if Stage II was recognized and documented upon admission.
- Any Stage II pressure ulcer that progresses to a Stage IV ulcer must also be reported.
- Unstageable pressure ulcers are not required to be reported under the current regulations but the Department strongly recommends that facilities voluntarily report these pressure ulcers and perform an RCA, as they represent full thickness tissue injuries.
- Deep tissue injuries (DTIs) are not required to be reported under the current regulations.
- 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.

What should I report under the Care Management Event “Other” category?

Report Care Management events which result in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven (7) days or present at discharge, which are not specifically listed under Care Management events. Other events may include, but are not limited to:

- Delay in care.
- Delay in the availability of test results.
- Failure to order or follow-up on appropriate tests/x-rays.
- Unstageable pressure ulcers

Click HERE to return to questions
What is considered “surgery”?

- Surgery* is an invasive operative procedure in which skin or mucous membranes and connective tissue are resected, including minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar.
- Surgery includes a range of dermatological procedures including biopsy, excision and deep cryotherapy for malignant lesions to extensive multi-organ transplant.
- Surgery begins at point of surgical incision, tissue puncture, or insertion of an instrument into tissues, cavities or organs.
- Surgery ends after the surgical incision has been closed and operative devices, such as probes, have been removed and counts have concluded, regardless of setting (recovery room or surgical suite).

* General Licensure Procedures and Enforcement of licensure Regulations (N.J.A.C. 8:43E-10)

What if the event is considered a complication of surgery or treatment?

If the event is a known complication of a procedure but causes harm to a patient, the event is generally reportable. Please call the Patient Safety Reporting System and discuss the case with one of the clinical staff. They will help determine if the event is reportable and whether or not an RCA is required.

Event Screen Definition Questions

How detailed should the Description of the Event be?

This should be about 2 to 3 sentences and should be brief. The Patient Safety Reporting System needs just enough information to determine if the event meets the statutory definition.

- Examples:
  - An 88 y/o female admitted from a LTC facility fell in her hospital room on 11/4/07 and sustained a hip fracture. She was taken to the OR for an ORIF on 11/5/07.
  - A 65 y/o female developed a Stage IV sacral pressure ulcer during her hospitalization following a lengthy, complicated clinical course.
What is the Event Date?
The date of the actual event.
- For pressure ulcers, including eschar formation, use the date of the first documentation in the chart for a reportable ulcer.
- For medication error, the date of the error is the date of the event.
- For surgery/procedure related events, the date is usually the date of the surgery.

What is the Event Time?
This is the time of the actual event, not the time it was discovered. The time may need to be estimated in the event of pressure ulcers or when a patient who is a poor historian sustains an unobserved injury.

What is Date Event Discovered?
This usually matches the Event Date, as it refers to when the *clinical staff* caring for the patient became aware of the event. This *does not* refer to the time the facility administration, risk management, or the patient safety department in the facility became aware of the event. If the serious injury is discovered hours or days after the event, there are two possibilities:
- If the serious injury is discovered by a physical assessment or diagnostic test that was completed *within six (6) hours* after the event, use the Event Date and Time.
- If the discovery of the serious injury occurred *more than six (6) hours* after the event, use the actual date and time of discovery even though it will differ from the Event Date and Time. Record the actual date and time when the serious injury was discovered/confirmed.
  - This can include multiple ways of discovery including but not limited to:
    - evaluation of the patient
    - report by staff
    - chart review or audit

What is the Time Discovered?
Usually matches the Event Time, but may differ when there is a delay in identifying the patient’s injury or with certain event types such as, retained foreign objects.

[Click HERE to return to questions]
How Was Event Discovered?

- Report by staff/physician – Any event which was initially discovered by any staff or physician. This event may have been discovered because of a loud noise or a patient calling out or the staff actually witnessed the event.
- Report by family/visitor – Any event which was initially reported by a family member or visitor.
- Report by patient/resident – Any event which was initially reported by the patient/resident or another patient.
- Assessment of patient/resident after event – Any event which is discovered by a physical assessment or a diagnostic test (i.e., x-ray) which occurs some period of time following the event (i.e., does not occur immediately following the event). There is usually an associated delay in the date and time of discovery.
- Review of chart/record – Any event which was initially discovered by a chart audit, review of hospital Code Blue (emergency resuscitations) documentation, or other quality review. There is usually an associated delay in the date and time of discovery.
  - Do not choose this item if staff at the facility previously identified and responded to the adverse event but failed to report the event to the Patient Safety Liaison in a timely manner.
- Other – rarely used

What do the different Admission through choices mean?

This item only refers to inpatients. If the patient is an outpatient, leave this item blank.

- Emergency Department - The patient was examined and may have been treated in the Emergency Department. This category is not used when patients are transferred from another hospital or are admitted directly from a Long Term Care facility.
- Direct Admission - The patient was not examined in the ED but was admitted directly into the hospital.
- Transfer from General Acute Care Hospital - The patient was sent to the current facility directly from a general acute care hospital as a direct admission or an admission through the ED. In either situation, only the “Transfer from General Acute Care Hospital” item is selected.
- Transfer from LTC (Long Term Care) - The patient was sent to the current facility from a Long Term Care facility as a direct admission or an admission through the ED. In either situation, only the “Transfer from LTC” item is selected.
How do I determine Race and Ethnicity?

Race - There are 6 categories listed which are based on the US Census Bureau 2000 specifications plus an ‘Unable to Determine’ category. The descriptions are located in next to the Race field. “Other” is rarely used.

The race designation can often be found on the hospital admission form.

Ethnicity - There are 2 categories listed which are based on the US Census Bureau 2000 specifications. The descriptions are located in next to the Ethnicity field.

What information is required for immediate clinical actions taken for the patient?
Provide the immediate clinical actions taken that involve the care of the patient.

What information is required for immediate corrective actions to prevent future similar events?
Provide the immediate corrective actions taken to prevent similar events from occurring. The following are examples, but not limited to:

- 1:1 observation for confused patients at high risk for falls.
- Ensure that toileting rounds are performed every 30 minutes for at least 3 hours after patients receive diuretics.
- Ensure that beds with weight-based alarm systems are zeroed for each new pt.
- Implement new turning and positioning system to ensure compliance with repositioning every 2 hours.

Click HERE to return to questions
XII. Additional Guidance for Ambulatory Surgery Centers

Questions

- When should events be reported?
- What events are reportable?
- What events are not reportable?

Responses to Questions

- When should events be reported?

Ambulatory Surgical Centers are mandated to report every serious preventable adverse event that results in patient death, loss of a body part, disability, or loss of bodily function lasting more than seven (7) days or present at discharge. Some events do not need to meet a threshold of injury due to the potential serious nature of the event.

- The facility must report the event within **five (5) business** days after discovery of the event.
- The facility must complete an RCA within **45 calendar days** after the submission of the initial report of the event.

- What events are reportable?

Some of the reportable events are self-explanatory, such as wrong site surgery, wrong surgical procedure, wrong patient, or retained object and should always be reported.

The following guidance should be used when there is uncertainty regarding a potentially reportable event:

In general, **any patient transferred to the Emergency Department and/or hospitalized with a procedure and/or anesthesia related complication which requires treatment other than observation should be reported to the Patient Safety Reporting System.**

Complications may include, but are not limited to:

- Aspiration
- Pneumothorax
- Perforation of an organ
- Cardiac and/or respiratory related problems which require intervention
- Moderate to severe bleeding which requires intervention
Serious infections which require intervention
Prolonged decrease in oxygenation and/or blood pressure which require intervention.

Treatment may include, but is not limited to:

- Fluid resuscitation
- Unscheduled blood transfusion
- Surgery
- IV Antibiotics

What events are not reportable?

The following types of events do not need to be reported to the Patient Safety Reporting System:

- Any patient who is transferred to the Emergency Department and/or hospitalized due to an unstable medical problem prior to the scheduled procedure and/or administration of anesthesia.
- Any patient who develops an expected or common complication of surgery, with the following qualifiers:
  - The complication should be identified on the consent form.
  - The patient does not require hospitalization and treatment of the complication.
  - Common complications that are not reportable may include:
    - Post-operative urinary retention.
    - The need for more intense post-operative pain control.
    - Post-operative bleeding following tonsillectomies that do not require transfusion or intervention.

If there is any question whether an event should be reported, the Department recommends that the Center err on the side of reporting in order to comply with the Patient Safety Act. The facility can always call the Patient Safety Reporting System to discuss the event.