Patient Safety Reporting System

State of New Jersey
Department of Health
March 2023

Facility User Guide

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I. Introduction

The Patient Safety Reporting System 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: https://nj.gov/health/healthcarequality/health-care-professionals/patient-safety-reporting-system/. 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 (PSRS).

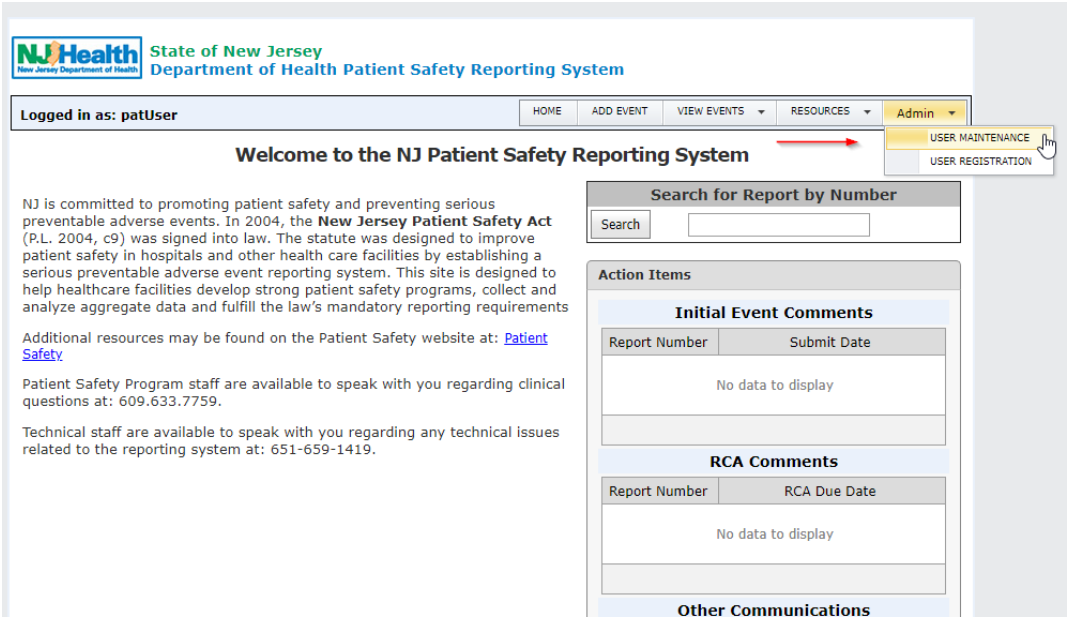
II. Managing Users – Used by Facility Administrative User (FacAdmins) only.

A. Role Information

- Each facility will have at least two designated Facility Administrative Users (FacAdmins).
- FacAdmin users will be created by DOH/PSRS.
- The FacAdmins will be responsible for assigning users and user roles for their organization.
- FacAdmins are responsible for keeping user information (phone, email, etc) up to date.
- Notifications **will always** be made to the FacAdmins even for event reports or comments submitted by other users within their facility; however, those facility users designated as readers or writers only will **not** receive any email notifications from the online system.

B. Creating Users

1. To create a user, goto the home page of the Patient Safety Reporting System and click on "Admin->User Maintenance"

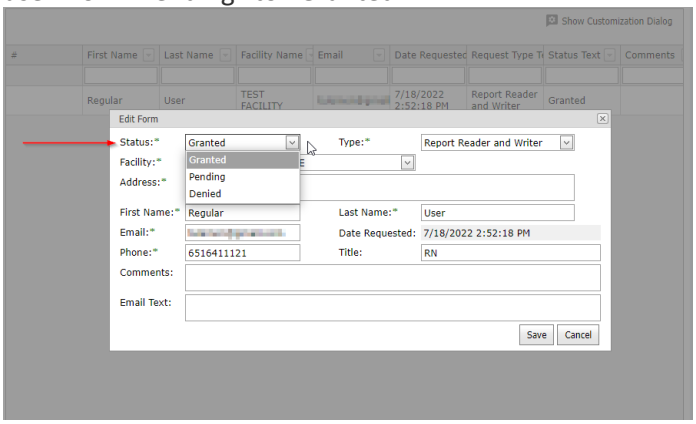


2. Click on “Create New User” and enter the email address for the user.

3. The new user will receive an email from the system with a link for registration. They must consent to the User Confidentiality Agreement and fill out the form and submit.

4. After the user has submitted the Confidentiality User Agreement, they will show on the User Registrations grid under “Admin->User Registration”.

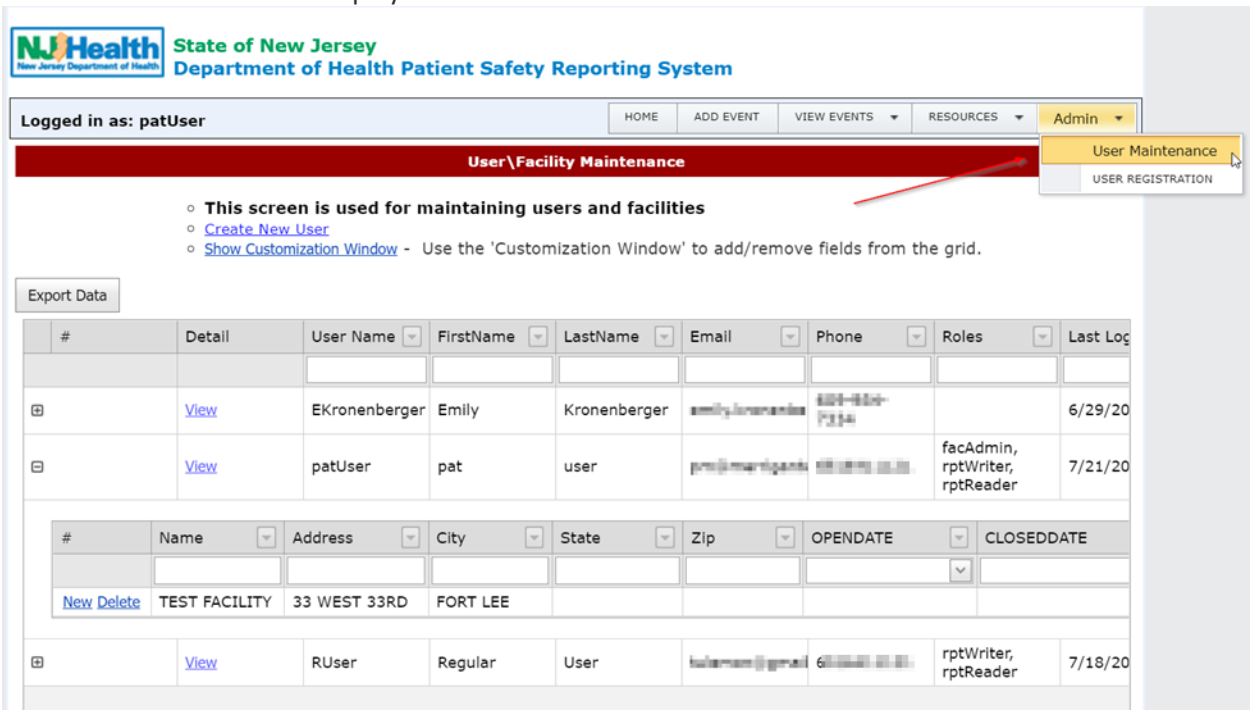
5. At this point the facility admin user can click on “Edit” and modify the status of the new user from “Pending” to “Granted”



6. Once the Facility Administrator approves the request, another email will be sent to the user with instructions on how to complete the registration process.

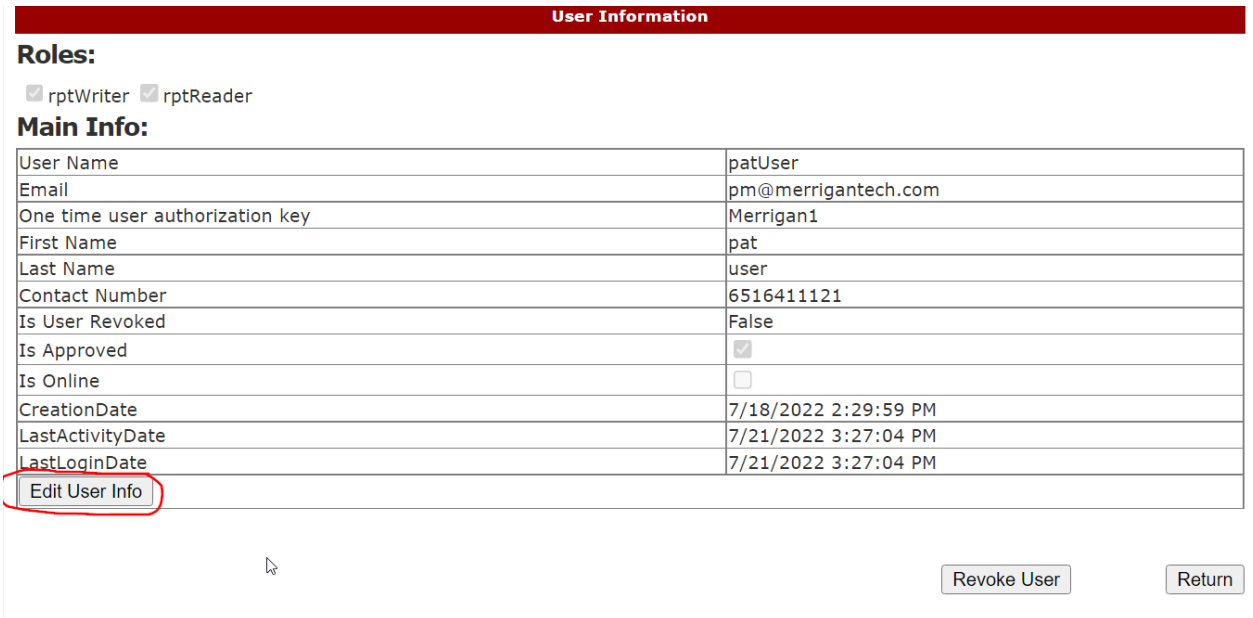
C. To View Existing Users

1. Click on “Admin->User Maintenance” .
2. Click on the plus [+] symbol to show the facilities assigned to the user.
3. Click on the “View” link to display the user information.



D. To Edit User Information

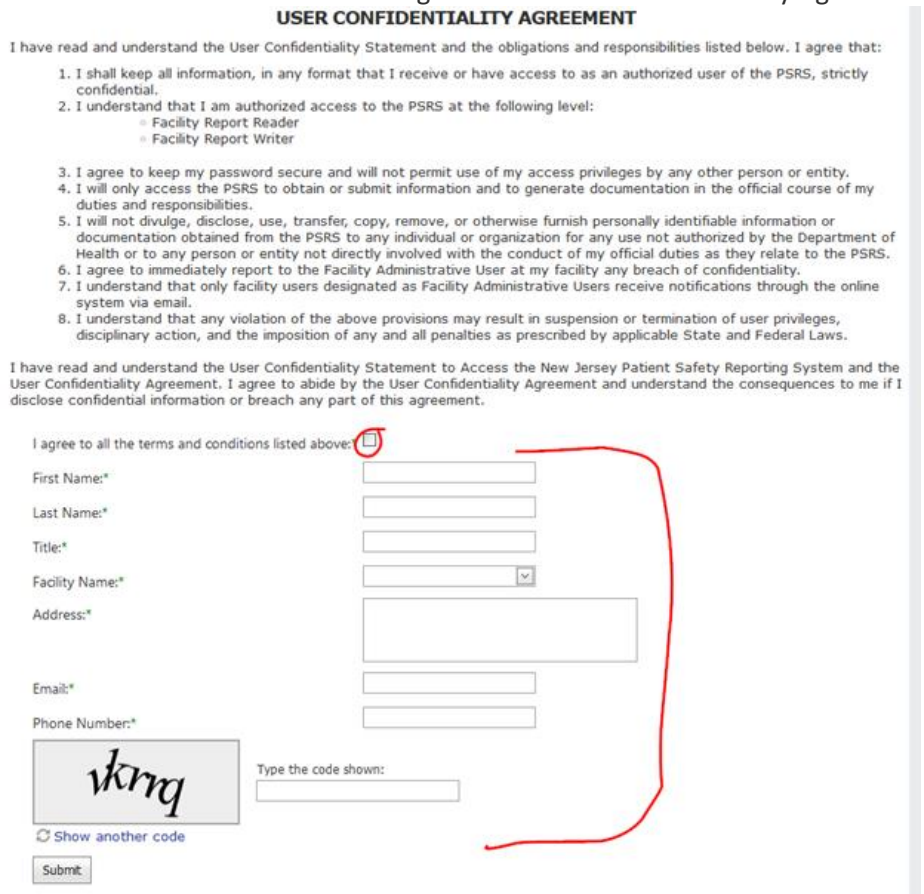
1. Click on “Edit User Info”
2. Edit the information, then click “Update”.
3. **Revoke User:** Revoking a user removes their access to the Patient Safety Reporting System. Use this option when a user leaves the facility.



III. Register as a new user

A. Contact the facility administrator

1. To register as a new user, you will need to know who the facility administrator is for your location.
2. After you contact the facility administrator, they will generate an email to you within the Patient Safety Reporting System. The email will have a link to continue the registration process.
3. You will need fill out all fields and agree to the User Confidentiality Agreement



USER CONFIDENTIALITY AGREEMENT

I have read and understand the User Confidentiality Statement and the obligations and responsibilities listed below. I agree that:

1. I shall keep all information, in any format that I receive or have access to as an authorized user of the PSRS, strictly confidential.
2. I understand that I am authorized access to the PSRS at the following level:
   - Facility Report Reader
   - Facility Report Writer
3. I agree to keep my password secure and will not permit use of my access privileges by any other person or entity.
4. I will only access the PSRS to obtain or submit information and to generate documentation in the official course of my duties and responsibilities.
5. I will not divulge, disclose, use, transfer, copy, remove, or otherwise furnish personally identifiable information or documentation obtained from the PSRS to any individual or organization for any use not authorized by the Department of Health or to any person or entity not directly involved with the conduct of my official duties as they relate to the PSRS.
6. I agree to immediately report to the Facility Administrative User at my facility any breach of confidentiality.
7. I understand that only facility users designated as Facility Administrative Users receive notifications through the online system via email.
8. I understand that any violation of the above provisions may result in suspension or termination of user privileges, disciplinary action, and the imposition of any and all penalties as prescribed by applicable State and Federal Laws.

I have read and understand the User Confidentiality Statement to Access the New Jersey Patient Safety Reporting System and the User Confidentiality Agreement. I agree to abide by the User Confidentiality Agreement and understand the consequences to me if I disclose confidential information or breach any part of this agreement.

I agree to all the terms and conditions listed above:*

First Name:*

Last Name:*

Title:*

Facility Name:*

Address:*

Email:*

Phone Number:*

vkrrq

Type the code shown:

Show another code

Submit

When you submit the form, the facility administrator will be notified that you have requested access, they will then approve you inside the PSRS.

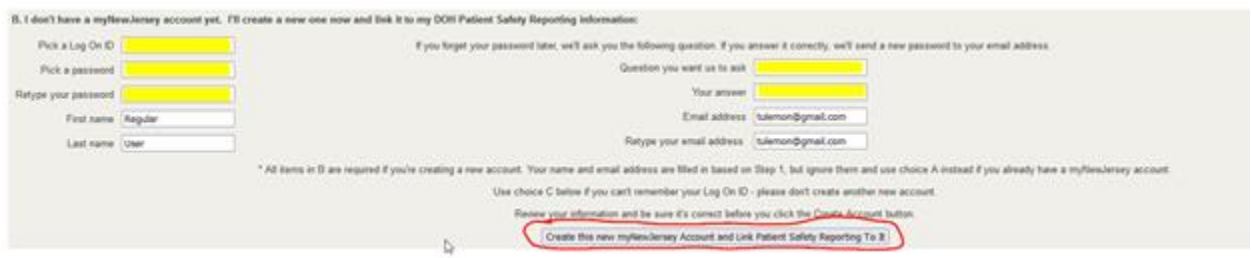
Once approved, the system will generate another email with further instructions on how to continue the registration process.

4. After the user clicks on the link in the email, the registration page will load. Some of the info will be pre-populated from step one. The email will contain the User ID and the **One time** user authorization key. It is recommended to copy and paste the **One time** key as it is case sensitive.

5. After you submit the Registration Information page, you will be brought to another screen to complete the process by either **creating** a myNewJersey account or **linking to an existing** myNewJersey account. If you do not have a myNewJersey account, please skip to step 7.

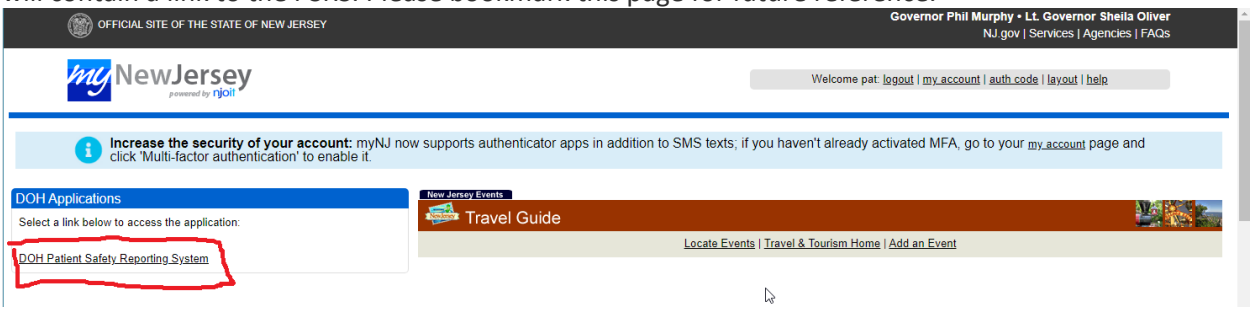
6. If you have a myNewJersey account, enter the Log On ID and password, then click the button to "Link Patient Safety Reporting to My Account".

7. If you do not have a myNewJersey account, please fill out the following fields:
   - Log On ID – this can be whatever you want, but it must be unique to the network.
   - Password – this must be at least 8 characters and contain both lower and upper case. This is the password you will use to logon to the myNewJersey system to access the Patient Safety Reporting System (PSRS).
   - Question you want us to ask – this will be the challenge question you will need to answer to recover your password.
   - Your answer – the answer to your challenge question.
   - Finally, click on the button "Create this new myNewJersey Account and Link Patient Safety Reporting to it".



8. If the registration was successful, you will be brought to a Welcome screen with a link to access your myNewJersey portal page.

9. On the myNewJersey portal page, you should see a section titled "DOH Applications" that will contain a link to the PSRS. Please bookmark this page for future reference.



IV. Log in as an existing user

B. Established Users logging in through the My New Jersey Network

10. Open a browser (internet) window
11. Enter the URL for the My New Jersey Network (https://my.state.nj.us/aui/Login)
12. Enter your Login ID and Password.
13. Click on the "DOH Patient Safety Reporting System" link located on your MyNewJersey Portal page.

- **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. Even if actively using the system, it will time out at 2 hours.**

V. 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 (Department) must report every serious preventable adverse event. Preventability may not be discernible at the time of the event and a root cause analysis may be needed to confirm or refute the presumed relationship.

DOH/PSRS should be making the determination regarding whether an adverse event is preventable and/or whether an RCA will be required to determine preventability. If a serious adverse event occurs in a NJ licensed health care facility that is currently reporting to DOH/PSRS, the event should be entered into the online reporting system and submitted to DOH/PSRS for review.

N.J.A.C. 8:43E-10.6(e) et seq. indicates that events should be reported in the appropriate category (Care Management, Environmental, Product/Medical Device-related, Surgery-related, or Patient Protection-related) to DOH/PSRS if it is ***reasonable to assume initially that the event is "associated with" the course of care.***

If there is not a specific event type listed in the regulations, the event should be submitted as an "Other" event in the appropriate category listed above. (i.e. Care Management—Other, Surgery—Other, etc.)

For example, if an event occurs to the mother, baby, or fetus that is associated with the course of care, but the mother would not be considered a "Low-risk pregnancy," that event should be reported in the "Care Management—Other" category.

Another example would be an event involving a hospital inpatient who has an event related to surgery and his/her course of care but is not considered an ASA Class I inpatient or a Same Day Surgery patient. That event should be reported in the "Surgery—Other" category.

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.

VI. When to Report

- The initial event information must be reported to the State (DOH/PSRS) through the web-based reporting system 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/PSRS within **forty-five (45) days** from the date when the initial event report was submitted to DOH/PSRS
- 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 associated with the facility becomes aware of the occurrence. This includes staff members on the unit or in any department, physicians, office staff or members of a group practice, etc. who become aware of the event.

VII. 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.

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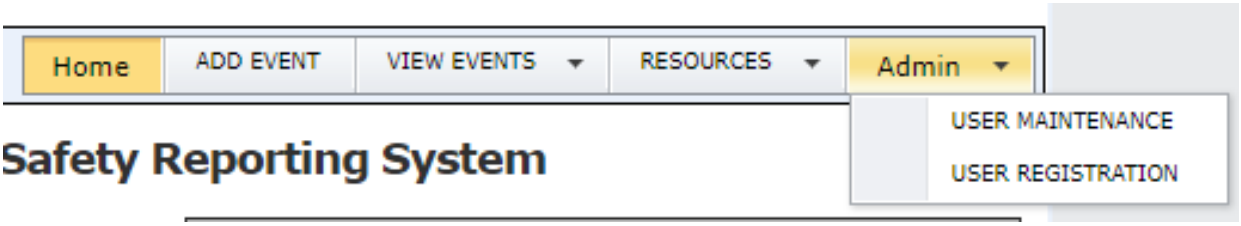
After logging into the system, the home page will appear. Use the menu located on the top right of the screen to select the section of the system to enter. Each of these options will be explained in detail in later sections.

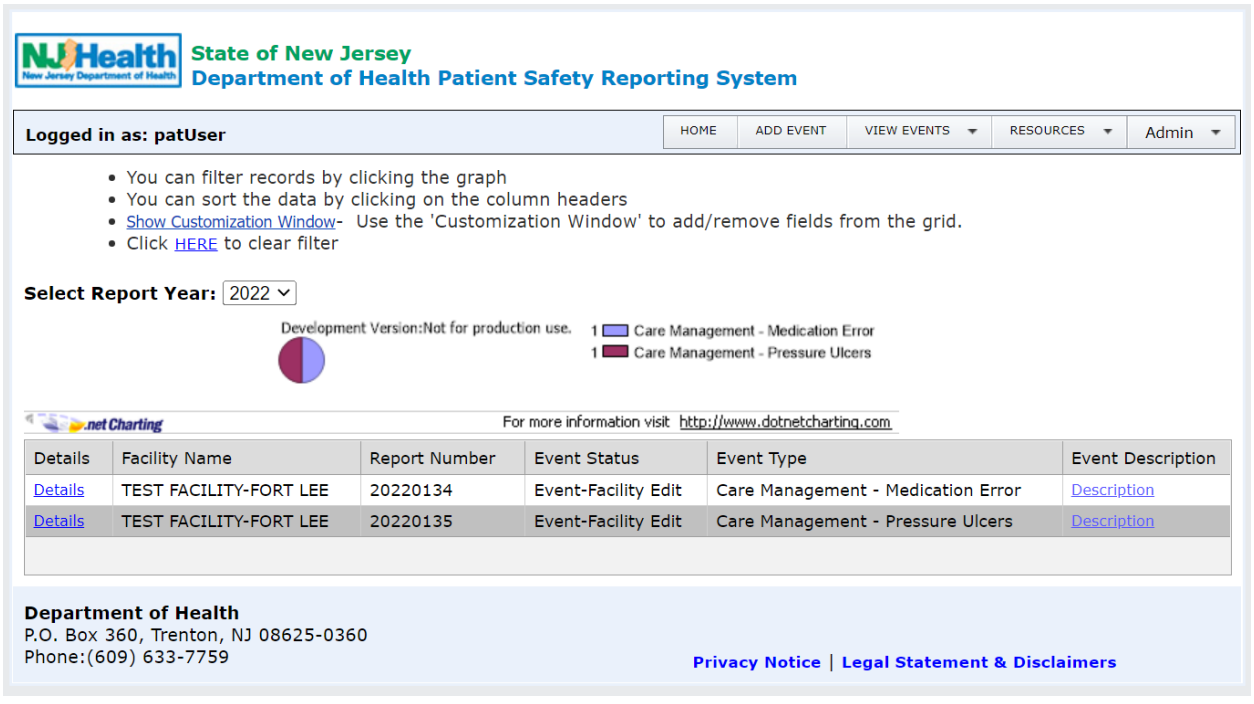


- **Add Event** – enter a new event report.
- **View Events** – there are 3 options under View Events.
  1. All Events – This provides a list of events by year
  2. Status Report – This provides a list of all events for a facility; a list of events by status (e.g. under review by DOH; needs additional information from facility).
  3. Export Data – This provides an option to export your facility data by year
- **Resources** – provides a list of resources consulted for event reports. Also contains information required to be entered for all of the types of events and for events and RCAs with specific questions
- **User Maintenance** – only available to FacAdmins.

- **User Registration –** only available to FacAdmins.

Listing and Selecting Events – "View Events->All Events"

The All Events menu presents the events in the system by year for all the facilities to which the user has access. To select an event, use the "Detail" link under the Details column *(see below)*. You can also click on the Event classification to filter.



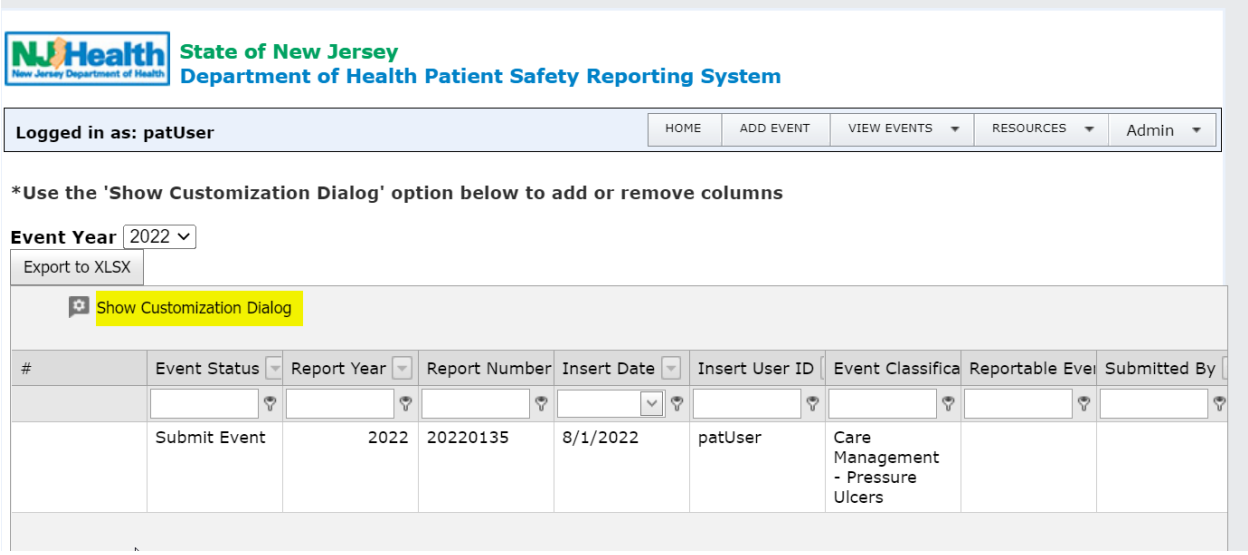
Listing and Selecting Events – "View Events->Status Report"

The Status Report provides the most complete look at all the events for which the logged in user has access. You can sort, filter, search and add or remove columns. Once you have the columns sorted and positioned how you want, click "Save a Report" and give it a name. The next time you come to the Status Report page you can click on "Saved Reports" to load your saved reports. For instance, in the

screen shot below, we have a saved report for 2022 that lists all the Pressure Ulcer events for our facility.

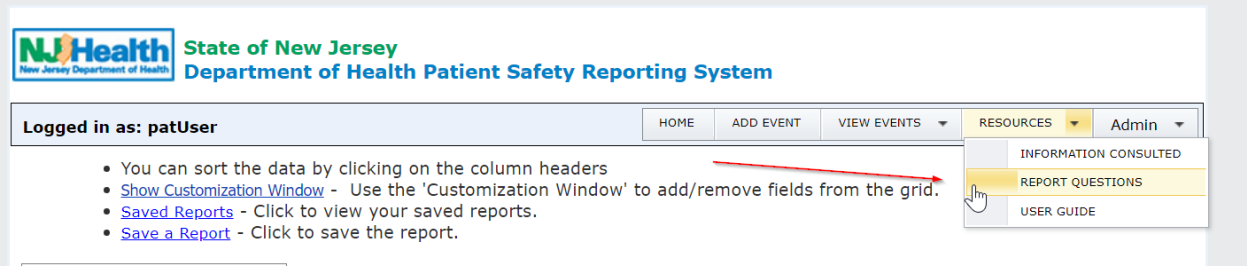
Listing and Selecting Events – "View Events->Export Data"

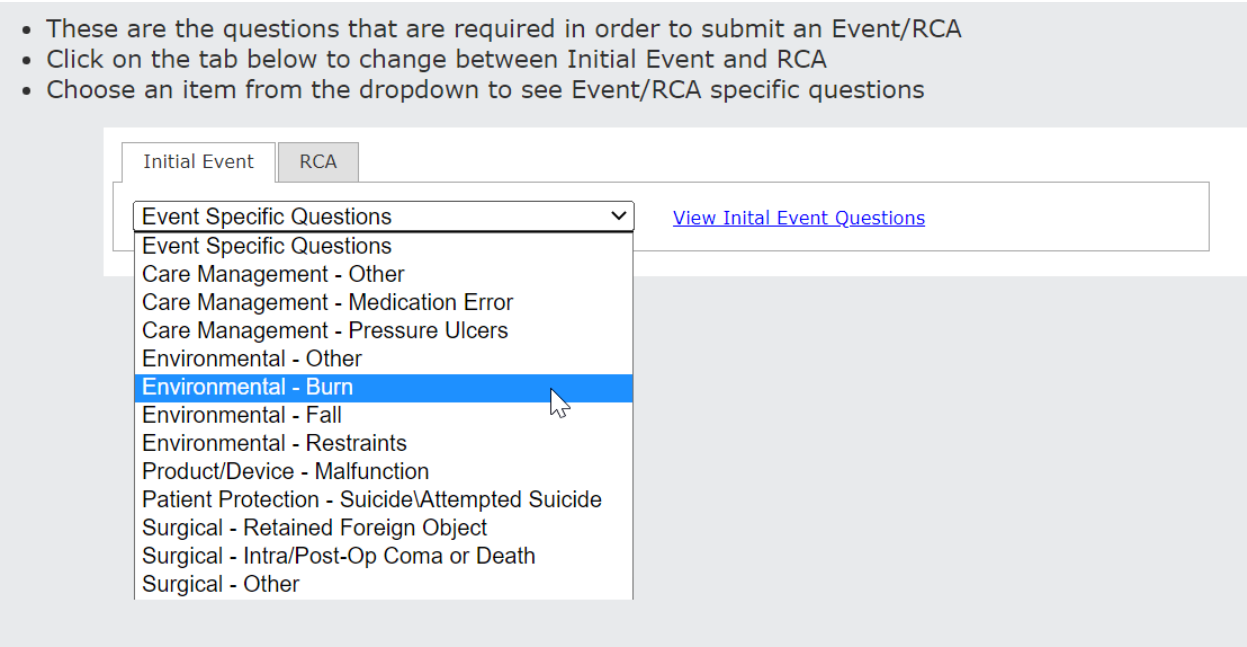
You also have the option to export your events. You can use the "Show Customization Dialog" button to add or remove fields for export.



VIII. 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” and select the event type to view the questions.





- 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/PSRS 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 mitigate the two-hour time window for using the system for a given logon.

IX. 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.
- It is essential to include information in the event report regarding the patient's level of injury, how the injury impacted the patient and how long the injury or impact of the event is expected to last. The "Description of the Event" is a narrative field that will allow you to enter an unlimited amount of information.

To submit events for the facility for which you are registered, go to the "myNewJersey" network located at: http://nj.gov/ and log in. Then click on the Patient Safety Reporting System link located under Applications. This site can also be reached via the DOH/PSRS website where it states, "Report a Serious Preventable Adverse Event."

Each licensed, reporting facility should have a ***minimum*** of two Facility Administrative Users registered for reporting within the DOH/PSRS online reporting system.

Any staff member can file an anonymous report in the DOH/PSRS online reporting system by visiting the DOH/PSRS website and following the links where it states, "Voluntary Anonymous Reporting for Facility Staff" or at this web address: https://www.nj.gov/health/healthcarequality/health-care-professionals/patient-safety-reporting-system/voluntary_anonymous_reporting.shtml

The following guidance is provided to expedite the review of the Initial Event submission:

1. The Initial Event submission should contain details about the impact on the patient:

a. The type of injury/harm to the patient
b. The severity of the injury/harm
c. Duration of injury/harm
d. Pertinent lab and imaging results
e. Impact on the patient's Activities of Daily Living and function

2. If a patient is either transferred, or subsequently presents to a different facility for care following the event, additional information from that facility providing follow-up care may be required. Examples may include transfer from an ambulatory surgery center to a hospital, from one hospital to another or an emergency department or physician's office visit. In these situations, the facility at which the event occurred may need to reach out to the facility that provided follow-up treatment through appropriate channels consistent with the facility's policies to obtain the required information.
The following information from the facility providing follow-up care may be required:

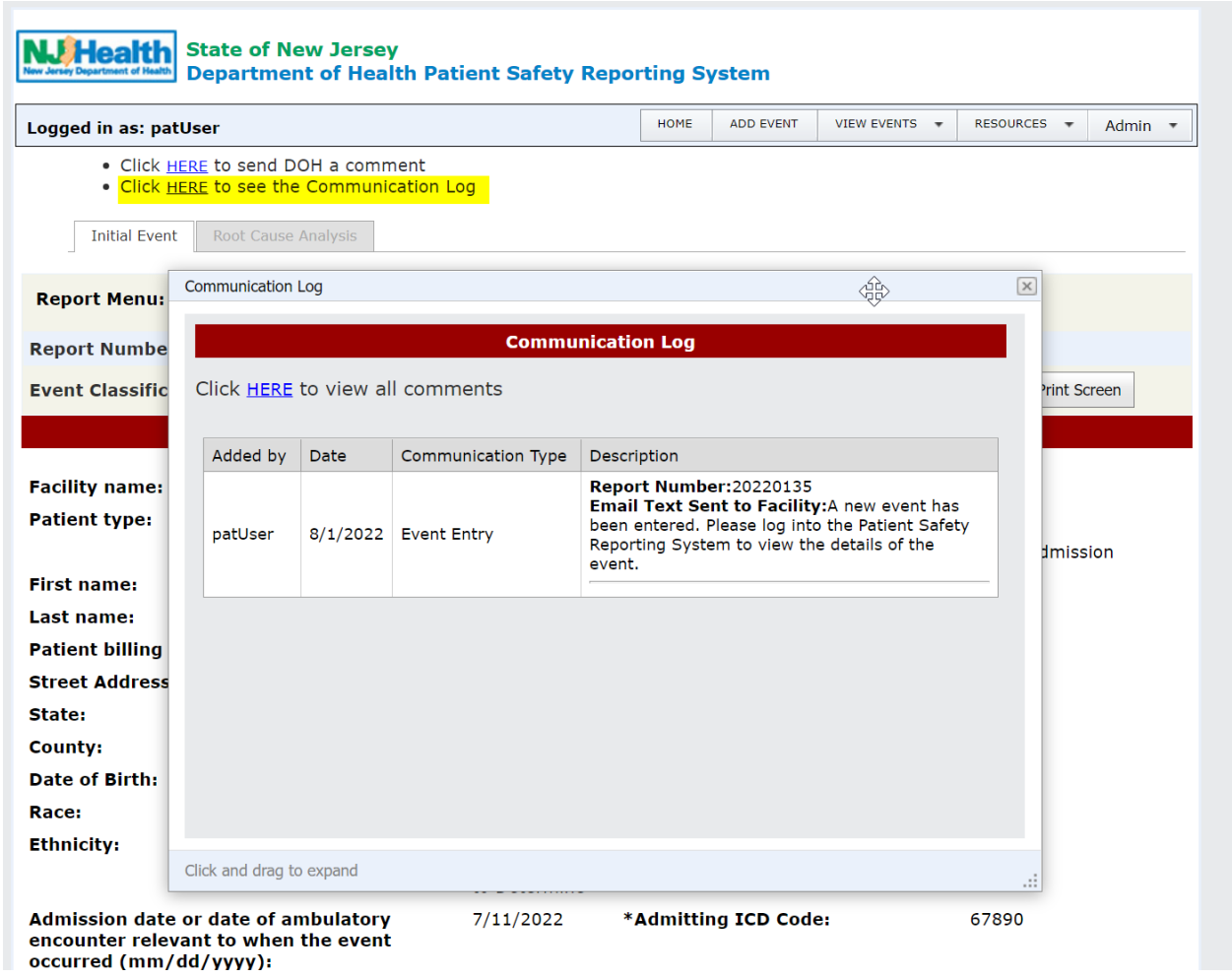
a. Date/time of the transfer/admission and discharge
b. Diagnosis upon presentation and the discharge diagnosis
c. Results of pertinent diagnostic testing
d. Treatments received including any new medications prescribed at discharge
e. Any surgeries, procedural interventions performed during the hospital admission.
f. Discharge disposition – where was this patient discharged to?

3. To expedite the review process, please do not submit an Initial Event report without information about the impact of the event on the patient.

- When the facility has entered the event report, the user must click on the word "Submit" to send the event to DOH for review.
- DOH/PSRS and the FacAdmins receive an automated email notification when the event is successfully submitted and "Event Entry" will appear in the Communication Log. PSRS recommends that the user check the Communication Log to ensure that the event was successfully submitted.

STEP II: **Event Review by DOH**

- DOH/PSRS is notified of event submission via email. DOH reviews the event to determine reportability.
- DOH/PSRS selects reportability decision option generating an automatic email to FacAdmin User(s) describing the reportability decision and next steps.
- If DOH/PSRS requires more information for a decision, the email message indicates that an event determination has been made and the facility should log into the system to view the details and respond accordingly. The comments from the DOH Reviewer can be found by going to the Communication Log and clicking on the word "HERE" where it indicates "Click HERE to view all comments."



- Changes to the event information and responses to the DOH/PSRS comments and questions should be placed within the appropriate fields of the event report, following the DOH reviewer's instructions. (Description of the event field for events is an unlimited field. RCA: Facts of the Event field is an unlimited field for RCA responses.)

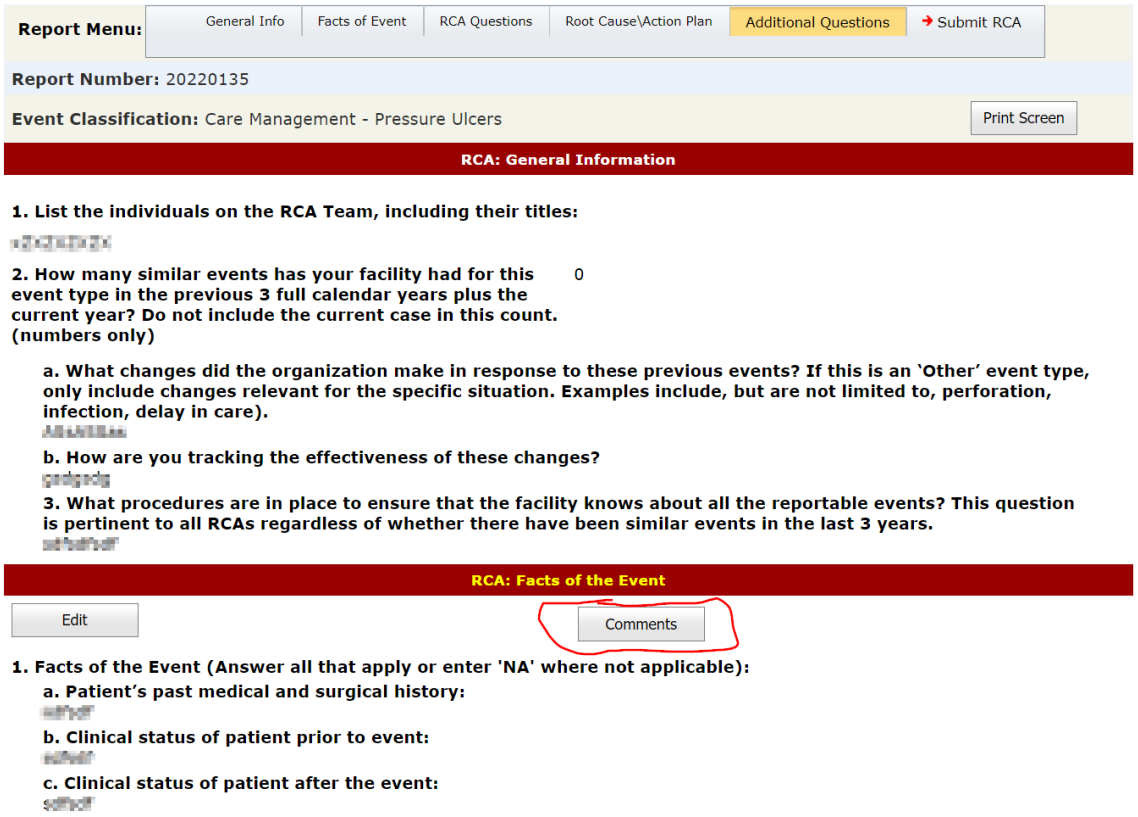
- These responses should not be sent via comment in the Communication Log unless instructed by the DOH/PSRS reviewer to do so. PSRS recommends working in a word processing document so that the reviewer's questions and the facility's responses can be copied and pasted into the event or RCA report.
- Once the facility has entered the additional information and thoroughly answered all the comments/questions from DOH/PSRS:
  - The facility user resubmits event information to DOH/PSRS by clicking on the word "Submit."
  - DOH/PSRS and the FacAdmins will receive an automated email notification when the event is resubmitted and "Event Entry" will appear in the Communication Log. PSRS recommends that the facility user check the Communication Log to ensure that the event was successfully resubmitted.
- If the event is determined to be reportable by DOH/PSRS, the email message indicates the event is reportable and directs the facility to submit an RCA and the system automatically generates a due date for submission of the RCA. The due date is 45 calendar days from event submission to DOH/PSRS
- NOTE: There are usually comments from the DOH Reviewer that require a response when the RCA is submitted. These comments can be found by going to the Communication Log and clicking on the word "HERE" where it indicates "Click HERE to view all comments."
- If the event is determined to be not reportable by DOH/PSRS, the email message indicates reasons for non-reportability, the event is closed, and no further action is required.
- DOH/PSRS may determine that an event would be considered Less Serious or a Near Miss. In that situation, an RCA would not be required, but may be submitted voluntarily by the facility. If the facility wishes to submit an RCA in this situation, the facility user should notify DOH/PSRS via a comment in the Communication Log and DOH/PSRS will enable the RCA submission function.

STEP III: **RCA Submission by Facility Including Causality Statement and Action Plan**

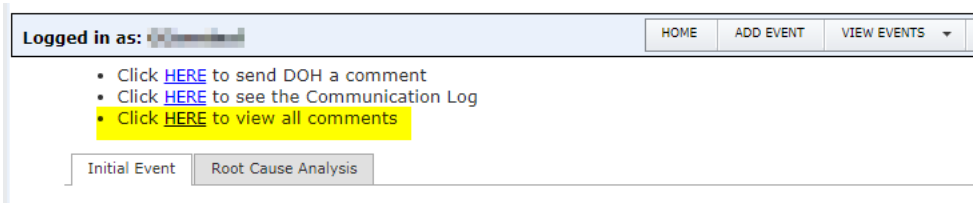
- The facility user submits the RCA information within 45 days of initial event submission.
- DOH/PSRS and the FacAdmins receive an automated email notification when the RCA is submitted.

STEP IV: **RCA Review by DOH**

- DOH/PSRS reviews the RCA to ensure it is a complete, thorough, and credible analysis of the event and meets the regulatory criteria.
- If the RCA is determined to be complete, thorough, and credible and regulatory criteria are met, an automated notification is sent to the FacAdmin User(s) and the RCA is complete. NOTE: Even though the email may indicate that the RCA is closed, DOH may ask the facility to submit additional information via the attachment feature or general comment. Follow the instructions of the DOH Reviewer to determine next steps.
- If the criteria are not met, DOH/PSRS provides comments in sections where additional information or clarification is needed.
- DOH/PSRS sends a notification email to the Facility Admin User(s) stating that action is required by the facility. Comments by the DOH Reviewer can be found by going to the details of the event and scrolling through each section. A "Comment" button will indicate that comments for this section have been added by DOH. For instance in the screen shot below, DOH has entered comments for "RCA: Facts of the Event":



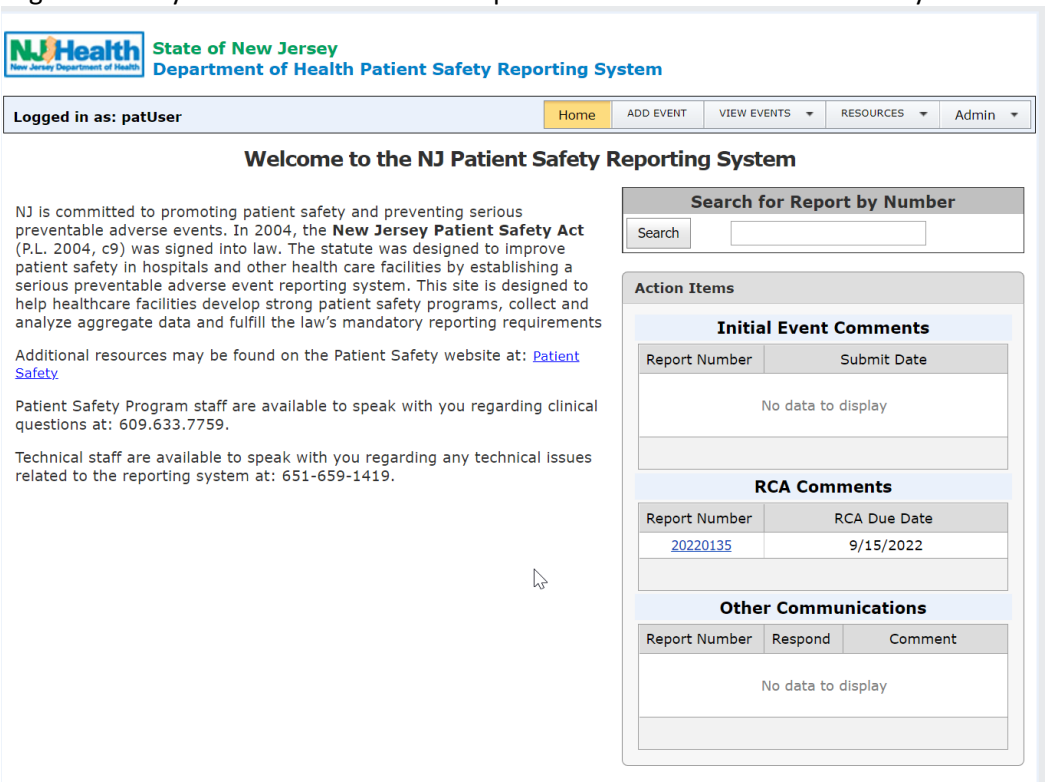
- Additionally, users can also view comments by using the link at the top of the event:



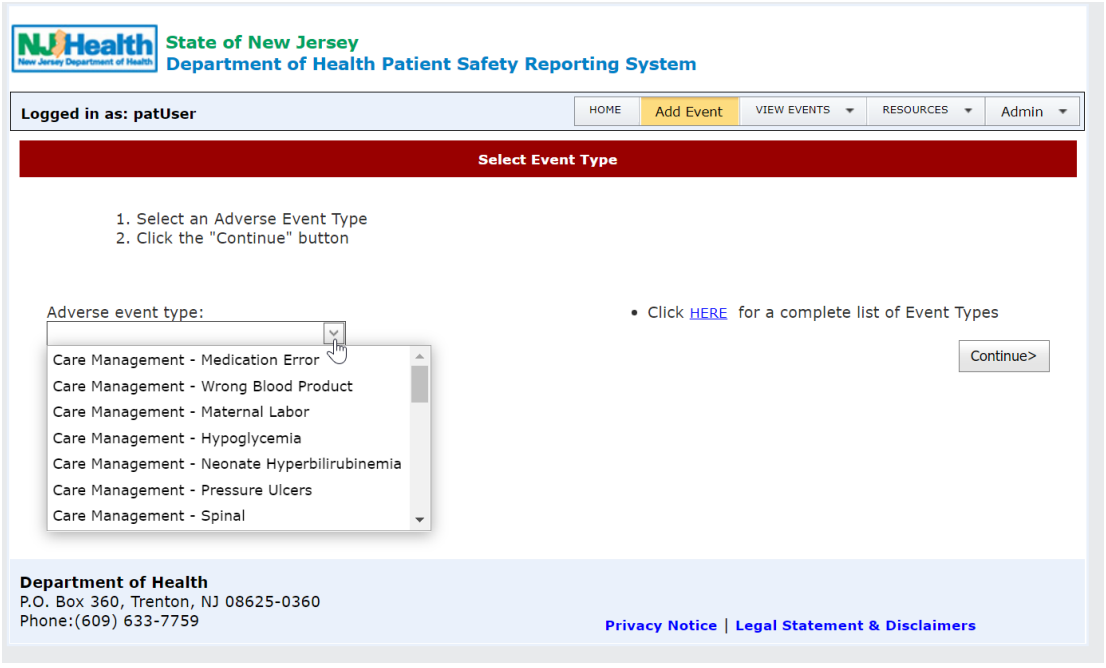
- The facility user resubmits the RCA to DOH/PSRS within the time frame specified.

Step I: Enter Initial Event Information

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



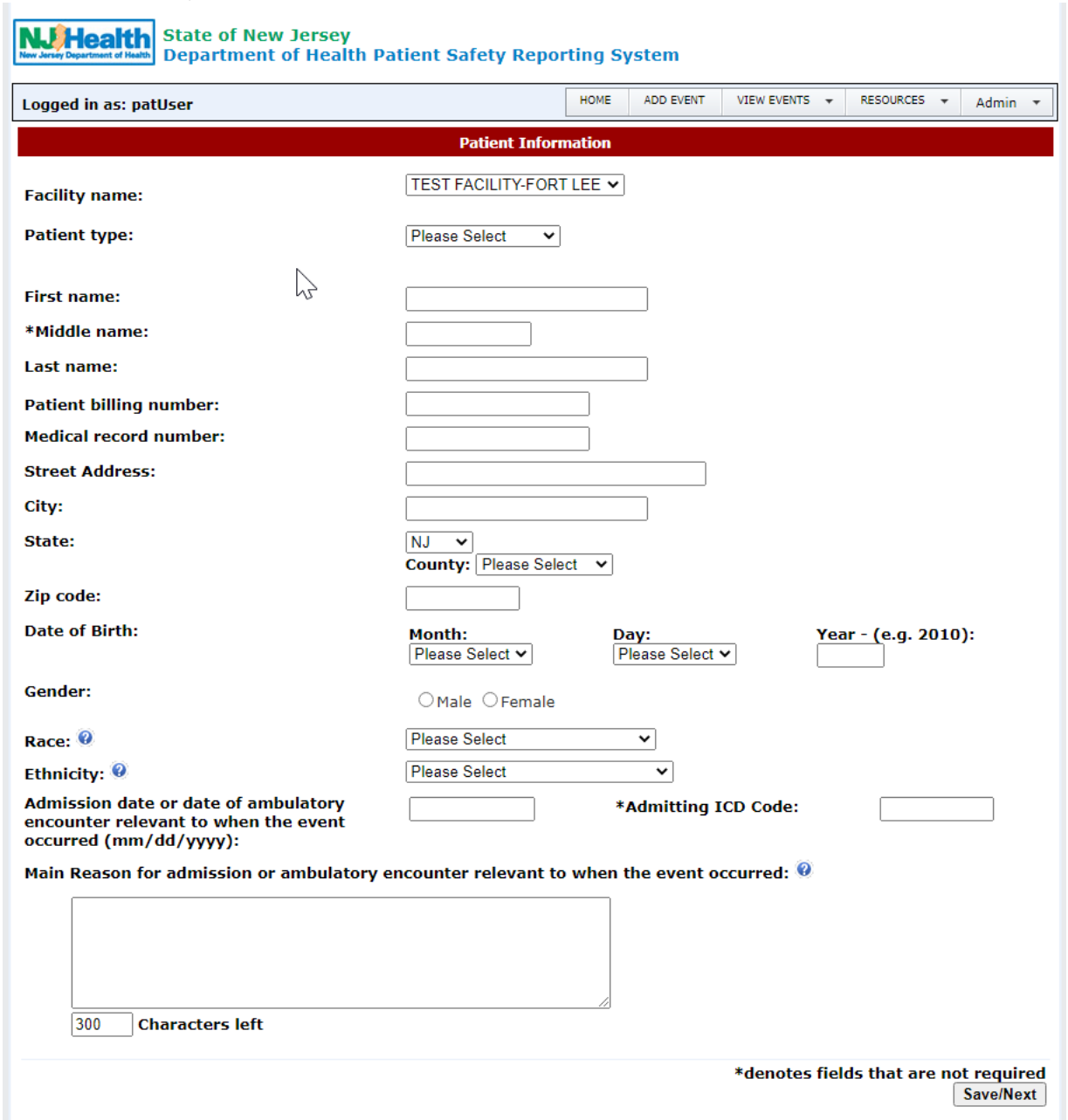
- Select "Add Event" from the menu bar on the top right of the screen *(see graphic below)*. Once the facility selects "Add Event," the reporting system automatically assigns a Report Number to that event. *Please make note of this Report Number and ensure that any further entries related to this Event/RCA are associated with the correct Report Number.* In addition, this Report Number should be used as a reference for any communication with DOH regarding this event.
- The list of Adverse Event Types will be displayed.
- Use the drop-down menu to select the Event Type. **NOTE: The Event Type cannot be changed by the facility 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.



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 Code.
- 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 **and cannot be retrieved**.

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 (**using the same Report Number**) at a later time and update any information that was previously omitted.

Event Information

- Use the scroll bar on the right to view the entire screen.
- All information is required.
- It is essential to include information in the event report regarding the patient's level of injury, how the injury impacted the patient and how long the injury or impact of the event is expected to last. The "Description of the Event" is a narrative field that will allow you to enter an unlimited amount of information.
- The following guidance is provided to expedite the review of the Initial Event submission:

1. The Initial Event submission should contain details about the impact on the patient:

   a. The type of injury/harm to the patient
   b. The severity of the injury/harm
   c. Duration of injury/harm
   d. Pertinent lab and imaging results
   e. Impact on the patient's Activities of Daily Living and function

2. If a patient is either transferred, or subsequently presents to a different facility for care following the event, additional information from that facility providing follow-up care may be required. Examples may include transfer from an ambulatory surgery center to a hospital, from one hospital to another or an emergency department or physician's office visit. In these situations, the facility at which the event occurred may need to reach out to the facility that provided follow-up treatment through appropriate channels consistent with the facility's policies to obtain the required information.

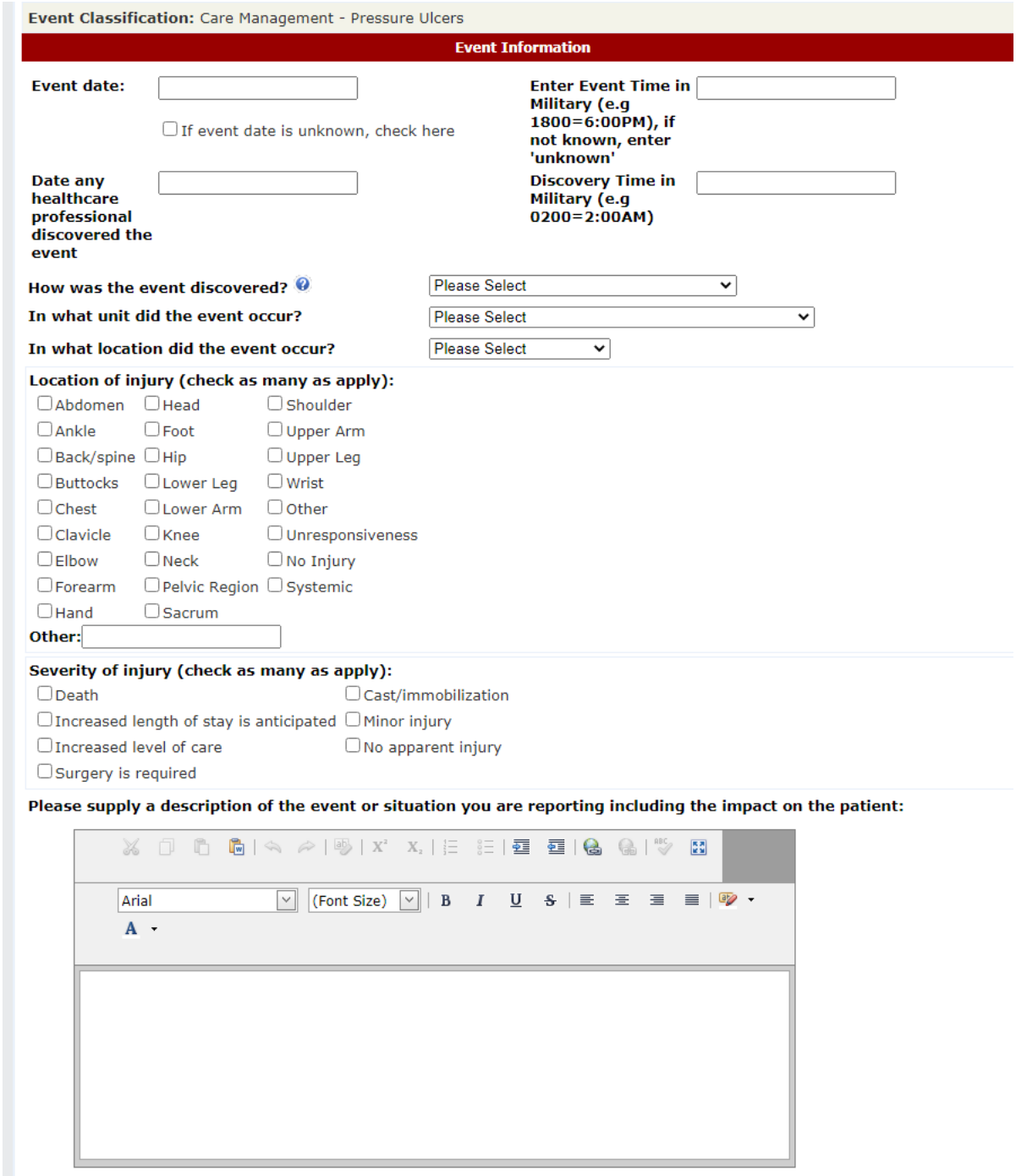
- The following information from the facility providing follow-up care may be required:

   a. Date/time of the transfer/admission and discharge
   b. Diagnosis upon presentation and the discharge diagnosis
   c. Results of pertinent diagnostic testing
   d. Treatments received including any new medications prescribed at discharge
   e. Any surgeries, procedural interventions performed during the hospital admission.
   f. Discharge disposition – where was this patient discharged to?

3. To expedite the review process, please do not submit an Initial Event report without information about the impact of the event on the patient.

- 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. NOTE: If you have been in the myNJ Network for more than the two-hour window, clicking on this button will cause you to lose your work and it will not be saved. DOH/PSRS recommends that the user work in a word processing document for any detailed information such as the description of the event to avoid this situation.



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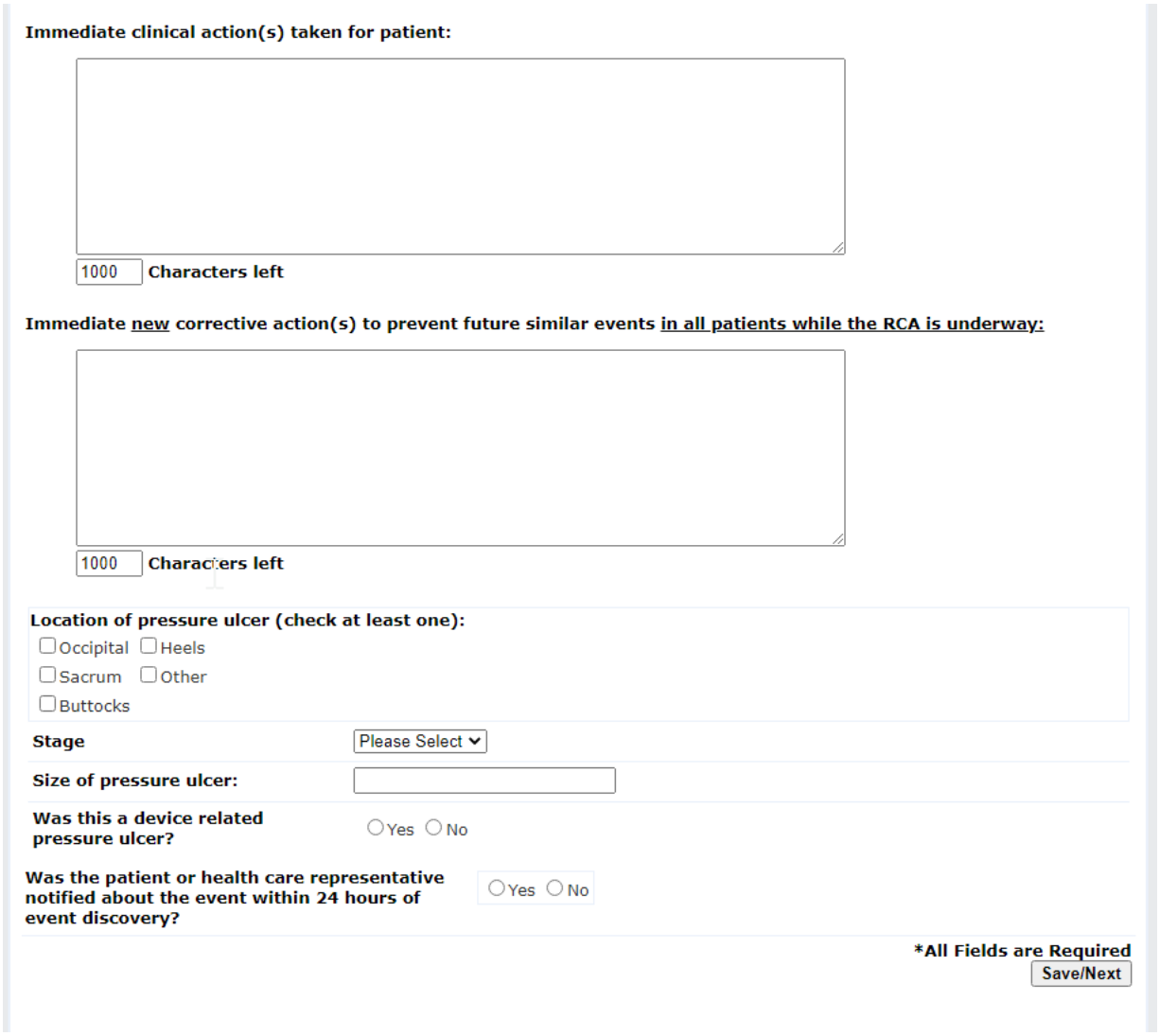


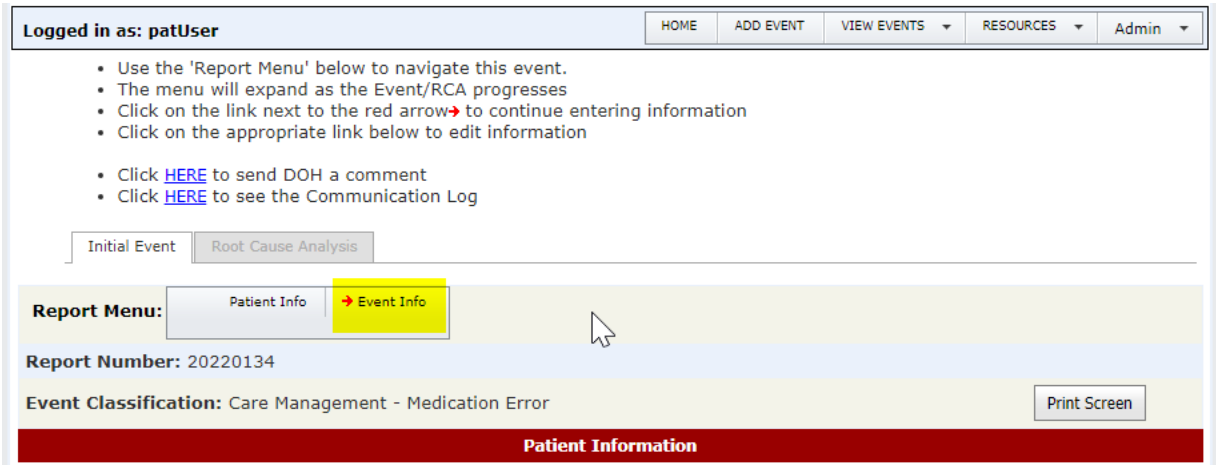
To Save the Event and Not Submit to DOH/PSRS

To save the event and NOT submit the event to DOH/PSRS, make sure you have not been in the myNJ portal for more than two hours, then click on the word "Save." NOTE: If you have been in the myNJ portal for more than two hours, it is suggested that you copy and paste your information into a separate word processing document to avoid losing your work.

Once you have saved your work, 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."

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

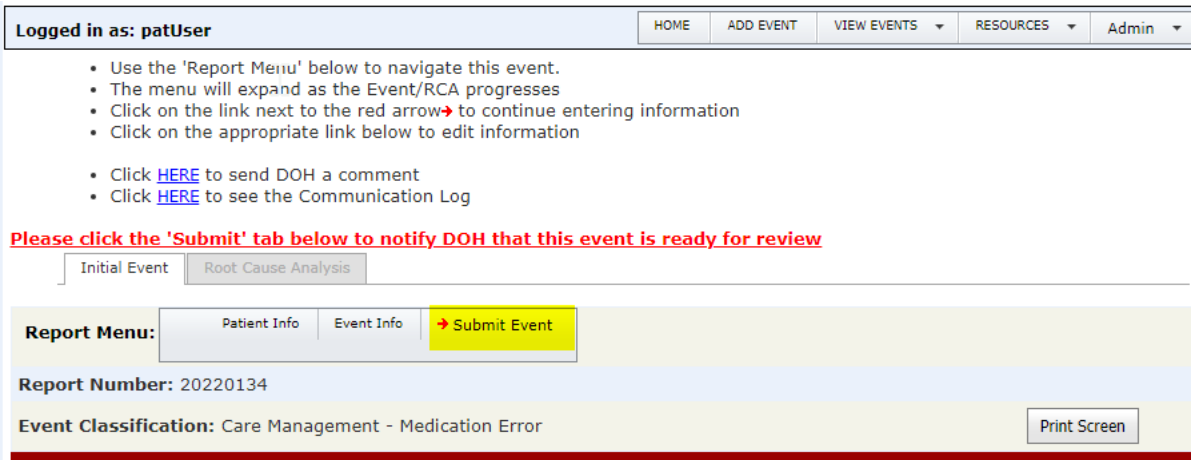
When an event is selected, use the Report Menu to navigate the event. The red arrow in the Report Menu will indicate where the event report is in the process. In this example, Event Info would be the next step in the entry process.



to DOH/PSRS for Review:

To Submit Event

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



Step II: Event Review by DOH/PSRS

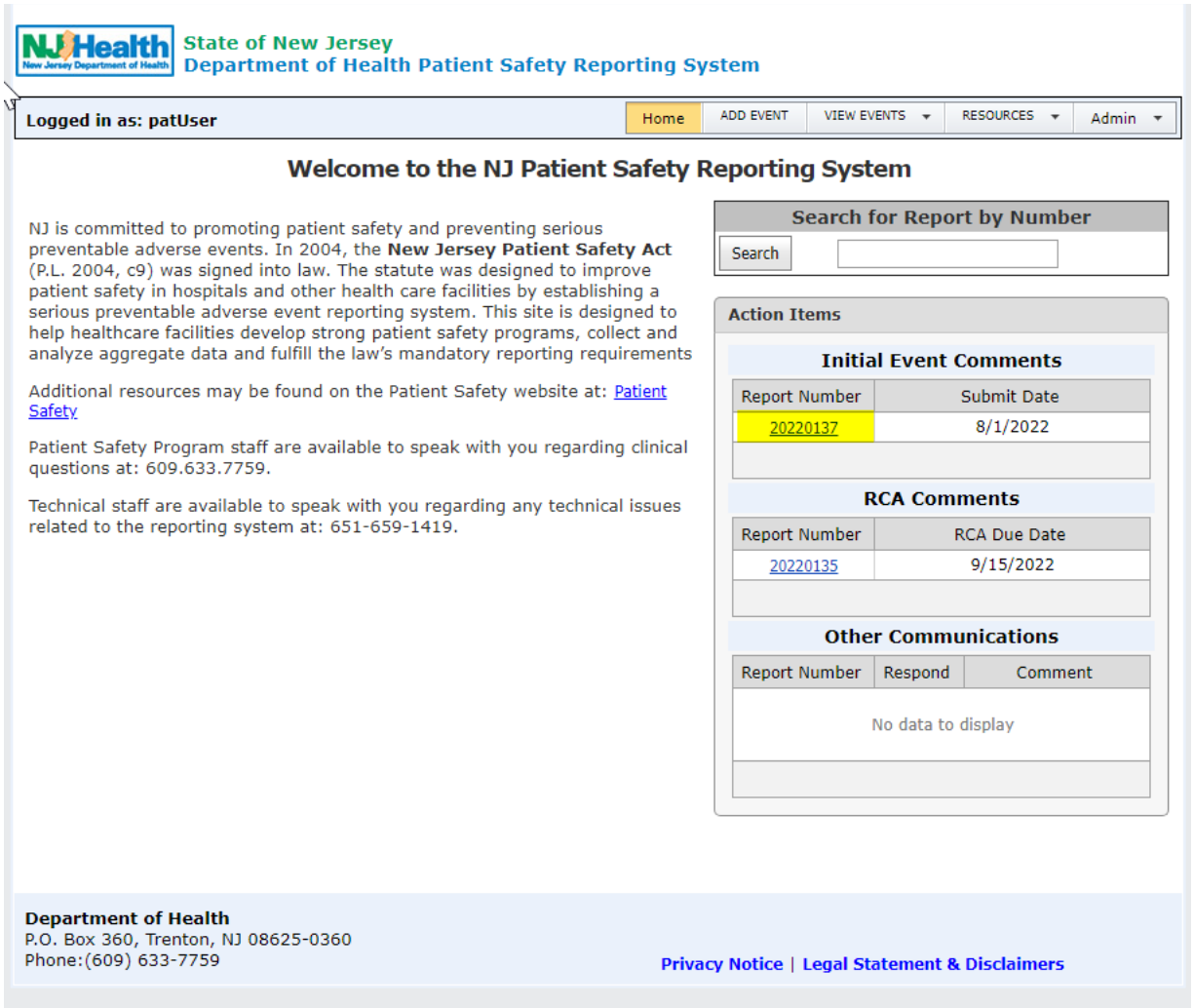
DOH will review the event information and determine the next action of the event report. The FacAdmins will be notified via email that a determination has been made and the facility user will need to log into the online system to view the Communication Log and instructions for next steps. Options for next steps include:

- No further reporting action needed for the State. (Less Serious, Near Miss, Reportable No RCA Required, Not Reportable)
- Additional information is needed.
- RCA required.

1. Additional Information Needed for Review

If additional Information is needed, DOH/PSRS will send an email that an event determination has been made and the facility should log into the system to view the details and respond accordingly. The facility can view the comments made about the event report and update the information before re-submitting the event to DOH/PSRS.

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



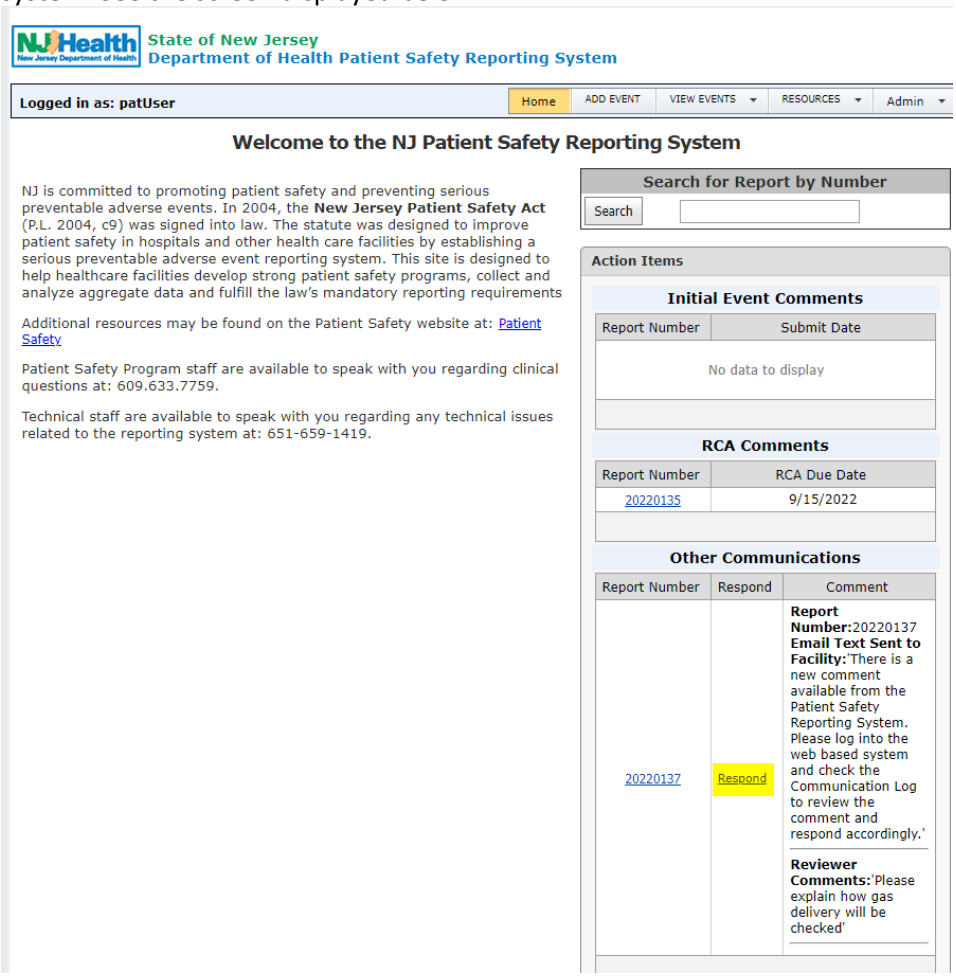
- Under each section there will be an indicator if comments were made for that section. The partial screen below shows how to access comments for the Patient Information section.

- Click on the "Comments" link to view the reviewer's comments.
- The comments from the DOH/PSRS Reviewer can also be found by going to the Communication Log and clicking on the word "HERE" where it indicates "Click HERE to view all comments." Changes to the event information and responses to the DOH comments and questions should be placed within the fields of the event report, following the DOH reviewer's instructions.
- Click the "Edit" link to make changes in order to address the reviewer's comments for that section.
- When completed with addressing comments, save the changes and click on the "Submit Event" option to resend the event to DOH/PSRS as shown below.
- There may be more than one cycle of responding to comments for the initial review process if the reviewer needs additional information to complete the event review.

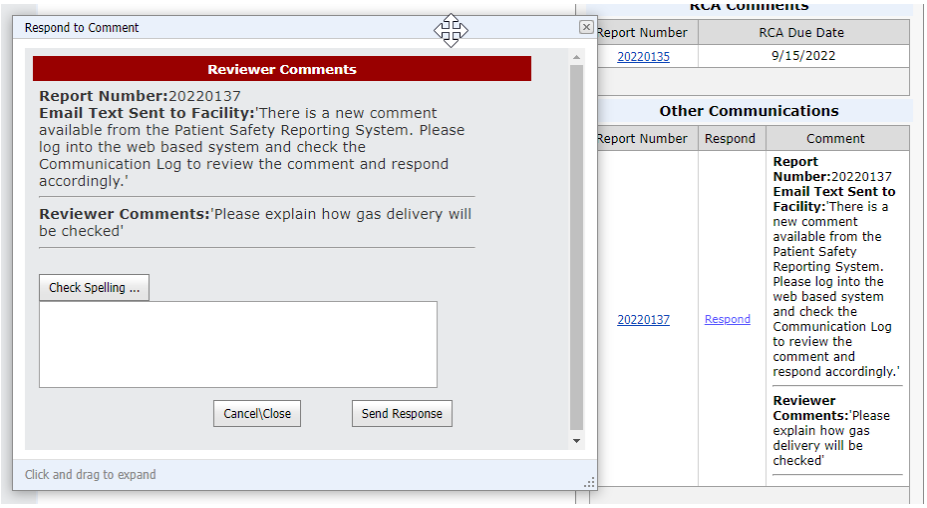
2. Explanation Needed for Event Report Without Returning to Facility for Changes

DOH/PSRS may request an explanation of some of the event report information. The facility will receive an email indicating that further explanation is needed. The event report cannot be updated and the response to the email will be made in the system using the comment process that can be found on the Communication Log page.

Event 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



- Enter a response and click "Send Response" to send to DOH/PSRS

3. Less Serious or Near Miss Event

If the determination is made that an event is less serious or near miss, then an RCA can be submitted for those events if the facility chooses to do so. 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. If the facility wishes to submit an RCA to DOH/PSRS for review, please contact DOH/PSRS 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.

4. Reportable No RCA Required

If the facility has submitted an event that occurred at another facility, such as a Retained Foreign Object (RFO) that happened during a surgery at another facility, the facility reporting the event may not be required to submit an RCA; however, the event is considered "Reportable" according to the regulations. When considering future "Reportable" events in that same category, the reporting facility should not include these in that count.

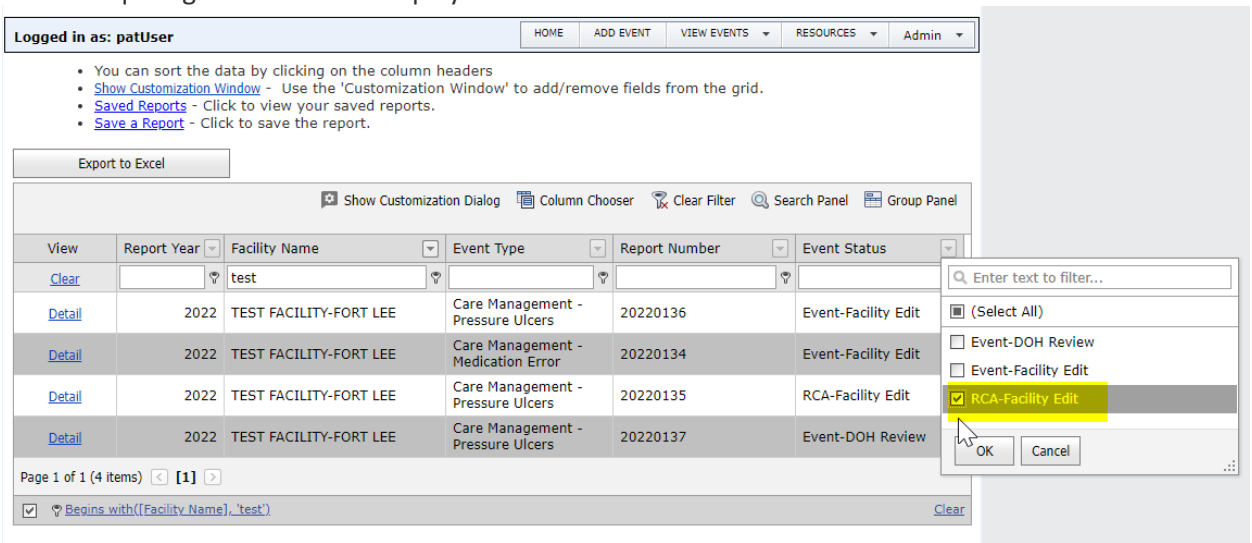
5. Reportable, RCA Required

DOH/PSRS has determined that this event meets the regulatory requirements and will require an RCA. Once DOH/PSRS makes this determination, the event moves into the RCA phase and the facility will no longer have the option to edit any information in the initial event submission fields.

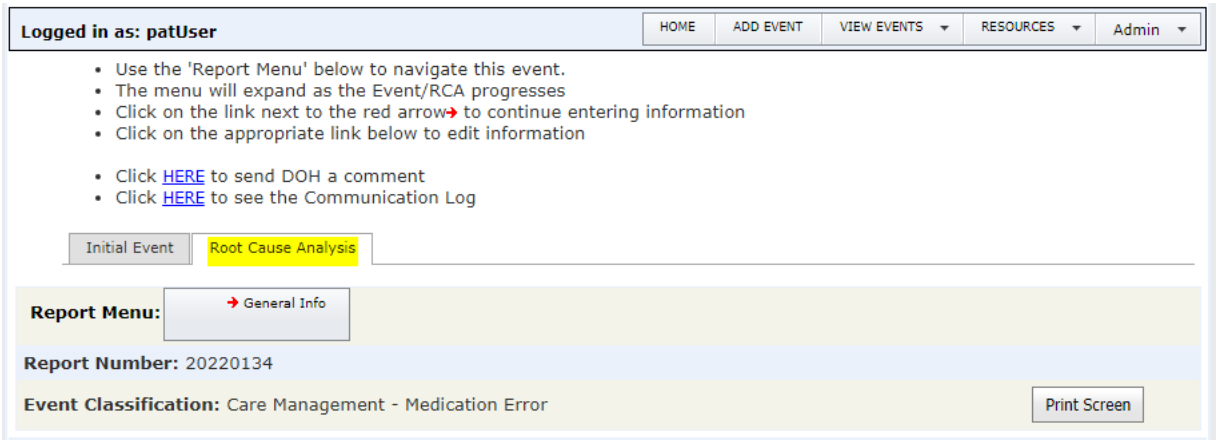
Step III: RCA Submission by Facility including Causality Statement and Action Plan

If the DOH/PSRS 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.
- Then click on Root Cause Analysis
- Screen displayed below is shown:

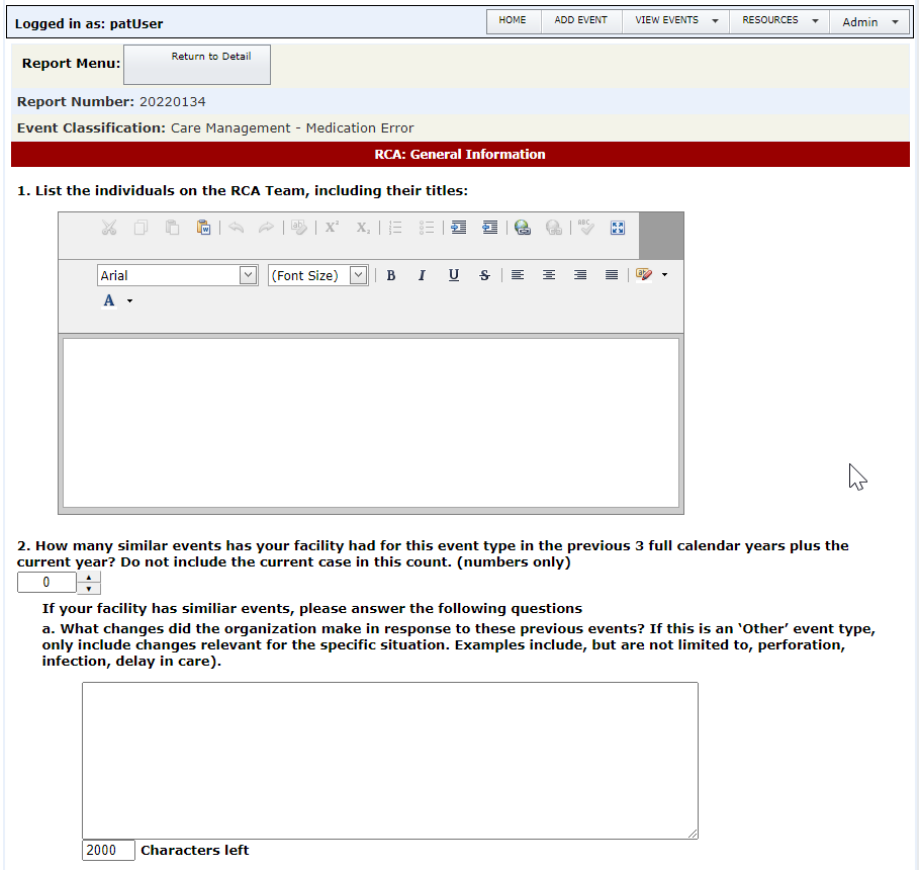


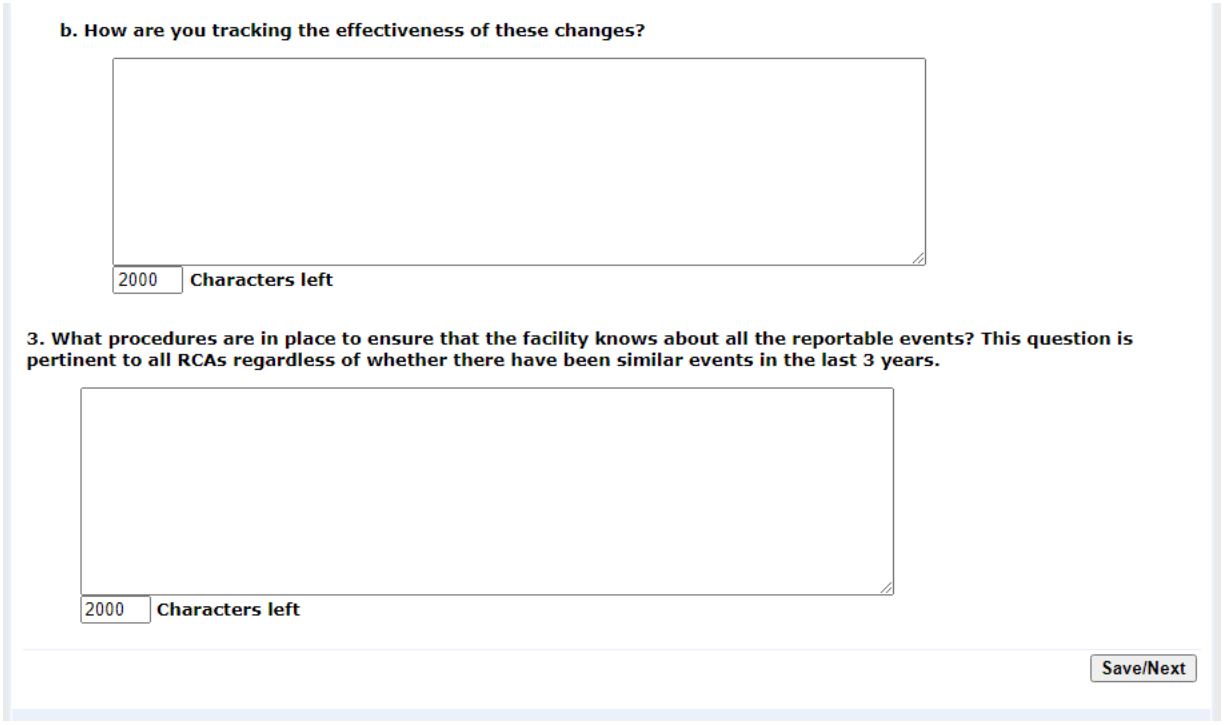
- Click on “General Info” to begin the RCA entry process. This first section of the RCA entry process may also be accessed from the Report Menu.
- The Report Menu can be used to select the specific section of the RCA to be completed later. The Report Menu is shown on the next page below

Report Menu

1. RCA: General Information

- Complete all fields in this section – all fields are required to submit the RCA.
- Click on "Save/Next" to save the completed information and move to the next section.



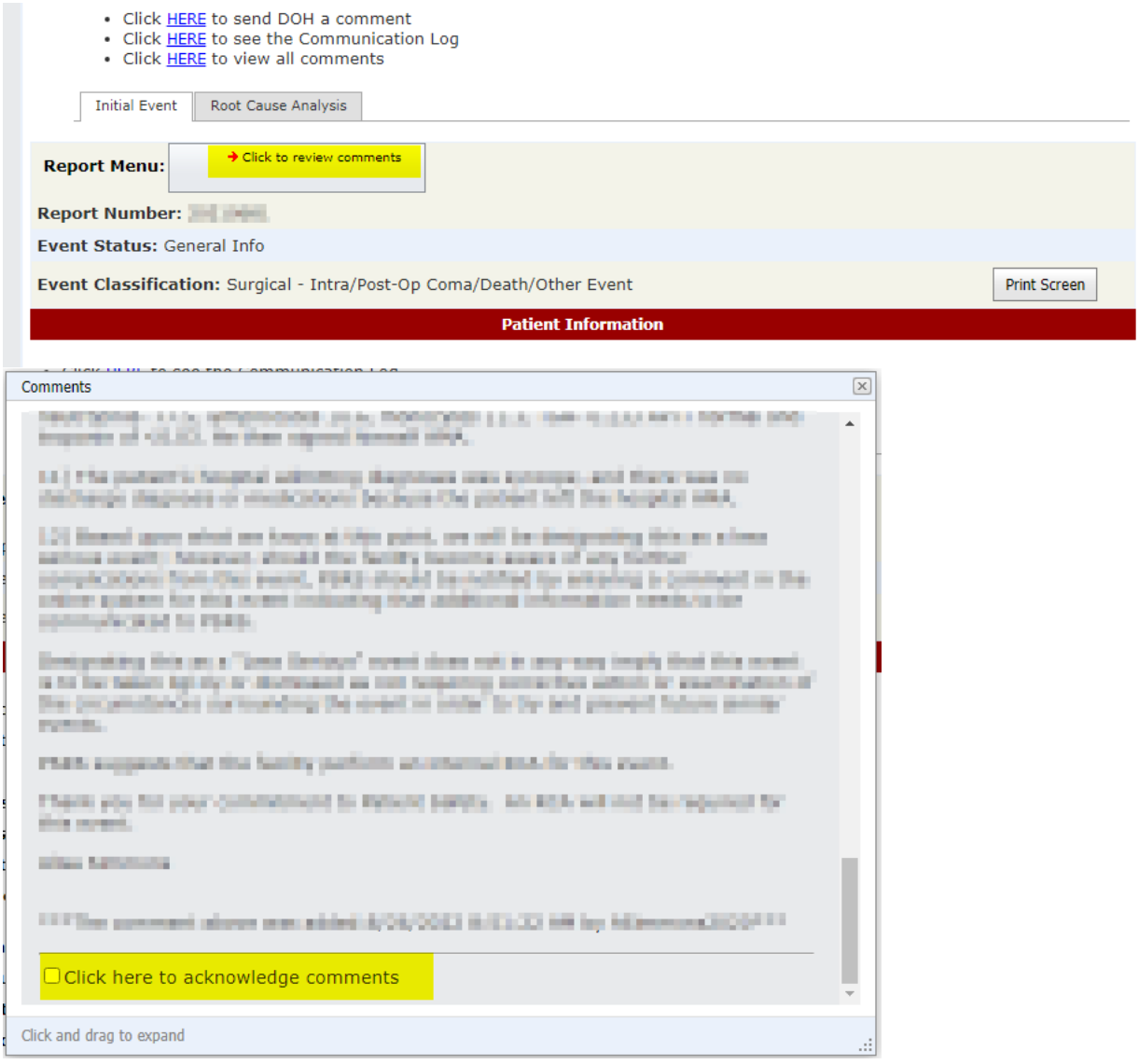


2. RCA: Facts of the Event

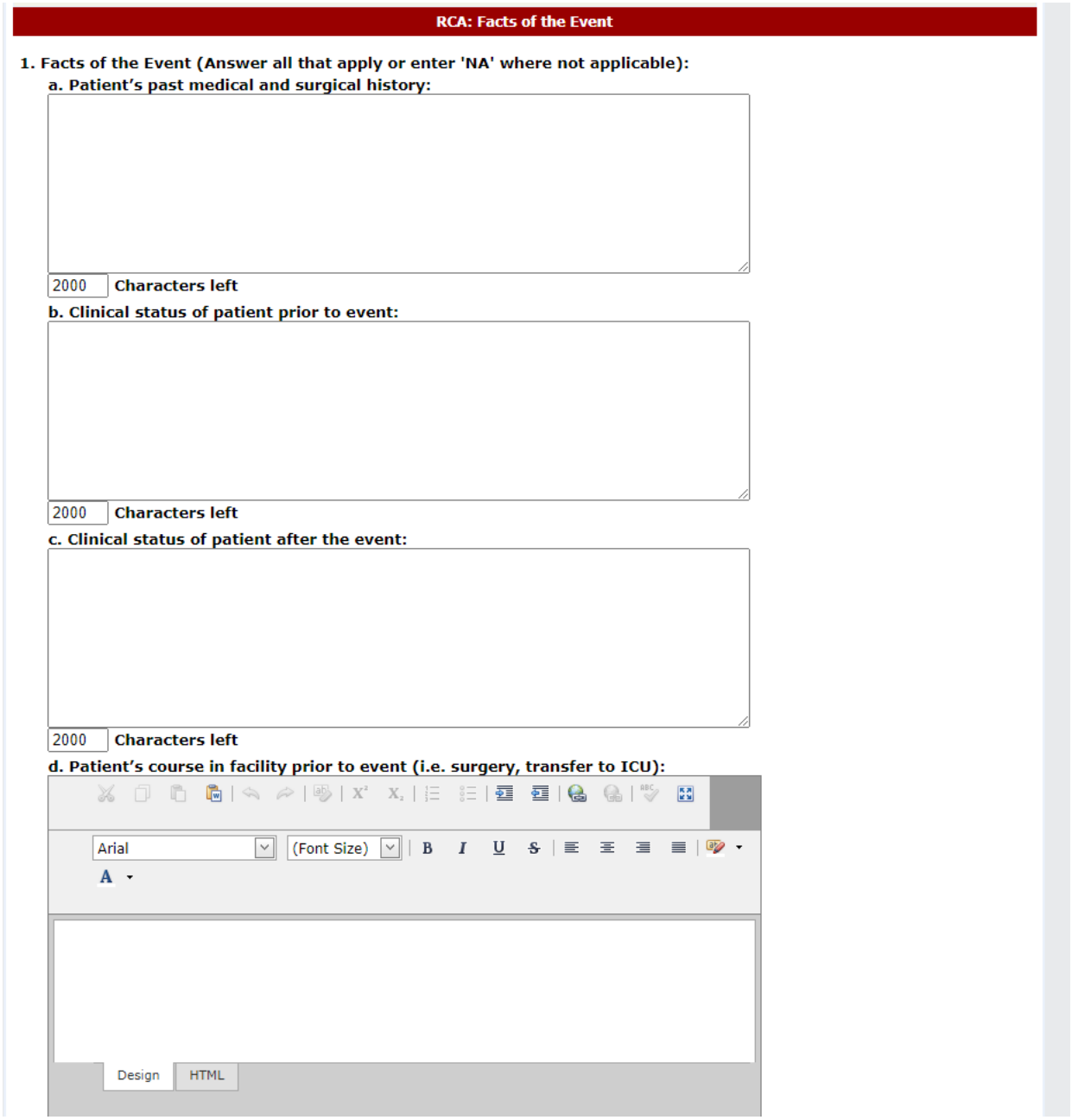
- Complete all fields in this section – all fields are required.
- The RCA Facts of the Event screen can be saved when partially completed. However, all fields must be completed prior to submitting the event to DOH/PSRS for review.
- Click on "Save/Next" at the bottom of the screen to save the completed information and move to the next section.

- The questions posed in the comments from the events screen must be answered in this section. The questions will appear in the "Additional Event Information" field. Please answer all these questions.

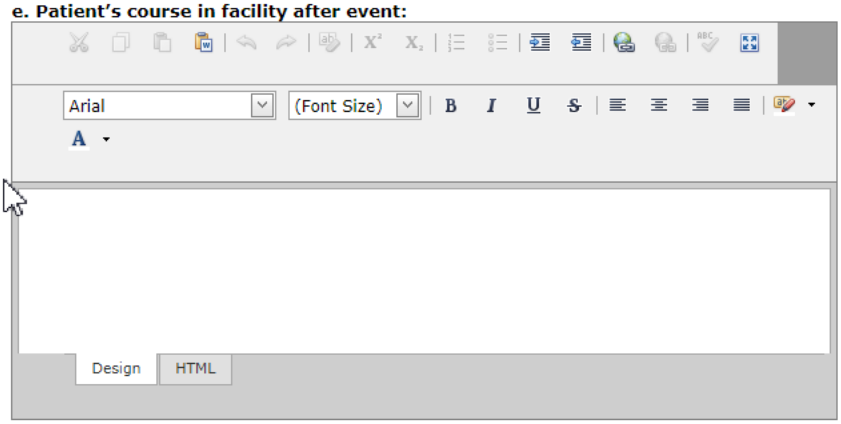
- The facility will be required to attest that they have reviewed and completed responses to event questions.



RCA Facts of the Event Fields:



e. Patient's course in facility after event:



f. Medication at home:

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g. Medication at facility: . If this is a fall event, please include the time the last dose of any high fall risk medications were administered prior to the fall

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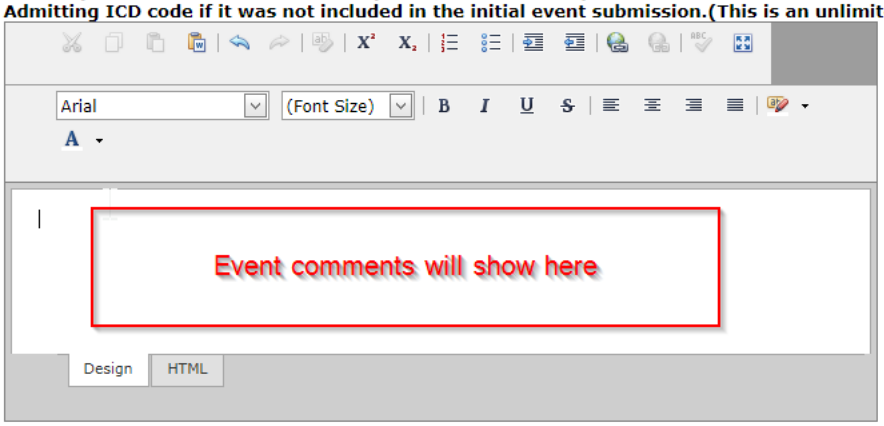
h.Other factors contributing to the event. Please include detailed information about staffing. Please include appropriate lab results.

2000 **Characters left**

2. Additional event information: should be clearly stated and in chronological order: Indicate the potential areas of causality reviewed and how the facility determined certain processes did not contribute to the event. Include the Admitting ICD code if it was not included in the initial event submission.(This is an unlimited text field.)



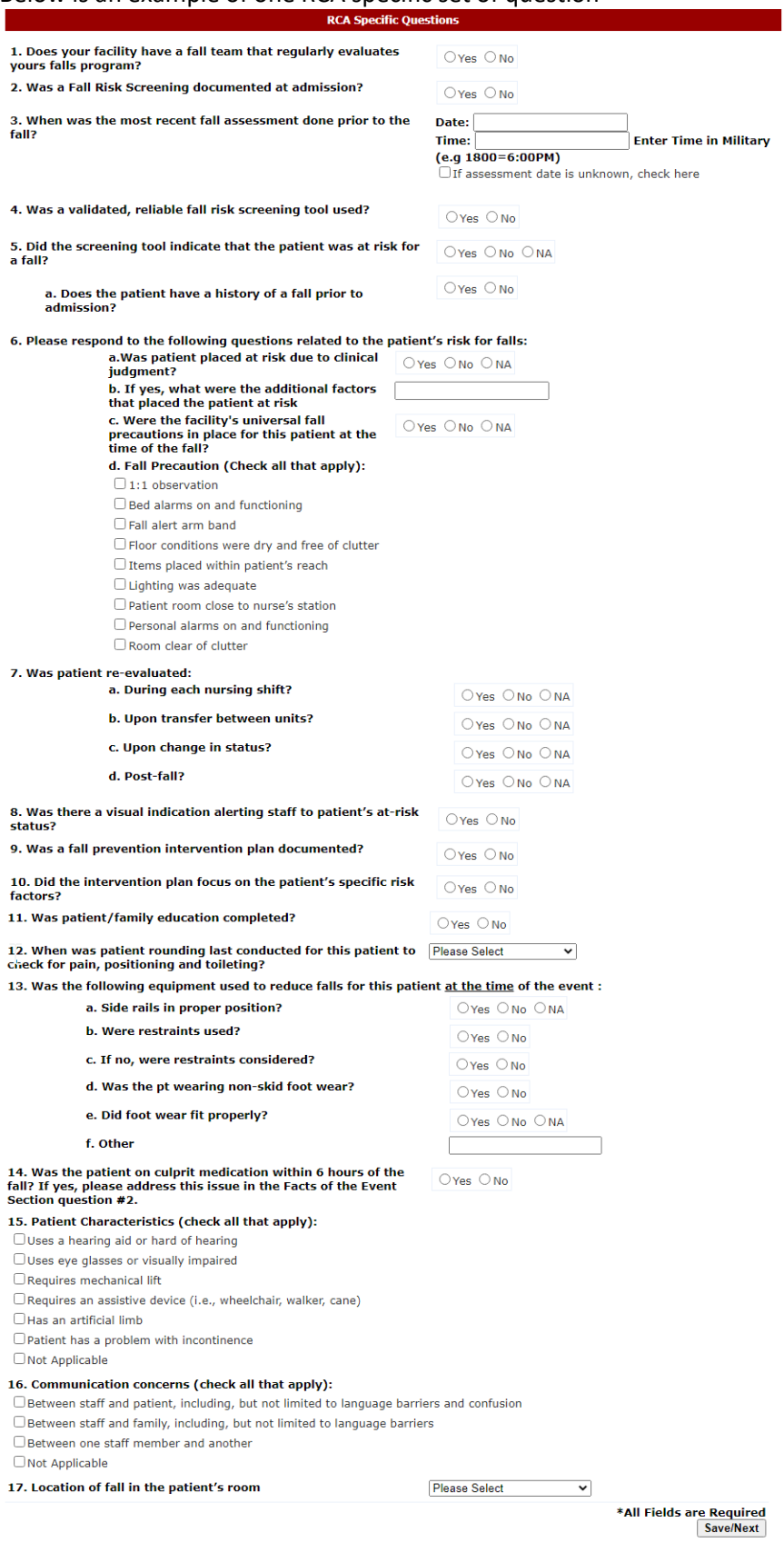
***All fields will need to be completed before the RCA can be submitted**

Save/Next

Note: 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.

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.
- Below is an example of one RCA specific set of question



RCA Specific Questions

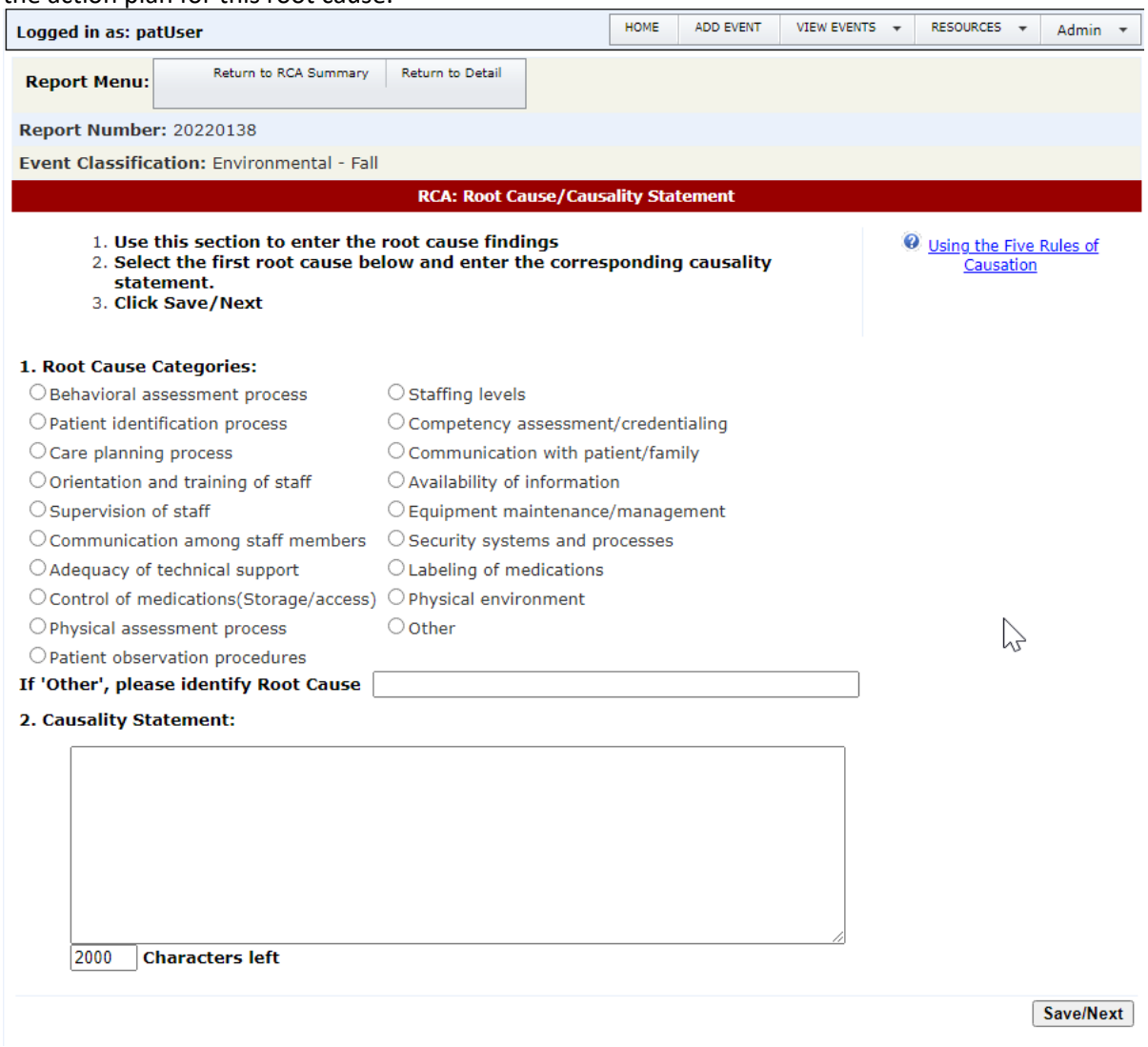
1. Does your facility have a fall team that regularly evaluates yours falls program? ○ Yes ○ No
2. Was a Fall Risk Screening documented at admission? ○ Yes ○ No
3. When was the most recent fall assessment done prior to the fall? Date: Time: Enter Time in Military (e.g 1800=6:00PM) ☐ If assessment date is unknown, check here
4. Was a validated, reliable fall risk screening tool used? ○ Yes ○ No
5. Did the screening tool indicate that the patient was at risk for a fall? ○ Yes ○ No ○ NA
   a. Does the patient have a history of a fall prior to admission? ○ Yes ○ No
6. Please respond to the following questions related to the patient's risk for falls:
   a. Was patient placed at risk due to clinical judgment? ○ Yes ○ No ○ NA
   b. If yes, what were the additional factors that placed the patient at risk
   c. Were the facility's universal fall precautions in place for this patient at the time of the fall? ○ Yes ○ No ○ NA
   d. Fall Precaution (Check all that apply):
   - ☐ 1:1 observation
   - ☐ Bed alarms on and functioning
   - ☐ Fall alert arm band
   - ☐ Floor conditions were dry and free of clutter
   - ☐ Items placed within patient's reach
   - ☐ Lighting was adequate
   - ☐ Patient room close to nurse's station
   - ☐ Personal alarms on and functioning
   - ☐ Room clear of clutter
7. Was patient re-evaluated:
   a. During each nursing shift? ○ Yes ○ No ○ NA
   b. Upon transfer between units? ○ Yes ○ No ○ NA
   c. Upon change in status? ○ Yes ○ No ○ NA
   d. Post-fall? ○ Yes ○ No ○ NA
8. Was there a visual indication alerting staff to patient's at-risk status? ○ Yes ○ No
9. Was a fall prevention intervention plan documented? ○ Yes ○ No
10. Did the intervention plan focus on the patient's specific risk factors? ○ Yes ○ No
11. Was patient/family education completed? ○ Yes ○ No
12. When was patient rounding last conducted for this patient to check for pain, positioning and toileting? Please Select
13. Was the following equipment used to reduce falls for this patient at the time of the event :
    a. Side rails in proper position? ○ Yes ○ No ○ NA
    b. Were restraints used? ○ Yes ○ No
    c. If no, were restraints considered? ○ Yes ○ No
    d. Was the pt wearing non-skid foot wear? ○ Yes ○ No
    e. Did foot wear fit properly? ○ Yes ○ No ○ NA
    f. Other
14. Was the patient on culprit medication within 6 hours of the fall? If yes, please address this issue in the Facts of the Event Section question #2. ○ Yes ○ No
15. Patient Characteristics (check all that apply):
    - ☐ Uses a hearing aid or hard of hearing
    - ☐ Uses eye glasses or visually impaired
    - ☐ Requires mechanical lift
    - ☐ Requires an assistive device (i.e., wheelchair, walker, cane)
    - ☐ Has an artificial limb
    - ☐ Patient has a problem with incontinence
    - ☐ Not Applicable
16. Communication concerns (check all that apply):
    - ☐ Between staff and patient, including, but not limited to language barriers and confusion
    - ☐ Between staff and family, including, but not limited to language barriers
    - ☐ Between one staff member and another
    - ☐ Not Applicable
17. Location of fall in the patient's room Please Select

*All Fields are Required

Save/Next

4. RCA: Root Cause/Causality Statement

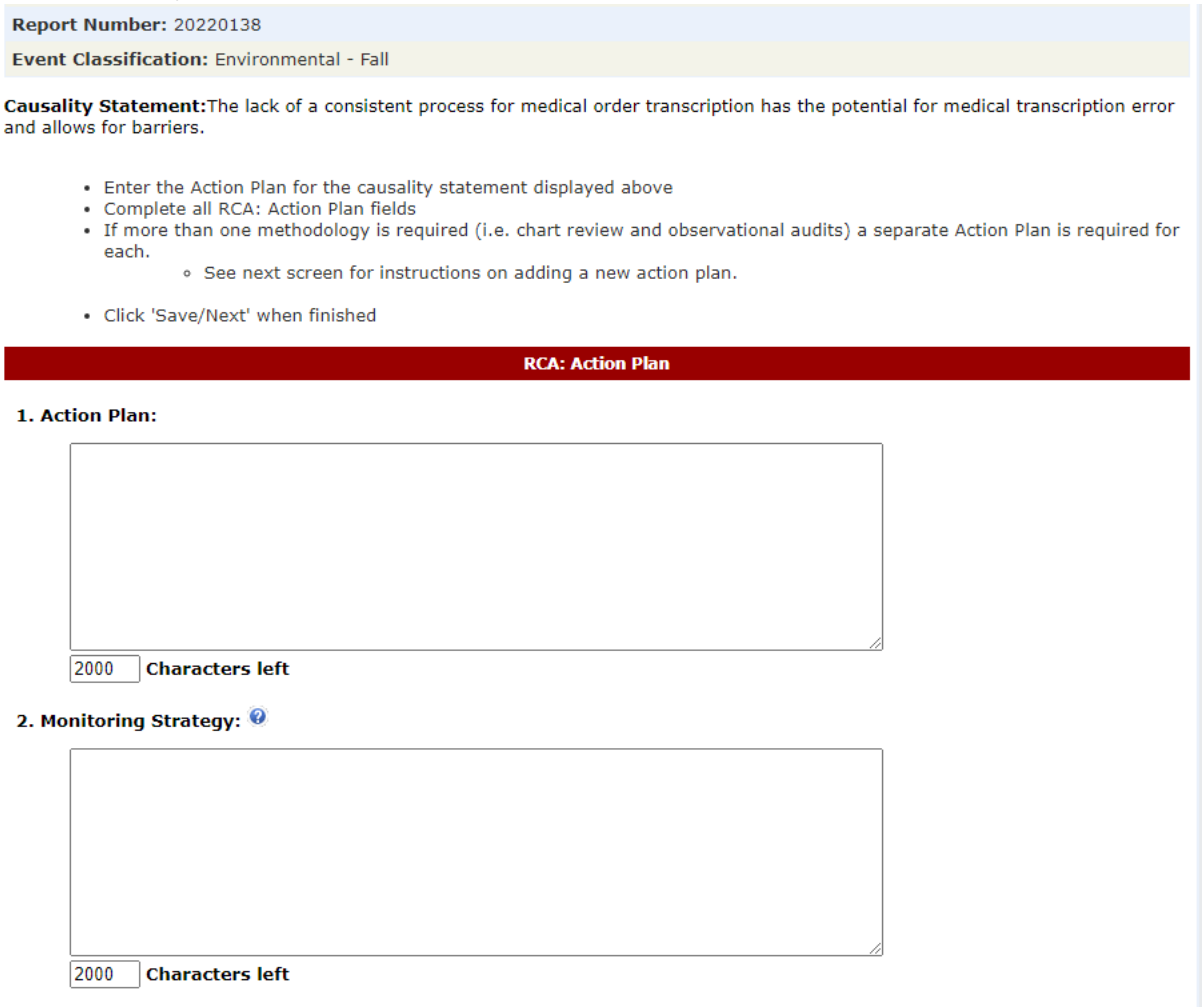
- Select a single root cause and enter the corresponding causality statement.
  - More than one root cause can be associated with an RCA. Additional root causes can be added after completion of the first root cause and associated action plan(s) and monitoring.
- When the entry for this screen is complete, click the "Save/Next" button to continue to the action plan for this root cause.



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



3. Methodology Please Select

4. Frequency Please Select

5. Sample Size

6. Implementation Start Date

7. Staff position responsible for implementation:

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8.Duration:

9. Goal Please Select

10. Threshold Please Select

11. How will effectiveness be monitored over time? :

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12. How will the Action Plan be communicated within and across departments? :

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*All Fields are Required

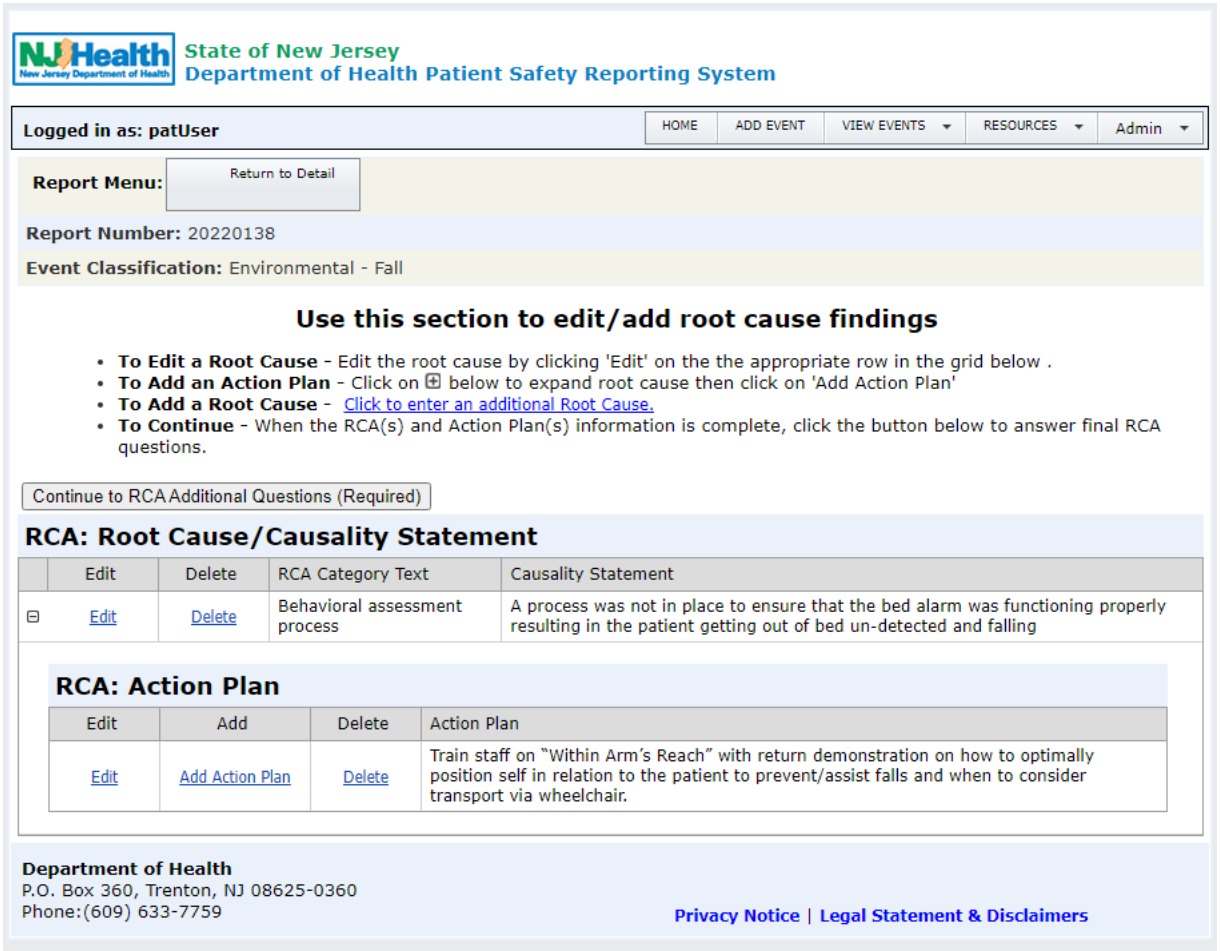
Save/Next

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 a least one action plan associated with it.
  - Select "Add Action Plan."
  - Complete action plan fields for the new action plan.

7. RCA Additional Questions

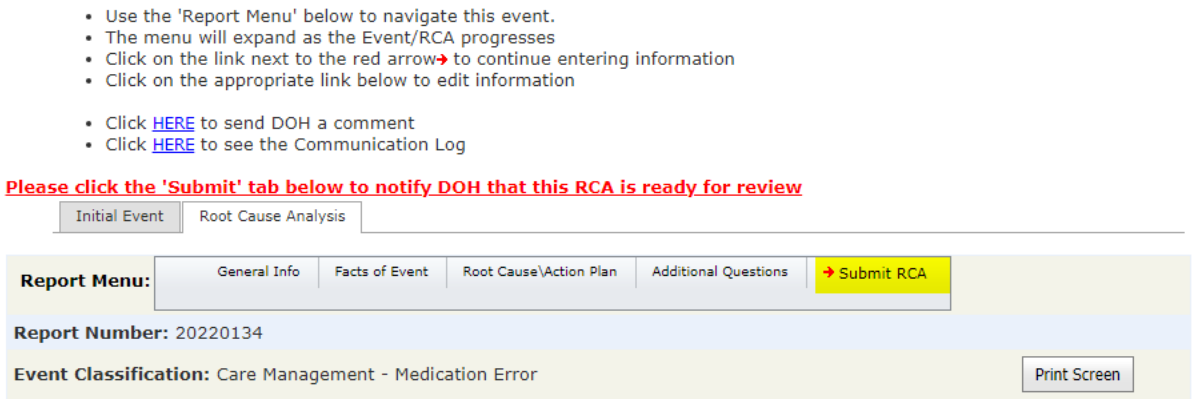
- When the root cause and action plan entries are complete:
  - Click "Continue to RCA Additional Questions" to complete the RCA entry process.



- 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

- 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.



Step IV: RCA Review by DOH/PSRS

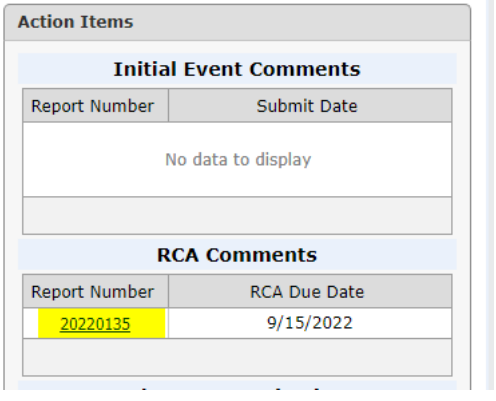
DOH/PSRS will review the RCA information and determine the next action of the RCA process. The FacAdmin will be notified via email of the decision and next steps. There may be more than one cycle for the RCA review process if DOH/PSRS needs additional information to accept the RCA as complete.

Options for DOH/PSRS next steps include:

- Email: RCA Comment Process – additional information needed.
- Email: Other
- Email: RCA Closed (although the RCA may be closed, be sure to check if additional information is required. Often, an RCA reviewer may still need more information.
- Email: RCA Closed Unresolved
- Phone Call (summary of phone call discussion will appear here)

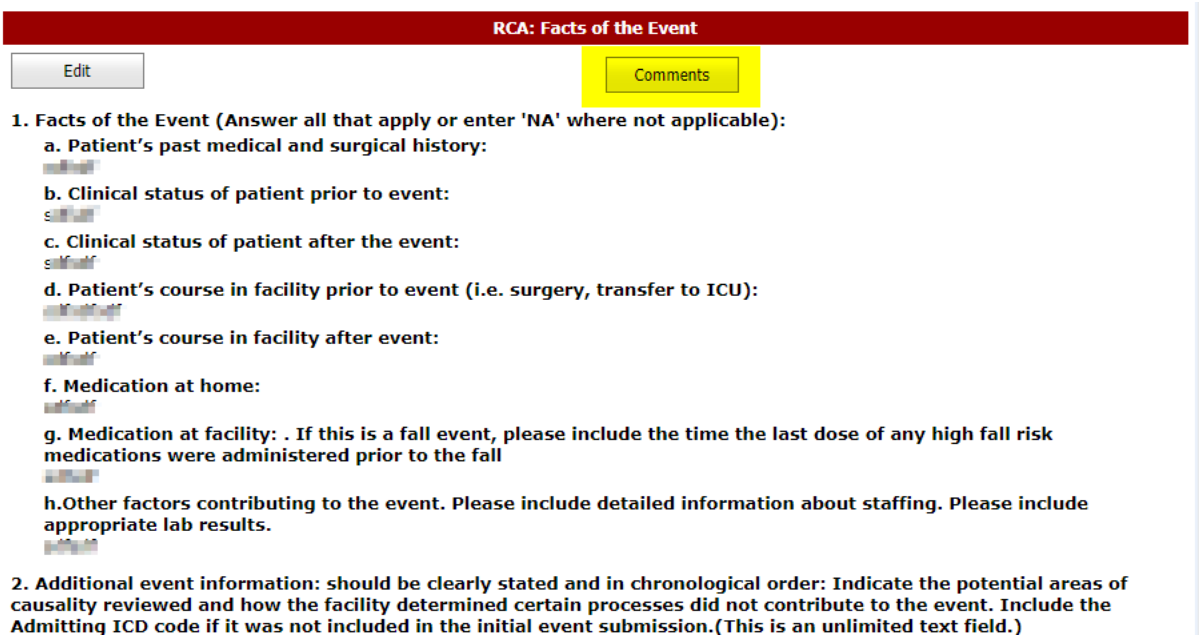
If additional information is needed:

- 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.

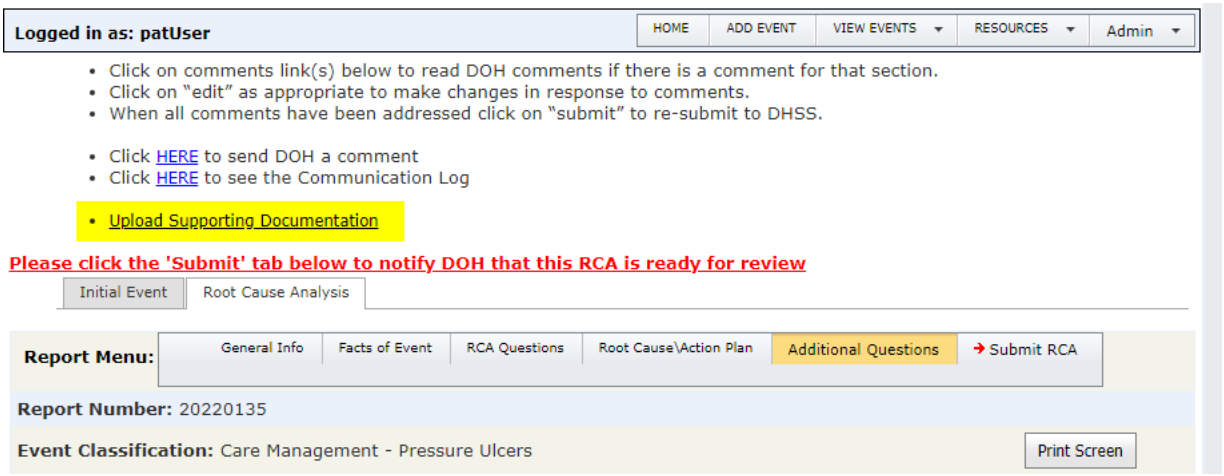
- Click on the "Comments" link to view the reviewer's comments. Most comments will be made in section 2 Facts of event section. The facility can reply to comments in this section as well.
- Click the "Edit" link to make changes to address the reviewer's comments for that section. This can be done directly in the section.
- ***Save*** the changes and click on the "Submit Event" option to resend the RCA to DOH.



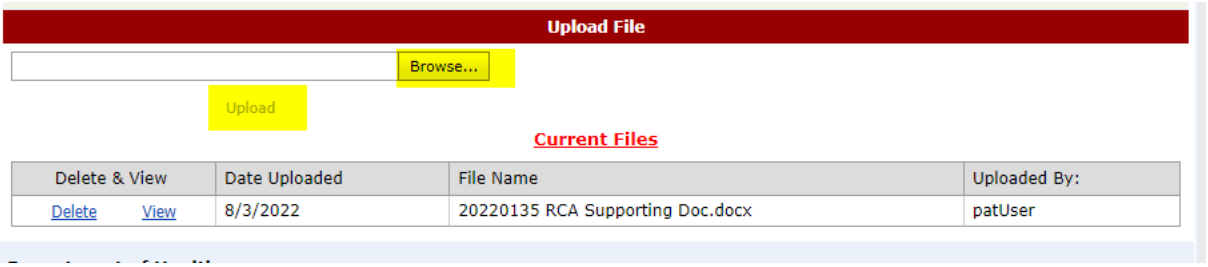
E. Providing Additional Documentation for Event and/or RCA

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. Attachment function will appear after PSRS has approved the attachment function for the RCA. **NOTE: Please do not include or attach Medical Records**.

- Contact DOH/PSRS and provide the report number and request to add attachments.
- When DOH/PSRS confirms that attachments can be made through an email or phone call then enter the Patient Safety System.
- Use the "View Events->Status Report" 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.
- Look for the link at the top of the event to Upload Supporting Documentation



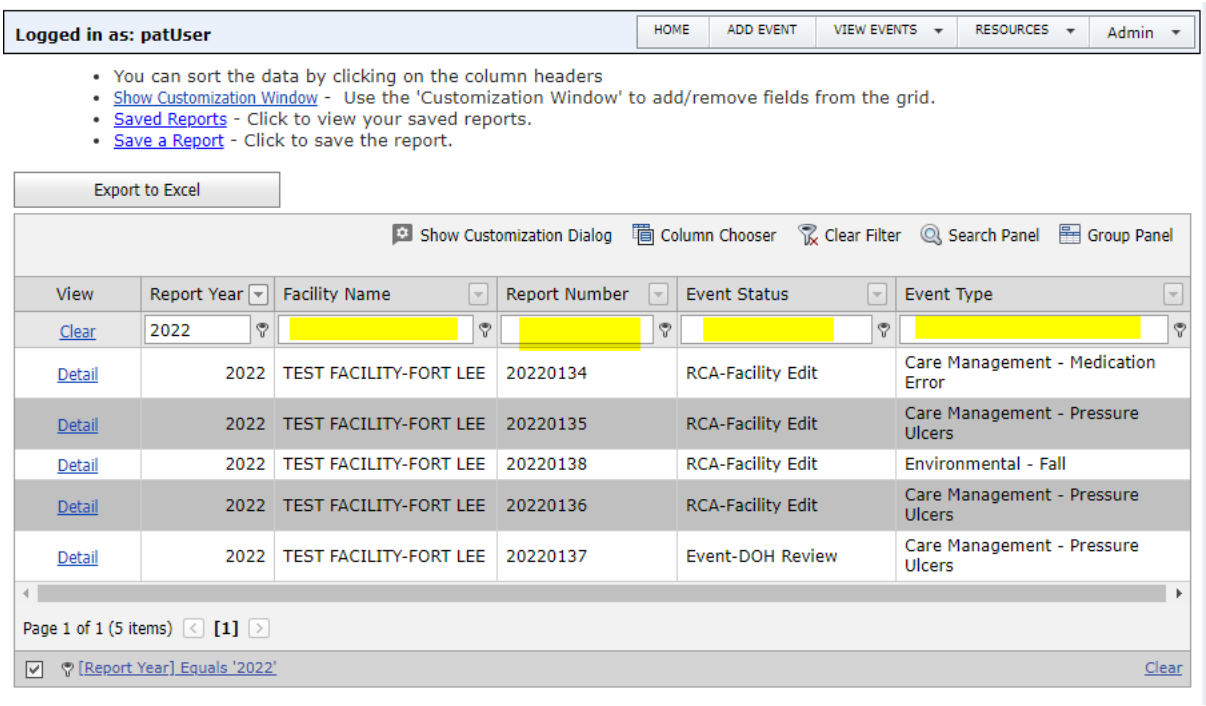
- Click on "Browse" then navigate to the desired document
- Click "Upload" (do not use special characters such as *,#,@ etc in the title of the document or it will not upload.)
- Multiple documents can be attached.
- The Document will now appear under "Current Files" and an email will be sent informing the reviewer that an attachment has been uploaded for this event.



X. 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->Status Report" option.

- Click on the "View Events->Status Report" option from the main menu on the top of the screen.
- To access an event or RCA, click on the "Detail" link in the "View" column for that event/RCA.
- To limit the list, you can filter by typing into any of the highlighted fields or by clicking on the drop-down arrow to show a list of choices available and selecting one of them by left-clicking on that choice.



- Please note that these columns can be moved or changed so your screen may not appear exactly as below.

XI. Completed Events and Root Cause Analyses

When an event report and RCA have been determined to be complete, DOH/PSRS will send an email notification that no further action is required. This completes the process for the event report and RCA.

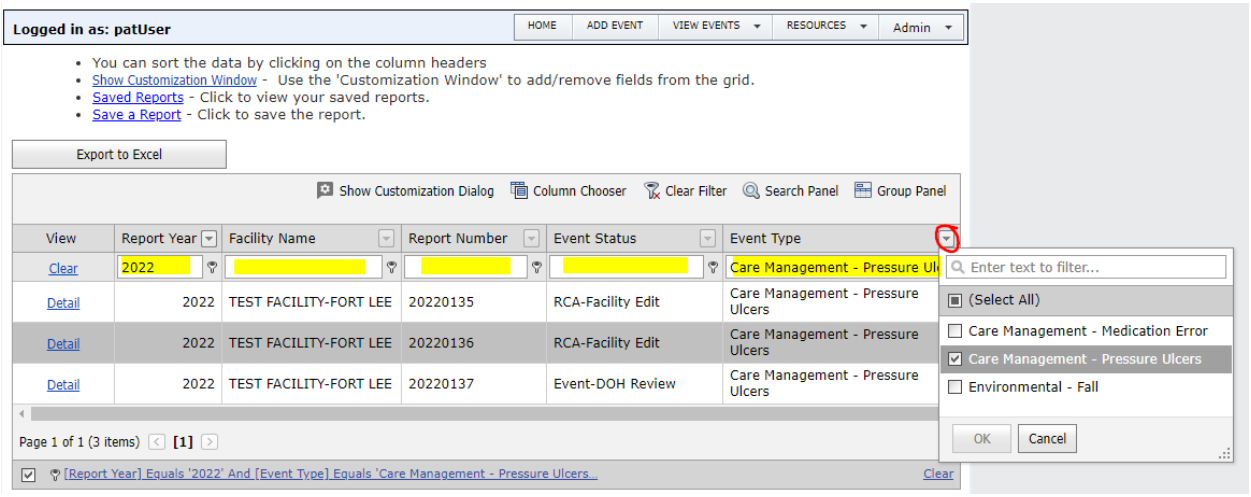
Sometimes, DOH/PSRS may close an RCA but request additional information. The facility should follow the instructions from DOH/PSRS about the timeline for submitting this information and whether the information should be sent via comment in the online system or via attachment to the Event/RCA.

Please do not send lengthy responses or comments via the communication log and do not copy and paste Medical Records into the communication log or attachments. The communication log has limited capacity and does not retain formatting, which makes it difficult to read and follow.

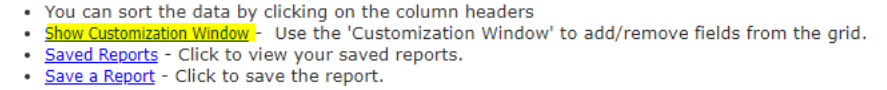
XII. Ad-Hoc Reports

Custom reports can be retrieved and saved in the system.

- To create custom reports, use the View Events-Status Report menu option.
- This will display a default report that can be changed and saved for future use.
- To filter the information provided on the reports, use the highlighted entry boxes or drop-down for each column of data
- For instance, in the screen shot below, we have limited the grid to show us Pressure Ulcer events for the year 2022

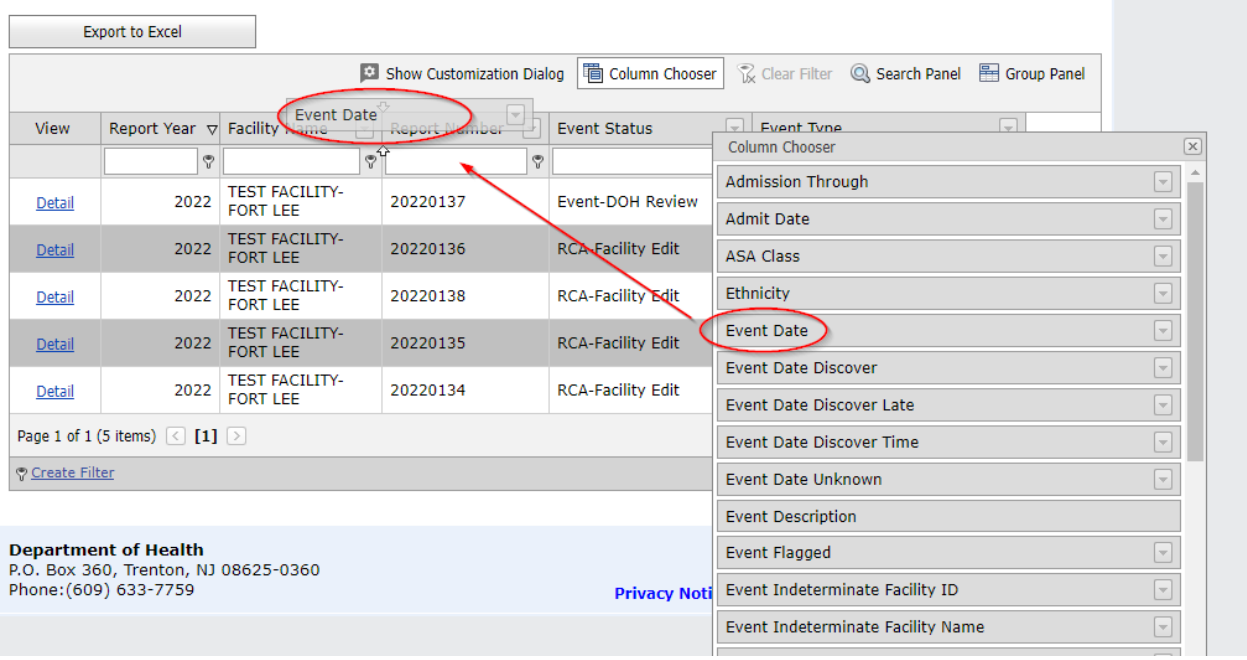


This grid also provides various options to customize the report. We will walk through each option starting at the top with “Show Customization Window”



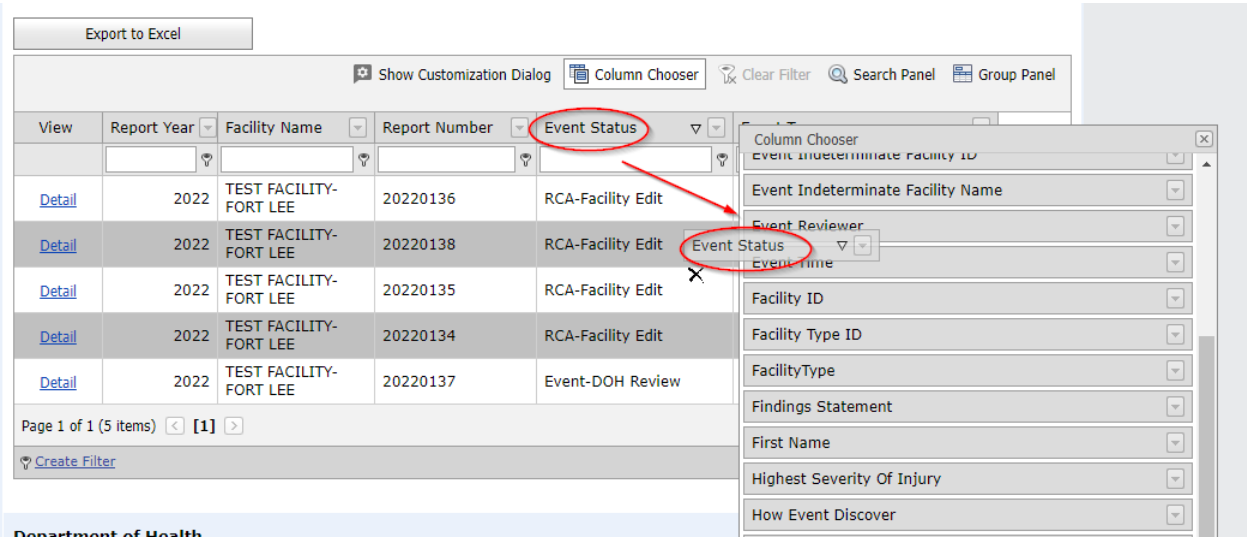
1. To Add a Column

- To add a column, click on the “Show Customization Window” – this will open a popup of the available fields. Click on the desired field and while holding the down left mouse button, drag the field onto the report (Drag and drop).



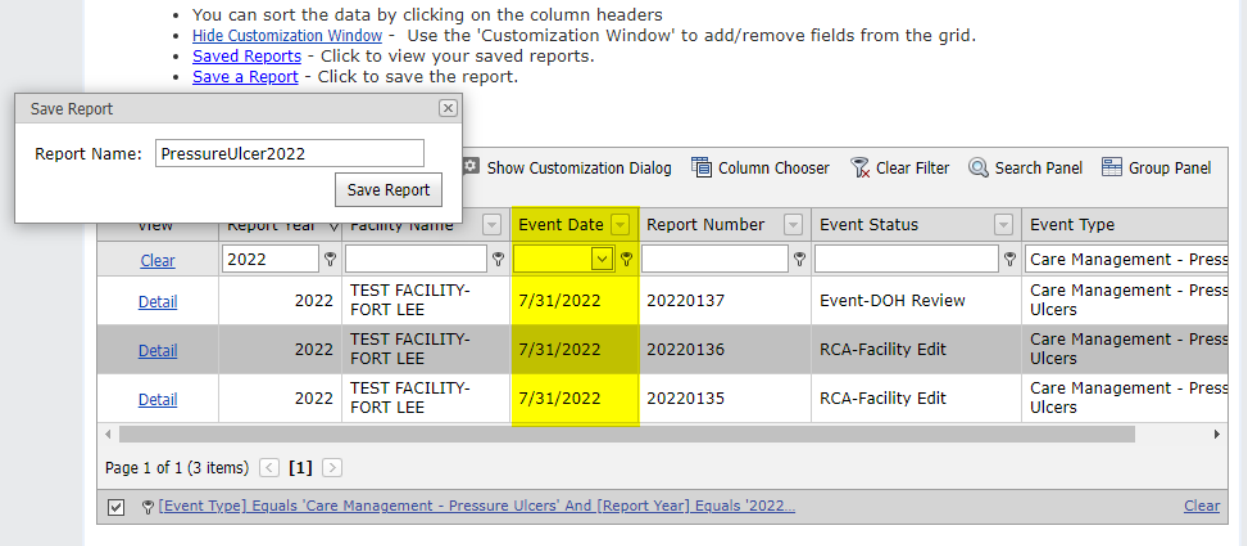
2. To Remove a Column

- Click on the column name and drag it to the Column Chooser list (Drag and drop).
  - In the example, the Event Status is being removed from the report



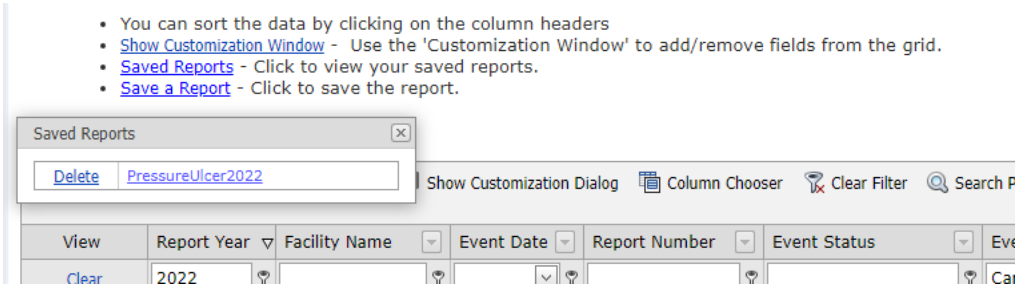
3. To Save a Report

- Once you have the desired columns on the grid, click on “Save a Report.” In the grid below, I have dragged the Event Date onto the report and saved the Report as “PressurerUlcer2022.”



4. Accessing Saved Reports

- You can access this new report anytime by clicking on “Saved Reports”
  - You can add as many reports as needed

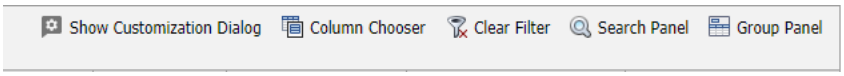


5. Deleting Saved Reports

   - Use the delete button to remove the report from your saved reports
   - Confirmation of the delete will be displayed

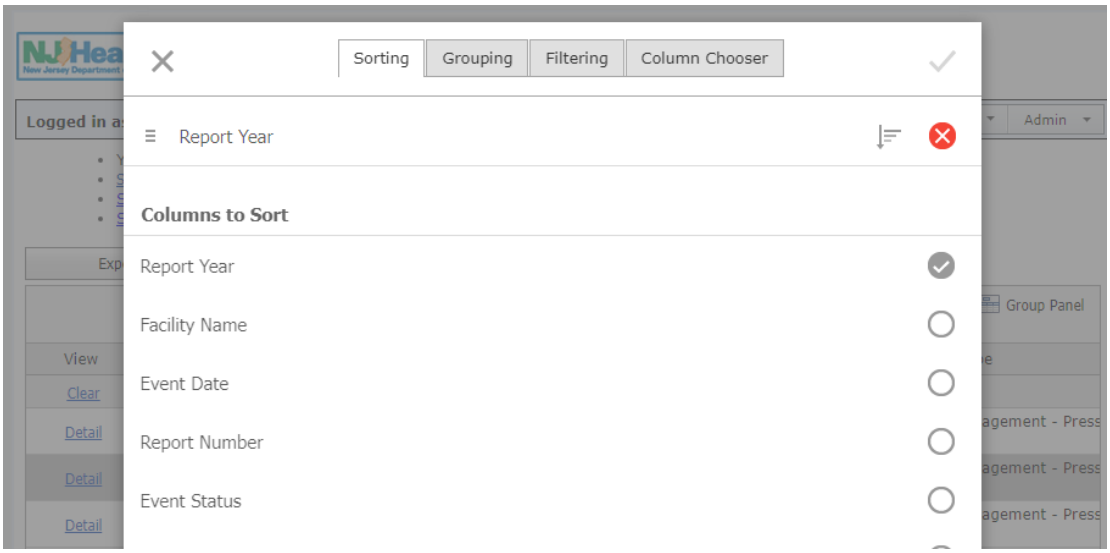
6. Further Customization Options

- Above the grid you will see more options for further customization of reports

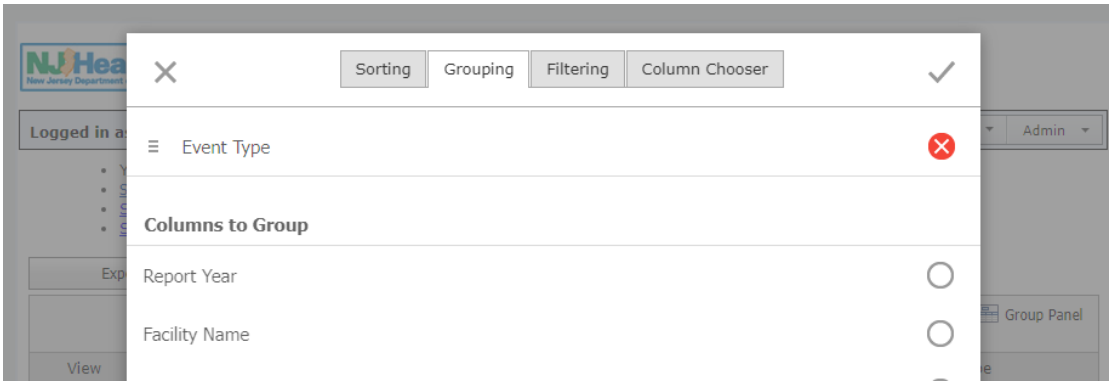


- The “Show Customization Dialog” opens a popup with several options that allow you to Sort, Group, Filter as well as add or remove columns.

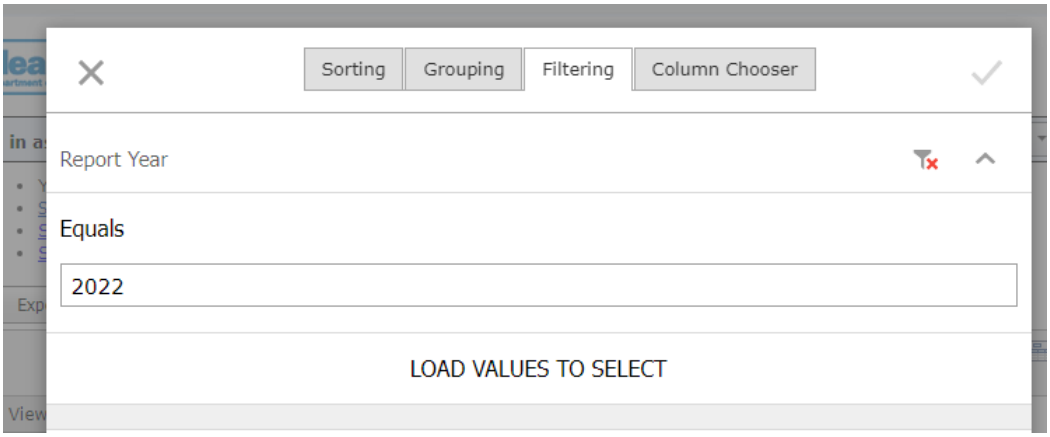
- In the example below we have “Clicked the “Show Customization Dialog” and are sorting by the Report Year.



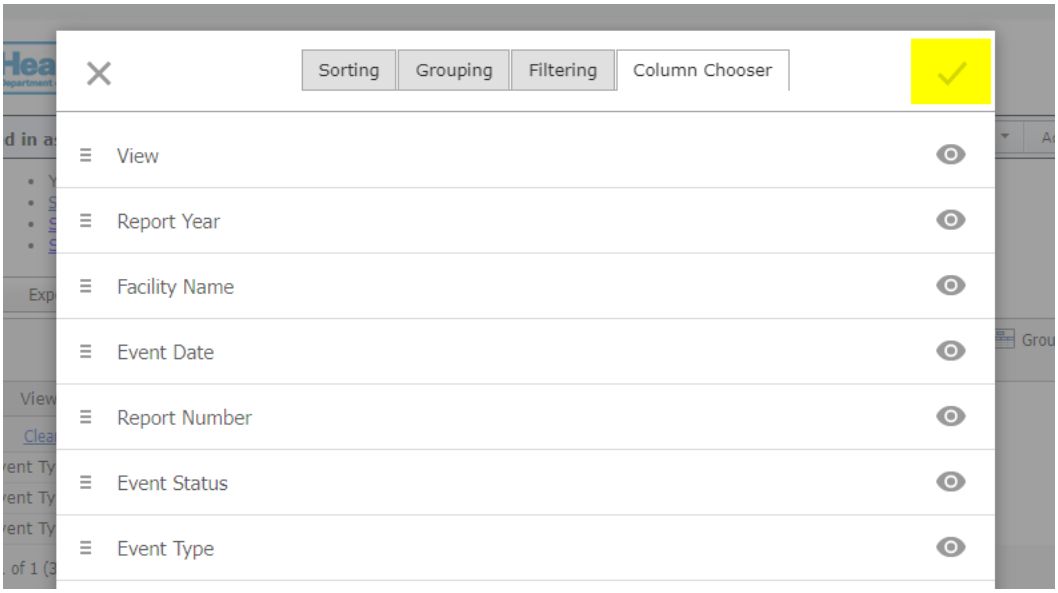
- If we move to the next tab, we can see that we are grouping by Event Type.



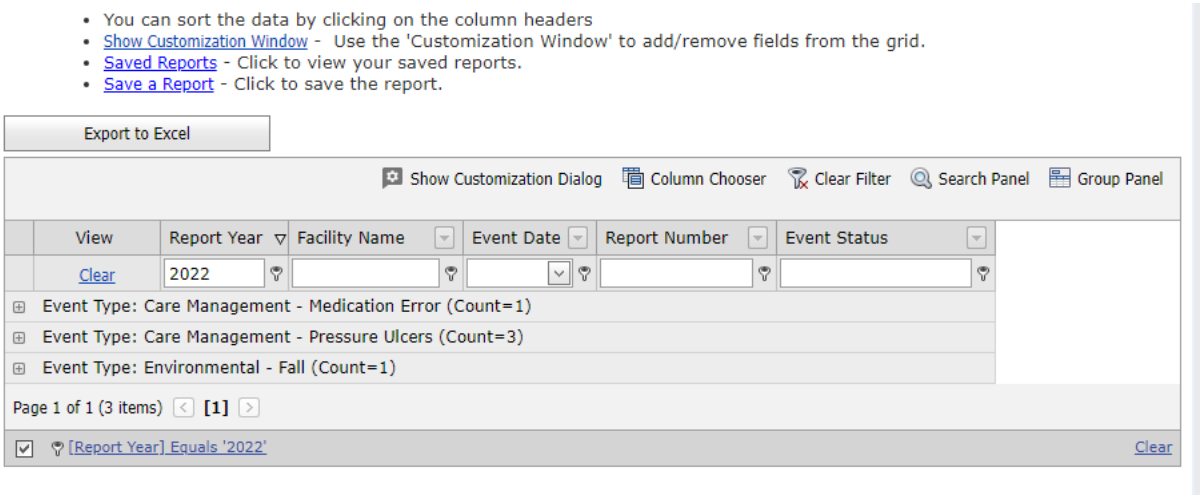
- The next tab shows us filtering on the Report Year



- The final tab shows us the columns that we have selected. To apply the changes, click on the check mark in the upper right corner.



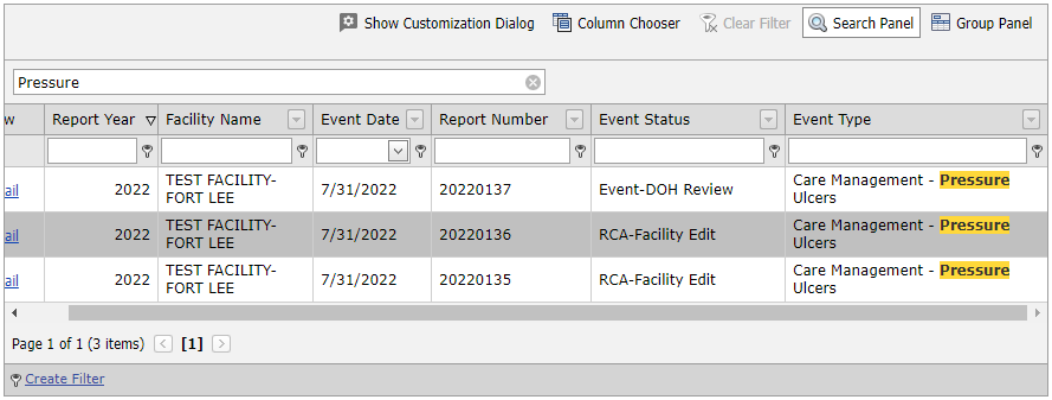
- The results from our selections are shown below – you can expand any of the Event Type groups by clicking on the [+] sign



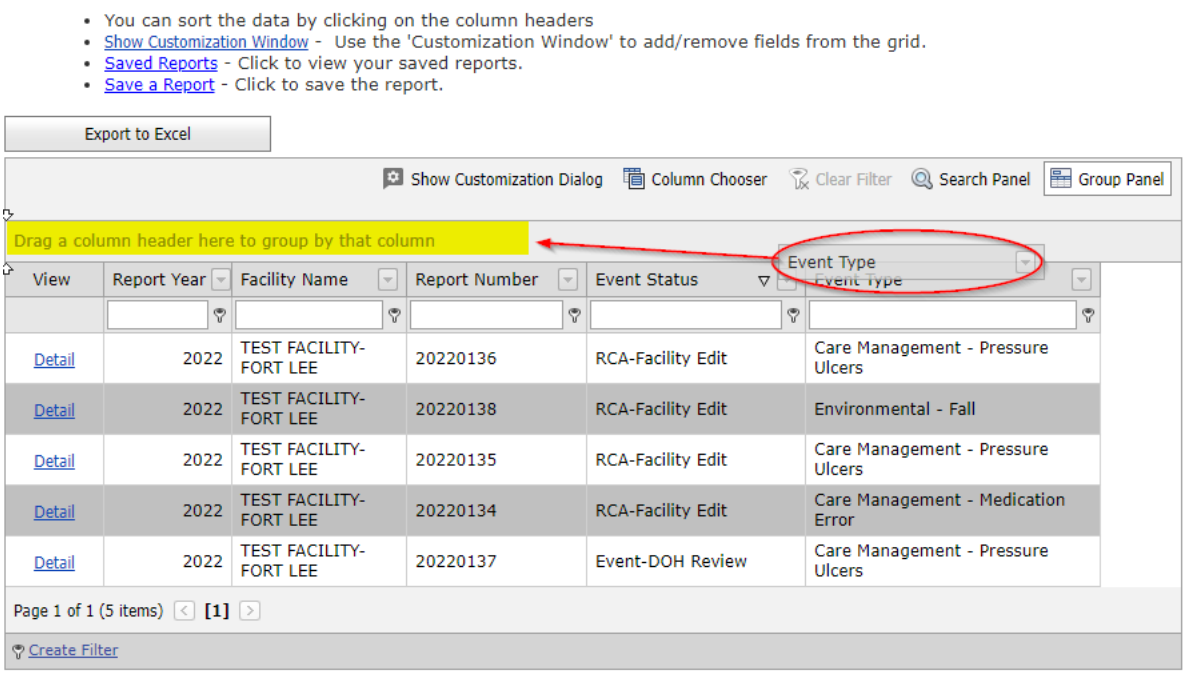
- The next option that we have is the “Column Chooser.” This opens the same popup as the “Show Customization Window” so we will not go into more detail on this.

- The “Clear Filter” button removes any filters that we have. If we were to click on it in the example, it would remove the Report Year = 2022 filter.

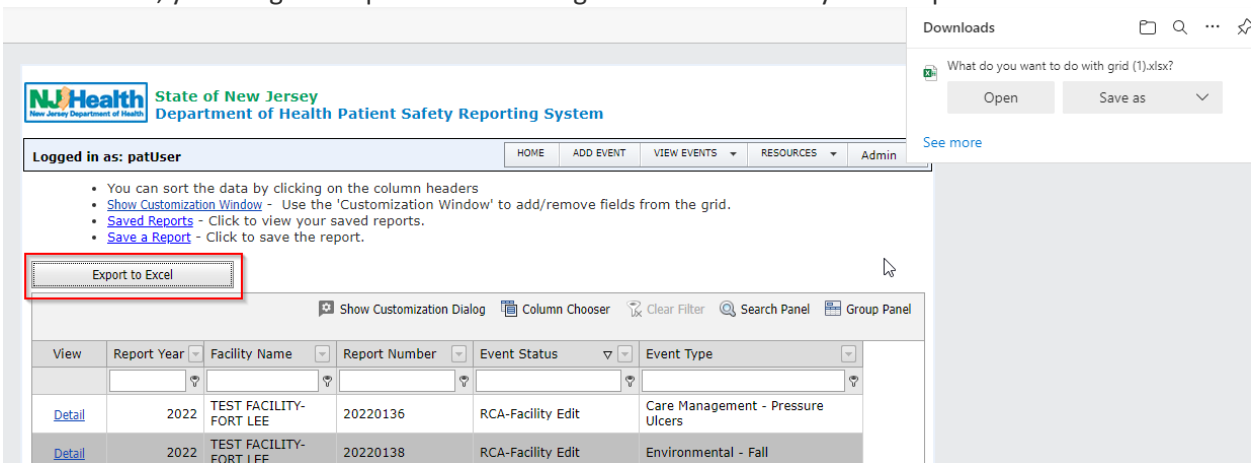
- The “Search Panel” opens a text box that allows us to search for words on the screen.
    - In the example below, we have opened the Search text box and started typing “Pressure.” The grid automatically filters as you type and highlights the words as they are found.



- The last customization option that we have is “Group Panel.” Clicking on this option opens a section where you can drag and drop column headers from which to group. In the example below, we are dragging the “Event Type” to the group panel, which gives us the result we had when we used the “Show Customization Dialog” from above.



7. To Export Report Information
    - To save the information in the report, use the “Export to Excel” option.
    - Depending on the type of browser (Microsoft Edge, Chrome, Firefox, etc.) you have, you will get an option to save the grid to a location on your computer.



XIII. 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?
- Where can I access the Patient Safety Regulations?

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?
- What information should be submitted for events involving anesthesia or procedural sedation?

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?

RCA Questions

- How do I count the number of similar events in the last three years?
- Where do I find reviewer's comments?
- What are the regulatory requirements an RCA must include?

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 (Department) must report every serious preventable adverse event. Preventability may not be discernible at the time of the event and a root cause analysis may be needed to confirm or refute the presumed relationship.

DOH/PSRS should be making the determination regarding whether an adverse event is preventable and/or whether an RCA will be required to determine preventability. If a serious adverse event occurs in a NJ licensed health care facility that is currently reporting to DOH/PSRS, the event should be entered into the online reporting system and submitted to DOH/PSRS for review.

N.J.A.C. 8:43E-10.6(e) et seq. indicates that events should be reported in the appropriate category (Care Management, Environmental, Product/Medical Device-related, Surgery-related, or Patient Protection-related) to DOH/PSRS if it is reasonable to assume initially that the event is "associated with" the course of care.

If there is not a specific event type listed in the regulations, the event should be submitted as an "Other" event in the appropriate category listed above. (i.e. Care Management—Other, Surgery—Other, etc.)

For example, if an event occurs to the mother, baby, or fetus that is associated with the course of care, but the mother would not be considered a "Low-risk pregnancy," that event should be reported in the "Care Management—Other" category.

Another example would be an event involving a hospital inpatient who has an event related to surgery and his/her course of care but is not considered an ASA Class I inpatient or a Same Day Surgery patient. That event should be reported in the "Surgery—Other" category.

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.

Preventability may not be discernible at the time of the event and a root cause analysis may be needed to confirm or refute the presumed relationship.

DOH/PSRS should be making the determination regarding whether an adverse event is preventable and/or whether an RCA will be required to determine preventability. If a serious adverse event occurs in NJ licensed health care facility that is currently reporting to DOH/PSRS, the event should be entered into the online reporting system and submitted to DOH/PSRS for review.

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 not in accordance with the consent form or as intended

- Catheter placement in the wrong vessel
- Retention of a foreign object
- Discharge of an infant to the wrong person
- Attempted suicide even if no harm. DOH/PSRS does not recognize "Attempts at attention-seeking" or "Suicidal gestures." These should be reported to DOH/PSRS.

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, send a comment to PSRS through the online system for the event that was already created in the reporting system with an update about the situation.
- In accordance with the regulations at N.J.A.C. 8:43E-10.6(e) et. seq., DOH/PSRS recommends submitting any serious adverse events where it is "reasonable to assume" that the event is "associated with" the patient's course of care.

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.

Preventability may not be discernible at the time of the event and a root cause analysis may be needed to confirm or refute the presumed relationship.

DOH/PSRS should be making the determination regarding whether an adverse event is preventable and/or whether an RCA will be required to determine preventability. If a serious adverse event occurs in NJ licensed health care facility that is currently reporting to DOH/PSRS, the event should be entered into the online reporting system and submitted to DOH/PSRS for review.

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 (that do not require sutures or some other type of intervention) and bruises that do not cause a decrease in hemoglobin or other complications.
- 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, such as splints, slings, casts, immobilization devices, closed reduction, etc. It is important to note in the event report if the injury is to the patient's dominant hand and how the injury affects the patient's ability to perform Activities of Daily Living (ADLs)
  - single compression fracture that requires only limited pain management for therapy, does not extend the length of stay, does not significantly impact function, and does not require major intervention, such as a back or neck brace or other type of immobilization or assistive device.
- Near Misses are occurrences that could have resulted in an adverse event but were prevented such as a medication error which was identified before the wrong medication was given to the patient.

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

How do I report events?

This is explained in detail in Section IX of this document. Please refer to that section for detailed answers to this question.

To submit events for the facility for which you are registered, go to the "myNewJersey" network located at: http://nj.gov/ and log in. Then click on the Patient Safety Reporting System link located

under Applications. This site can also be reached via the DOH/PSRS website where it states, “Report a Serious Preventable Adverse Event.”
Each licensed, reporting facility should have a ***minimum*** of two Facility Administrative Users registered for reporting within the DOH/PSRS online reporting system.

Any staff member can file an anonymous report in the DOH/PSRS online reporting system by visiting the DOH/PSRS website and following the links where it states, “Voluntary Anonymous Reporting for Facility Staff” or at this web address: https://www.nj.gov/health/healthcarequality/health-care-professionals/patient-safety-reporting-system/voluntary_anonymous_reporting.shtml

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 any member of the health care facility team discovers the event. NOTE: This includes physicians or practices who have privileges and/or perform procedures at a licensed health care facility.
- 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.

N.B. Reporting to the appropriate authorities, Acute Care Survey, or to the Patient Safety Reporting System (PSRS) may not be exclusive depending on the situation. The event may need to be reported to more than one entity. ***If there are any questions about reporting, please contact PSRS.***

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 ***unless*** these interruptions resulted in harm to patients.

Where do I report communicable and infectious diseases?

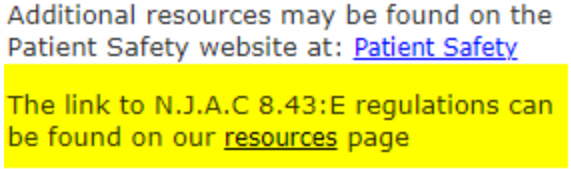
Communicable diseases should be reported in accordance with the requirements of N.J.A.C. 8:57-1 et seq.

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

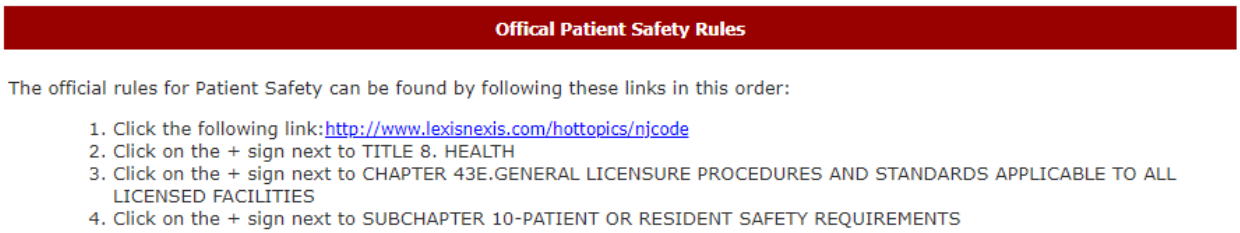
These events may also be reportable to the Patient Safety Reporting System. ***If the facility is uncertain regarding the need to report, contact the Patient Safety Reporting System.***

Where do I access the Patient Safety Regulations?

The link and instructions to access the regulations can be found on the Patient Safety Reporting website home page in the left column:



On the resource page, there are detailed instructions on how to access the regulations:



Offical Patient Safety Rules

The official rules for Patient Safety can be found by following these links in this order:

1. Click the following link: http://www.lexisnexis.com/hottopics/njcode
2. Click on the + sign next to TITLE 8. HEALTH
3. Click on the + sign next to CHAPTER 43E.GENERAL LICENSURE PROCEDURES AND STANDARDS APPLICABLE TO ALL LICENSED FACILITIES
4. Click on the + sign next to SUBCHAPTER 10-PATIENT OR RESIDENT SAFETY REQUIREMENTS

Direct access to the link is provided below:
http://www.lexisnexis.com/hottopics/njcode

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, that information should be provided to the Patient Safety Reporting System in the event report.
    - 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 event report should include where the object was retrieved from anatomically, a description of the object (size, color, material, shape, etc.), and results of any pathology reports
    - The event report should include information regarding any previous procedures when the object may have been retained and where those procedures were performed
    - The event report should include any pertinent imaging results prior to the discovery of the retained object
    - ***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
- Lacerations that require sutures
- Injuries that require casts or immobilization devices
- 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.

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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 be reported.
- Unstageable pressure ulcers are not required to be reported within the Pressure Ulcer event type in the current regulations, but the Department strongly recommends that facilities voluntarily report these pressure ulcers as "Care Management—Other" events and perform an RCA, as Unstageable pressure ulcers represent full thickness tissue injuries.
- Deep tissue injuries (DTIs) are not required to be reported under the current regulations.
- Pressure Ulcers do 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. These types of pressure ulcer events should be reported to the Patient Safety Reporting System to determine whether an RCA will be required. The facility should include in the event report the comorbidities and extenuating factors that demonstrate why the facility feels the pressure ulcer would not require an RCA or was not "preventable."

If the facility has any questions about whether a pressure ulcer should be reported, please contact the Patient Safety Reporting System.

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.
- Dialysis related events
- Unstageable pressure ulcers
- Maternal/ Labor events in non-low risk pregnancies
- Neonatal/Fetal events

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.

NOTE: Just because something is a known complication does not mean it is not preventable and does not mean it is not reportable. It is best to report any event that is associated with the course of care regardless of whether it is a "known complication."

What information should be submitted for events involving anesthesia or procedural sedation?

The following questions/comments refer to surgeries/procedures where anesthesia or moderate sedation is utilized.

1) Please describe when the full required H&P prior to the planned procedure was performed and when the H&P update was performed. Please list any abnormal findings noted on the H&P and H&P update.

a. please list the patient's medical conditions

b. please list the patient's prior surgeries

c. please list the outpatient medications to include name, dose, route of administration, frequency, and date/time of last dose taken before admission and/or procedure

d. for inpatients, please list the previous 48 hours of medications delivered to include name, dose, route of administration, date/time.

2) Were there hospital admissions, ED or urgent care visits within the last few months? If so, what were the admitting/discharge diagnoses? Describe results/recommendations of consults and primary care visits within the same time frame.

3) Please describe the pre-anesthesia/pre-procedural sedation or moderate sedation assessment. Please note the following:

a. who performed the assessment.

b. What time was the pre-anesthesia/sedation assessment performed? What time did the patient enter the OR/procedure room?

c. Were the meds, allergies, medical diagnoses reviewed?
d. Was there a noted previous problem with anesthesia? If so, please describe. If not known, then why not?
e. What was the documented airway assessment such as Mallampati?
f. Were pre-op labs and imaging available for anesthesia or for the physician ordering moderate sedation for review? If so, what were the results?
g. What was the anesthesia or sedation plan?
h. In the OR or procedure room, was the patient reassessed prior to the first dose of anesthesia or sedation? What was the result? Please include the vitals to include HR, cardiac rhythm, BP, RR, temp, pulse oximeter reading, ET CO2 as well as the time of this reading and the time of the first dose of anesthesia/sedation.
i. Describe the type of airway inserted, when it was inserted, and when it was removed. For example, intubated with 7.0 oral ETT at (date/time) and extubated at (date/time).
j. Was the patient reassessed after anesthesia/sedation prior to discharge from the peri-procedural area? If so, please note pertinent findings.
k. Was the patient NPO for the procedure? If so, when was the date/time of last intake?

Event Form Definition Questions

How detailed should the Description of the Event be?

The Patient Safety Reporting System needs enough information to determine if the event meets the statutory definition. It is essential for the description of the event to include pertinent information that will allow PSRS to understand what happened and how the event affected the patient. The description of the event should include at least, but not limited to, the following: Pertinent medical, surgical, and/or behavioral health history, imaging and lab results, how the injury impacted the patient, treatments and consults required, and the duration of those treatments and injuries.

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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.

For surgery events, the event time is often considered the time the procedure ended unless the time is clearly known. For example, if the patient had a colon perforation during a colonoscopy and the practitioner or member of the team knew the actual time it occurred, that would be the event time. If the actual time is not known, the event time would be considered the time the procedure ended.

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:
        - Assessment of the patient after the event
        - 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.

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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. There is usually minimal or no delay after 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 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) or Assisted Living- The patient was sent to the current facility from a Long Term Care or Assisted Living facility as a direct admission or an admission through the ED. In either situation, only the “Transfer from LTC or Assisted Living” item is selected.

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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 patient.
- Implement new turning and positioning system to ensure compliance with repositioning every 2 hours.

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RCA Questions

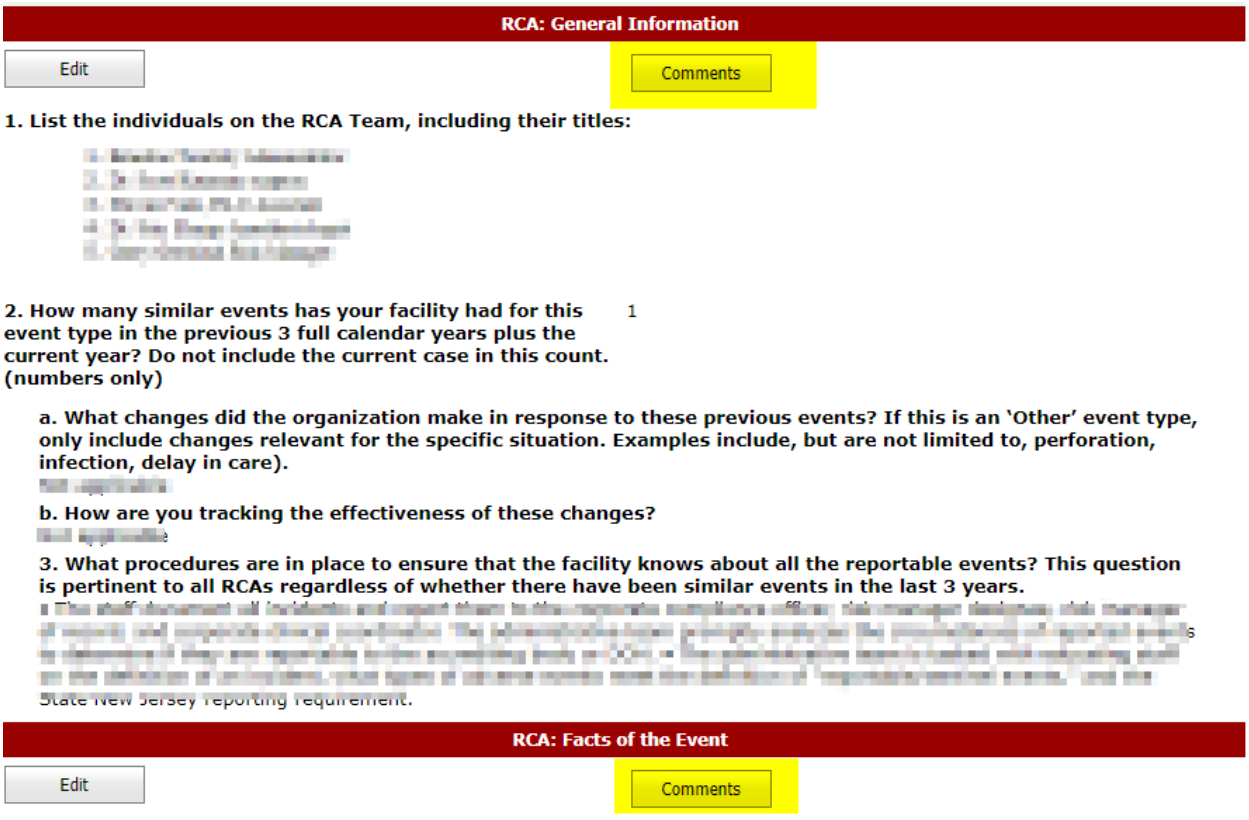
How do I count the number of similar events in the last three years?

Similar events are events within the same classification – e.g. environmental falls if the event is a fall we would look back 3 calendar years for reported falls and the present year up until the event reported. (Similar to directions when completing the report – we could also use the exact words provided in the report)

If the event seemed unique for any reason, we would still look back into the same classification.

Where do I find reviewer's comments?

Reviewer comments can be found in the different sections (RCA:General Information, RCA: Facts of the Event etc) of the RCA by looking for the "Comment" link:



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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. ***N.B. 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 less than 24 to 48 hours after a procedure or care received at a facility should be reported to the Patient Safety Reporting System (PSRS).***

"Known Complications" that should be reported to PSRS 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 such as, but not limited to, needle aspiration, incision and drainage, treatment with antibiotics, wound vacs, etc.
- Prolonged decrease in oxygenation and/or blood pressure which requires intervention.
- Wound dehiscence

Treatment may include, but is not limited to:

- Fluid resuscitation
- Unscheduled blood transfusion
- Surgery
- 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. For example, the patient arrives at the center, is placed on a monitor and is noted to be in atrial fibrillation and no anesthesia is administered, the procedure is canceled, and the patient is transferred to the hospital.

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.

XIII. Additional Guidance for Dialysis Facilities (End Stage Renal Disease—ESRD Facilities)

Questions

- What event type should be used for dialysis events?
- What should I choose for the Unit and Location of the event?
- What type of events do I need to report?
- What type of information should I include in the event report?

What event type should be used for dialysis events?

Most events from dialysis facilities would be considered "Care Management—Other" events if they are related to the patient's dialysis treatment or their course of care.

If the patient falls and sustains an injury, that would be submitted as a "Fall" event.

If the patient has an event related to low blood sugar, it should be submitted as a "Hypoglycemia" event.

If the facility is uncertain about which event type to use, please contact the Patient Safety Reporting System.

What should I choose for the Unit and Location of the event?

If the event is related to the dialysis treatment and the event occurred when the patient was in the treatment station, "Procedure Room" would be the appropriate choice for these fields.

For some events, "Hallway/Common Area" or "Patient Bathroom" might be more appropriate for the location of the event.

What type of events do I need to report?

In accordance with N.J.A.C. 8:43E-10.6(e), the dialysis facility should be reporting any adverse events where it is reasonable to assume the event is associated with the patient's course of care.

If the dialysis patient suffers cardiac arrest, becomes unresponsive, dies, has an episode of bleeding, requires blood transfusion, or requires transfer or treatment at another facility either during treatment or within 24 hours of a treatment, the event should be reported to the Patient Safety Reporting System via the online reporting system. This includes any events that occur during or related to home dialysis treatments.

Please also refer to Section III of this document for a list of other event types.

What type of information should I include in the event report?

For dialysis facilities, it is important to provide the Patient Safety Reporting System with information

regarding the patient's medical and treatment history. It is also important to include information regarding how the event impacted the patient. That means that the dialysis facility may need to obtain information from other facilities and sources to complete the event report.

The following information should be included in the event report:

- Physician's orders for the treatment that include Blood Flow Rate (BFR), Dialysis Flow Rate (DFR), Ultrafiltration Rate (UFR), duration of treatment, fluid volume to be removed. Specify if there was any deviation from the physician's orders for the treatment related to the event with the reasons for the deviations. Please refer to policies and procedures followed for any deviations to include when the physician is notified of the patient status and of any deviations from the prescribed treatment.
- The date and time when the patient was last evaluated by the nephrologist prior to the event. Please note if any changes in dialysis plans occurred based on that evaluation and what those changes were.
- The patient's Estimated Dry Weight (EDW) and when that was determined and re-evaluated.
- The last weight of the patient before and after treatment on the last date treatment was performed.
- Type of access, when it was inserted or created, and any relevant issues with that access and what actions were taken.
- What was noted on assessment of that access prior to initiation of the procedure on the day of the event.
- Any problems or issues the patient typically has during treatments.
- The time the treatment began and ended that day and whether the blood was returned from the circuit.
- The vital signs before, during, and after the procedure with the times these measurements were taken.
- The last pertinent lab values and when they were obtained and how any abnormalities were treated and when.
- Information regarding any specialists that this patient might be seeing such as cardiologists and when the last appointments were with any specialists prior to the event. Please provide any pertinent testing or recommendations related to these other specialists.
- Information regarding any recent hospitalizations prior to the event to include admission/discharge diagnoses and any new treatments, medications, or therapies.
- Medications that the patient takes at home with date and time last taken prior to the treatment. Include name of medication, dose, and route.
- Medications the patient received at the dialysis facility on the day of the treatment related to when the event occurred. Include the name of the medication, dose, route, and time of administration.
- Whether the patient was receiving any anticoagulants and any pertinent labs related to this.

NOTE: If the patient was transferred or required additional treatment at another facility, it is important to obtain the information about what happened at that other facility. Please refer to Section VII of this document for more detailed information about this.

Please do not submit an event report without including the information regarding the impact of the event on the patient and the duration of any impacts.