

## **Patient Safety Reporting System**

State of New Jersey Department of Health March 2023

**Facility User Guide** 

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#### I. Introduction

<u>The Patient Safety Reporting System</u> 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: <u>https://nj.gov/health/healthcarequality/health-care-professionals/patient-safety-reporting-system/.</u> 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

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

Logged in as: patUser	HOME	ADD EVENT	VIEW EVENTS		▼ Admin	-
Welcome to the NJ Patient Saf	ety F	Reporting	g System		USE	R MAINTENANC
NJ is committed to promoting patient safety and preventing serious preventable adverse events. In 2004, the <b>New Jersey Patient Safety A</b> (P.L. 2004, c9) was signed into law. The statute was designed to improve patient safety in hospitals and other health care facilities by establishing serious preventable adverse event reporting system. This site is designed	et a to	Search Action It	earch for R	eport by Nun	nber	
help healthcare facilities develop strong patient safety programs, collect a analyze aggregate data and fulfill the law's mandatory reporting requirem	ind ients					
Additional resources may be found on the Patient Safety website at: <u>Patie</u> <u>Safety</u>	<u>nt</u>	Report Number         Submit Date           No data to display         No				
Patient Safety Program staff are available to speak with you regarding cli questions at: 609.633.7759.	nical					
Technical staff are available to speak with you regarding any technical iss	ues					
related to the reporting system at, our our off intro.			RCA C	Comments		
		Report N	lumber	RCA Due Da	te	
			No da	ta to display		
			Other Co	mmunication	S	

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

<b>Number</b> State of New Jersey Department of Health Patient Safety Rep	orting S	ystem			
Logged in as: patUser	HOME	ADD EVENT	VIEW EVENTS 🔻	RESOURCES 🔻	Admin 🔻
Users are now required to register for access to the Patient Sa 1. Enter the email address of the person who will be registeri 2. Click "Send Email" 3. An email will be sent with a link to the registration form 4. Once the user registers they will show on the <u>User Registration</u> Email Address newUser@gmail.com Send Email	fety Repo ng ions Grid	where you ca	e <b>m.</b> In approve or de	ny access.	
Department of Health P.O. Box 360, Trenton, NJ 08625-0360 Phone:(609) 633-7759	Priv	acy Notice	Legal Statement	& Disclaimers	

- 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".

ogged in as:	patUser				HOME	ADD EVENT	VIEW EVENTS 🔻	RESOURCES +	Admin 🔻	
			Use	er Registrat	tions				USER M	AINTENAN
									USELK	(egisti ati
• In	is screen is use	d for managin	ig user reques	ts to acce	ss the	application				
							_			
							_	Show Customi	zation Dialog	
								Show Customi	zation Dialog	
#	First Name 💌	Last Name 💌	Facility Name	Email		ate Requested	Request Type Te	Show Customiz	zation Dialog Comments	
#	First Name 🖃	Last Name 💌	Facility Name	Email	Da	ate Requested	Request Type To	Show Customi Status Text	zation Dialog Comments	
#	First Name 💌	Last Name 🖃	Facility Name	Email	Da	ate Requested	Request Type To Report Reader	Status Text	Comments	

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

												Show Cus	tom	ization Dialog
#	First (	Name 🖃	Last	Name 🖃	Facility Name	e 🖸	Email		Date	Requested	Request Type To	Status Text		Comments
	Regul	ar Edit Form	User	r	TEST FACILITY		Landa		7/18/ 2:52:	/2022 :18 PM	Report Reader and Writer	Granted	×	
		Status:* Facility: Address:	-	Granted Granted Pending	×	E E	Type:*		~	Report Re	eader and Writer	~		
		First Nar Email:*	ne:=	Regular	portant.		Last Na Date Re	ime: eque	:* ested:	User 7/18/202	2 2:52:18 PM			
		Commer	its:	65164111	21		Title:			RN				
		Linai le	A.C.								Savi	e Cancel		

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.

ogged in as:	patUser			HOME	ADD EVENT V	IEW EVENTS 🔻	RESOURCES -	Admin 🝷
			User\Facil	lity Maintenance	e			User Maint
Export Data	This scre <u>Create Nev</u> <u>Show Custo</u>	een is used for m v User mization Window - L	naintaining us	ers and facilit	ies ' to add/remov	e fields from t	he grid.	
#	Detail	User Name 🖃	FirstName 🖃	LastName 🖃	Email 🖃	Phone 👻	Roles	Last Loc
ŧ	View	EKronenberger	Emily	Kronenberger	unity in each of	400-800- 7334		6/29/20
⊕	View	EKronenberger patUser	Emily pat	Kronenberger user	projementoped	400-460- 7254	facAdmin, rptWriter, rptReader	6/29/20 7/21/20
œ ₽ #	View View Name	EKronenberger patUser Address	Emily pat City	Kronenberger user State	amily branchin profilment gant Zip v	420-820- 7314	facAdmin, rptWriter, rptReader	6/29/20 7/21/20 DDATE
æ = #	View View	EKronenberger patUser Address	Emily pat City v	Kronenberger user State v	amilyloweada projemenigani Zip v	OPENDATE	facAdmin, rptWriter, rptReader	6/29/20 7/21/20 DDATE

#### 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.

Roles:	
🗹 rptWriter 🕑 rptReader	
Main Info:	
User Name	patUser
Email	pm@merrigantech.com
One time user authorization key	Merrigan1
First Name	pat
Last Name	user
Contact Number	6516411121
Is User Revoked	False
Is Approved	
Is Online	
CreationDate	7/18/2022 2:29:59 PM
LastActivityDate	7/21/2022 3:27:04 PM
LastLoginDate	7/21/2022 3:27:04 PM
Edit User Info	

Revoke User

Return

#### III. Register as a new user

#### Α. 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.
- I will only access the PSRS to obtain or submit information and to generate documentation in the official course of my duties and responsibilities.
   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 organizations 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.

agree to all the terms and condit	ions listed above:		
First Name:*			
Last Name:*			
Title:*			
Facility Name:"		~	
Address:*			
Email:*			
Phone Number:*			
sking	Type the code shown:		
C 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.

	Registration Information	
usiness Name	Test Facility	
Contact Name	Test User	
mail Address	Test@gmail.com	
Reenter Email Address	Test@gmail.com	The email will
Jser ID		contain the
one time user authorization key		information to populate these two
Submit Registration	-	fields

- 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".

Request access to Patient Safety Reporting		2. Link your Patient Safety Reporting service to your myNewJersey account			
Use this page to tell us about your	myNewJersey account by picking one of the t	hree choices below:			
A. I already have a myNewJer	sey account. Link it to my DOH Patient Sa	afety Reporting information:			
My Log On ID is	and my password is	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".

B. I don't have a mylle	wJensey account yet, IT	Il create a new one now and link it to my COII Patient Safety Reporting Information:		
Pick a Log On ID		Fyre legel your password later, we'll ask you the following question. Fyre	over it correctly, we'll send a new password h	r your email address.
Pick a password		Question you want us to ask		
Retype your passwood		Your arrayor		
First.tame	Regder	Enal address	ulemon@gmail.com	
Last name	User	Ratype your email address	ulemon@gmail.com	
		* All items in ID are required if you're creating a new account. Your name and email address are Wed in based or	top 1, but ignore there and use choice A inst	sat if you already have a myllendersey account.
		Use choice C below if you can't remember your Log On ID	fease don't create arother new account.	
		Faster your information and be sure it's correct before	ov click the Course Account button	
		Create this new myllex-densey Account and Lin	where Safety Reporting To R	

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

State of New Jersey Department of Health Patient Safety Reporting System					
	Welcome				
:	You have successfully linked your portal ID to the DOH Patient Safety Reporting System Any future access to this application must be made through the portal Click <mark>HERE</mark> to go to your portal page				
epartmen O. Box 36 hone:(609	nt of Health D, Trenton, NJ 08625-0360 ) 633-7759				

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.

OFFICIAL SITE OF THE STATE OF NEW JERSEY		Governor Phil Murphy • Lt. Governor Sheila Oliver NJ.gov   Services   Agencies   FAQs
		Welcome pat: logout   my.account   auth code   layout   help
Increase the security of your account: myNJ n click 'Multi-factor authentication' to enable it.	ow supports authenticator apps in addition to SMS texts;	if you haven't already activated MFA, go to your $\underline{my_{account}}$ page and
DOH Applications Select a link below to access the application:	New Jansey Events	nts I Travel & Tourism Home I Add an Event
DOH Patient Safety Reporting System		

#### 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 (<u>https://my.state.nj.us/aui/Login</u>)
- 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.

2

### 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 webbased 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.

ogged in as: pMerriganTest	Home	ADD EVENT	VIEW EVENTS	RESOURCES -	Admin
Welcome to the NJ Patient	t Safety I	Reporting	g System		
J is committed to promoting patient safety and preventing serious reventable adverse events. In 2004, the <b>New Jersey Patient Sa</b> P.L. 2004, c9) was signed into law. The statute was designed to im atient safety in hospitals and other health care facilities by establi- erious preventable adverse event reporting system. This site is de	Search Action It	earch for Re	port by Numb	er	
elp healthcare facilities develop strong patient safety programs, co nalyze aggregate data and fulfill the law's mandatory reporting rec	ollect and quirements		Initial Eve	nt Comments	
dditional resources may be found on the Patient Safety website at a <u>fety</u>	ources may be found on the Patient Safety website at: Patient				
atient Safety Program staff are available to speak with you regard uestions at: 609.633.7759.	ing clinical		No data	a to display	
echnical staff are available to speak with you regarding any techni	cal issues				
elated to the reporting system at: 651-659-1419.			RCA C	omments	
		Report N	lumber	RCA Due Date	
			No data	a to display	

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.

	Home	ADD EVENT	VIEW EVENTS 🔻	RESOURCES	•	Adm	nin 🔻	
		Home     ADD EVENT     VIEW EVENTS     RESOURCES     Admin       fety Reporting System     USER MAINTENANCE						
S	afety F	Reporting	j System				USER REGISTRATION	

- 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.

Logged i	n as: patUser		Н	OME ADD EVENT	VIEW EVENTS 🔻	RESOURCES	▼ Admin ▼
Select R	• You can filter records by c • You can sort the data by c • Show Customization Window- • Click HERE to clear filter eport Year: 2022 ~ Development	licking the graph licking on the colu Use the 'Customiza nt Version:Not for producti	mn headers ation Window' to ad jon use. 1 🛄 Care Mar 1 🛑 Care Mar	Id/remove fields f nagement - Medication E nagement - Pressure Uk	rom the grid. Fror Sers		
a 🥥 🥟.nel	t Charting	For	r more information visit <u>ht</u>	tp://www.dotnetchartin	iq.com		
Details Facility Name Report Number Event Status Event Type Event Descrip							
			Event-Facility Edit	Care Manageme	when Mandlandian Eu	ror Dec	
Details	TEST FACILITY-FORT LEE	20220134	Event racincy Earc		ent - Medication Er		cription
Details Details	TEST FACILITY-FORT LEE TEST FACILITY-FORT LEE	20220134 20220135	Event-Facility Edit	Care Manageme	ent - Pressure Ulce	ers <u>Des</u>	cription
Details Details	TEST FACILITY-FORT LEE TEST FACILITY-FORT LEE	20220134	Event-Facility Edit	Care Manageme	ent - Pressure Ulce	ers <u>Des</u>	<u>cription</u>

## 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.

	New Jersey Department of H	State of I Departm	New Jersey ent of Health Patient :	Safe	ty Reporting Sys	tem			
	Logged in as:	patUser			HOME	ADD EVENT	VIEW EVENTS 🔻	RESOURCES +	Admin 🔻
Saved Reports           Delete         2022PressureUlcers	× You • Sho • Sav	u can sort the d w <u>Customization W</u> red <u>Reports</u> - Clic re a <u>Report</u> - Clic	ata by clicking on the colu findow - Use the 'Customiz: k to view your saved repo k to save the report.	mn h ation rts.	eaders Window' to add/rem	ove fields	from the grid.		
	Export	to Excel							
			😰 Show Custo	Patient Safety Reporting System         Image: Control of the system         the column headers         Customization Window' to add/remove fields from the grid.         aved reports.         ort.         Show Customization Dialog         © Column Chooser         © Clear Filter         © Search Panel         © Care Management - I         ORT LEE         Care Management - I         ORT LEE         Care Management - 20220135         Event-Facility Edit         DRT LEE         Care Management - 20220136         Event-Facility Edit         DRT LEE         Care Management - 20220136         Event-Facility Edit         Dressure Ulcers         20220136         Event-Facility Edit         Dressure Ulcers         Clear					
	View	Report Year 💌	Facility Name	-	Event Type	<ul> <li>Report</li> </ul>	Number	Event Status	; –
	Clear	2022		Ŷ	Care Management - I	8		7	Ŷ
	Detail 🔓	2022	TEST FACILITY-FORT LEE		Care Management - Pressure Ulcers	20220	135	Event-Facilit	y Edit
	Detail	2022	TEST FACILITY-FORT LEE		Care Management - Pressure Ulcers	20220	136	Event-Facilit	y Edit
	Page 1 of 1 (2 it	ems) < [1] >							
	▼ ¶[Report ]	Year] Equals '2022	' And [Event Type] Equals 'Care	Mana	gement - Pressure Ulcer	<u></u>		arch Panel Group Panel Event Status Clear	
			t the data by clicking on the column headers ixaton Window - Use the 'Customization Window' to add/remove fields from the grid. the - Click to view your saved reports. th - Click to save the report. Show Customization Dialog Column Chooser Clear Filter Click Search Panel Group Panel Year  Facility Name  Event Type  Report Number  Event Status  Care Management - 1  Care Management - 1  Care Management - 20220135 Event-Facility Edit 2022 TEST FACILITY-FORT LEE Care Management - 20220135 Event-Facility Edit 2022 TEST FACILITY-FORT LEE Care Management - 20220136 Event-Facility Edit 1] Care Management - Pressure Ulcers. Clear						
	Department of P.O. Box 360, Phone:(609) 6	of Health Trenton, NJ 086 33-7759	25-0360		Privac	Notice	Legal Statement	& Disclaimers	

### 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.

New Jersey Department of	State of N Departme	lew Jersey ent of Health	Patient Safe	ety Reporting	g System			
Logged in as	: patUser			ног	ME ADD EVENT	VIEW EVENTS 🔻	RESOURCES 🔻	Admin 🔻
*Use the 'Sh Event Year 2 Export to XLSX Show	ow Customizati	ion Dialog' op	tion below to	add or remov	e columns			
#	Event Status 🔻	Report Year 🖃	Report Number	Insert Date 🖃	Insert User ID [	Event Classifica	Reportable Ever	Submitted By [
	Ŷ	Ŷ	Ŷ	~ 🕈	7	7	7	9
	Submit Event	2022	20220135	8/1/2022	patUser	Care Management - Pressure Ulcers		

## 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.

Nite attack of New Jersey Department of Health Patient Safety Report	rting S	ystem				
ogged in as: patUser VIEW EVENTS						Admin 🔻
- You can part the data by clicking on the column beaders					INFORMAT	ION CONSULTED
<ul> <li>Show Customization Window - Use the 'Customization Window' t</li> </ul>	o add/re	move fields	from the arid.	Im	REPORT Q	UESTIONS
Saved Reports - Click to view your saved reports.						DE
<ul> <li><u>Save a Report</u> - Click to save the report.</li> </ul>						

- These are the questions that are required in order to submit an Event/RCA
- Click on the tab below to change between Initial Event and RCA
- Choose an item from the dropdown to see Event/RCA specific questions

Event Specific Questions	View Inital Event Questions
Event Specific Questions	
Care Management - Other	
Care Management - Medication Error	
Care Management - Pressure Ulcers	
Environmental - Other	
Environmental - Burn	
Environmental - Fall	
Environmental - Restraints	
Product/Device - Malfunction	
Patient Protection - Suicide\Attempted Suicide	
Surgical - Retained Foreign Object	
Surgical Intro/Post On Comp or Dooth	
Surgical - Initia/Fust-Op Conta of Death	

- 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: <u>http://nj.gov/</u> 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: <u>https://www.nj.gov/health/healthcarequality/health-careprofessionals/patient-safety-reporting-system/voluntary\_anonymous\_reporting.shtml</u>

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?

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

- 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."

ged in as: patl	Jser			HOME	ADD EVENT	VIEW EVENTS	•	RESOURCES 🔻	Admin
<ul> <li>Click <u>HE</u></li> <li>Click <u>HE</u></li> </ul>	<u>RE</u> to send D RE to see the	OH a comn Communi	nent <mark>cation Log</mark>						
Initial Event	Root Cause	Analysis							
eport Menu:	Communication	Log				æ		×	
port Numbe			Commu	nication Log					
ent Classific	Click <u>HERE</u>	to view al	ll comments					Print Se	creen
	Added by	Date	Communication Type	Description					
cility name: tient type:	patUser	8/1/2022	Event Entry	Report Number Email Text Service Servi	dmiss	sion			
st name:								_	
st name:									
tient billing									
eet Address									
ite:									
te of Birth									
ce:									
nicity:									
-	Click and drag to	o expand						.:	

 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 <u>should not be sent via comment in the Communication Log</u> 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":

Report Menu:	General Info	Facts of Event	RCA Questions	Root Cause\Action Plan	Additional Questions	→ Submit RCA
Report Number: 2	0220135					
vent Classificatio	on: Care Manag	ement - Pressi	ure Ulcers			Print Screen
	-		RCA: Gene	ral Information		
L. List the individu	uals on the RC	A Team, Inclu	uding their tit	les:		
. How many simi vent type in the urrent year? Do i numbers only)	lar events has previous 3 ful not include th	s your facility I calendar yea e current cas	had for this ars plus the e in this coun	0 <b>t.</b>		
a. What chang only include cl infection, dela	es did the org nanges releva y in care).	anization ma nt for the spe	ke in respons cific situatior	e to these previous 1. Examples include,	events? If this is a but are not limited	n `Other' event type, l to, perforation,
b. How are you	ı tracking the	effectiveness	s of these cha	nges?		
3. What proceed is pertinent to	dures are in p all RCAs rega	lace to ensure rdless of whe	e that the fac other there ha	ility knows about al ve been similar eve	the reportable events in the last 3 yes	ents? This question ars.
			RCA: Fac	ts of the Event		
Edit			(	Comments	J	
L. Facts of the Eve	ent (Answer a	ll that apply o	or enter 'NA' v	where not applicable	e):	
a. Patient's pa	st medical an	d surgical his	tory:			
b. Clinical stat	us of patient	orior to event				
c. Clinical state	us of patient a	fter the even	it:			

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

Logged in as:	HOME	ADD EVENT	VIEW EVENTS	•
<ul> <li>Click <u>HERE</u> to send DOH a comment</li> <li>Click <u>HERE</u> to see the Communication Log</li> <li>Click <u>HERE</u> to view all comments</li> </ul>				
Initial Event Root Cause Analysis				

• 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.

ogged in as: patUser	Home	ADD EVENT	VIEW EVENTS	* RESOURCES	•	Admin	
Welcome to the NJ Patient S	Safety I	Reportin	g System				
IJ is committed to promoting patient safety and preventing serious reventable adverse events. In 2004, the <b>New Jersey Patient Safe</b> P.L. 2004, c9) was signed into law. The statute was designed to impr atient safety in hospitals and other health care facilities by establish erious preventable adverse event reporting system. This site is desig	<b>ty Act</b> ove ing a ined to	Search for Report by Number Search Action Items					
elp healthcare facilities develop strong patient safety programs, colle nalyze aggregate data and fulfill the law's mandatory reporting requi	ect and irements	Initial Event Comments					
dditional resources may be found on the Patient Safety website at: <u>a</u>	Patient	Report	Number	Submit D	ate		
atient Safety Program staff are available to speak with you regarding uestions at: 609.633.7759.	g clinical	No data to display					
echnical staff are available to speak with you regarding any technica elated to the reporting system at: 651-659-1419.	l issues	RCA Comments					
		Report	Number	RCA Due E	ate		
		2022	20135	9/15/20	22		
]	ъ́						
			Other Co	nmunicatio	ns		
		Report	Number Resp	ond Co	mmer	nt	
			No da	a to display			

- 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. <u>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.</u> 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.

iged in as: patUser	HOME	Add Event	VIEW EVENTS 🔻	RESOURCES -	Admin
Sele	ct Event Type				
1. Select an Adverse Event Type 2. Click the "Continue" button					
Adverse event type: Care Management - Medication Error Care Management - Wrong Blood Product Care Management - Maternal Labor Care Management - Hypoglycemia Care Management - Neonate Hyperbilirubinemia Care Management - Pressure Ulcers Care Management - Spinal		Click <u>HERE</u>	for a complete li	st of Event Typ	es ontinue>
<b>Dartment of Health</b> . Box 360, Trenton, NJ 08625-0360 ne:(609) 633-7759	Priv	acy Notice	Legal Statement	& Disclaimers	

#### **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.

Logged in as: patUser	HOME ADD EVENT VIEW EVENTS - RESOURCES - Admin -
	Patient Information
Facility name:	TEST FACILITY-FORT LEE 🗸
Patient type:	Please Select
First name:	
*Middle name:	
Last name:	
Patient billing number:	
Medical record number:	
Street Address:	
City:	
State:	
Zip code:	
Date of Birth:	Month:     Day:     Year - (e.g. 2010):       Please Select V     Please Select V
Gender:	OMale OFemale
Race: 🥺	Please Select
Ethnicity: 🥹	Please Select
Admission date or date of ambulatory encounter relevant to when the event occurred (mm/dd/yyyy):	*Admitting ICD Code:
Main Reason for admission or ambulatory	encounter relevant to when the event occurred: ${oldsymbol arepsilon}$
300 Characters left	
	*denotes fields that are not required

**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 (<u>using the same</u> <u>Report Number</u>) 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.

Event Classific	ation: Care Ma	nagement - Pressure	Ulcers			
			Event In	ormation		
Event date: Date any healthcare professional discovered the event	If event da	ite is unknown, check	here	Enter Event Time in Military (e.g 1800=6:00PM), if not known, enter 'unknown' Discovery Time in Military (e.g 0200=2:00AM)		
How was the e	event discover	ed?	Please Selec	t	~	
In what unit d	id the event o	ccur?	Please Selec	t		~
In what locatio	on did the eve	nt occur?	Please Selec	t 🗸		
Location of ini	ury (check as	many as apply):				
Abdomen Ankle Back/spine Buttocks Chest Clavicle Elbow Forearm Hand Other:	<ul> <li>Head</li> <li>Foot</li> <li>Hip</li> <li>Lower Leg</li> <li>Lower Arm</li> <li>Knee</li> <li>Neck</li> <li>Pelvic Region</li> <li>Sacrum</li> </ul>	Shoulder  Upper Arm  Upper Leg  Wrist Other Unresponsiveness No Injury Systemic				
Death	ury (check as	many as apply):	mobilization			
□Increased le	ngth of stay is a	anticipated 🗌 Minor in	jury			
Increased lev	vel of care	🗌 No appa	arent injury			
□ Surgery is re	equired					
Please supply	a description	of the event or situa	ntion you are	reporting including	the impact o	n the patient: -
X	0 6 🖻	A A A A A A A A A A A A A A A A A	2   1   0   <b>2</b>	I I   🔒 🔒   💱	53	
Aria	il •	(Font Size) 🗸	B I U	\$ ≣ ≞ ≣ ≣	i   🖗 🔹	

Continued next page

Immediate clinical action(s) ta	ken for patient:
	·
1000 Characters left	
india characters lett	
Immediate <u>new</u> corrective acti	on(s) to prevent future similar events in all patients while the RCA is underway:
1000 Characters left	
location of prossure ulcor (ch	nck at least one):
	et at least one).
Buttocks	
Stage	Please Select 🗸
Size of pressure ulcer:	
Was this a device related pressure ulcer?	⊖Yes ⊖No
Nas the patient or health care notified about the event within event discovery?	representative     OYes ONo       24 hours of     OYes ONo
	*All Fields are Required Save/Next

#### 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." <u>NOTE: If you</u> 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.

Logged in as: patUser	HOME	ADD EVENT	VIEW EVENTS	SOURCES	r Admin ▼
<ul> <li>Use the 'Report Menu' below to navigate this event.</li> <li>The menu will expand as the Event/RCA progresses</li> <li>Click on the link next to the red arrow to continue entering</li> <li>Click on the appropriate link below to edit information</li> <li>Click <u>HERE</u> to send DOH a comment</li> <li>Click HERE to see the Communication Log</li> </ul>	informa	tion			
Initial Event Root Cause Analysis					
Report Menu:					
Report Number: 20220134					
Event Classification: Care Management - Medication Error				Print	Screen
Patient Infor	mation				

#### 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.

Logged in as: patUser	HOME ADD EVENT	VIEW EVENTS 🔻	RESOURCES 🔻	Admin 👻
<ul> <li>Use the 'Report Menu' below to navigate this event.</li> <li>The menu will expand as the Event/RCA progresses</li> <li>Click on the link next to the red arrow to continue entering</li> <li>Click on the appropriate link below to edit information</li> <li>Click <u>HERE</u> to send DOH a comment</li> <li>Click <u>HERE</u> to see the Communication Log</li> </ul> Please click the 'Submit' tab below to notify DOH that this event Initial Event Root Cause Analysis	information <u>is ready for reviev</u>	<u>v</u>		
Report Menu:         Patient Info         Event Info         → Submit Event				
Report Number: 20220134				
Event Classification: Care Management - Medication Error			Print So	reen

#### 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.

ogged in as: patUser	Home	ADD EVENT VIE	V EVENTS 🔻	RESOURCES 👻	Admin
Welcome to the NJ Patie	ent Safety F	Reporting Sy	stem		
NJ is committed to promoting patient safety and preventing series preventable adverse events. In 2004, the <b>New Jersey Patient</b> (P.L. 2004, c9) was signed into law. The statute was designed to patient safety in hospitals and other health care facilities by esta serious preventable adverse event reporting system. This site is help healthcare facilities develop strong patient safety programs	ous Safety Act improve iblishing a designed to , collect and	Search Action Items	h for Repoi	rt by Numbe	er
analyze aggregate data and fulfill the law's mandatory reporting	requirements	In	tial Event (	Comments	
Additional resources may be found on the Patient Safety website Safety	at: <u>Patient</u>	Report Numb	er	Submit Date	
Patient Safety Program staff are available to speak with you rega questions at: 609.633.7759.	arding clinical	<u>20220137</u>		8/1/2022	
Technical staff are available to speak with you regarding any tec	hnical issues		RCA Com	ments	
related to the reporting system at: 651-659-1419.		Report Numb	er F	RCA Due Date	
		20220135		9/15/2022	
		Ot	her Commu	unications	
		Report Numb	er Respond	Comme	nt
			No data to	display	

• 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.

Event Classification: Care I	Management - Pressu	re Ulcers		Print Screen
		Patient Inf	ormation	
Edit		ſ	Comments	
Facility name:		TEST FACILITY-F	ORT LEE	
Patient type:		Inpatient		
			Admission through:	Direct Admission
First name:		LUCY	*Middle name:	
Last name:		USER		
Patient billing number:		10046542	Medical record number:	44289007
Street Address:		1234 West 4th	City:	Trenton
State:	N	L		
County:	2	ATLANTIC	Zip code:	22234
Date of Birth:		4/13/1998	Gender:	Female
Race:		Black		
Ethnicity:		Non- Hispanic/Unable to Determine		

- 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.

Arrivy Department of Health Patient Safety Reporting Sy	ystem			
ogged in as: patUser Home	ADD EVEN	VIEW I	EVENTS 🔻	RESOURCES - Adm
Welcome to the NJ Patient Safety I	Reporti	ng Sys	tem	
J is committed to promoting patient safety and preventing serious		Search	for Rep	ort by Number
reventable adverse events. In 2004, the <b>New Jersey Patient Safety Act</b> P.L. 2004, c9) was signed into law. The statute was designed to improve	Search			
atient safety in hospitals and other health care facilities by establishing a rious preventable adverse event reporting system. This site is designed to	Action	Items		
elp healthcare facilities develop strong patient safety programs, collect and halyze aggregate data and fulfill the law's mandatory reporting requirements		Initi	ial Event	Comments
Iditional resources may be found on the Patient Safety website at: Patient	Repor	rt Number		Submit Date
i <u>tety</u> itient Safety Program staff are available to speak with you regarding clinical			No data t	o display
lestions at: 609.633.7759.				
chnical staff are available to speak with you regarding any technical issues ated to the reporting system at: 651-659-1419.			RCA Cor	nments
	Repor	rt Number		RCA Due Date
	20	220135		9/15/2022
		Oth	er Comn	nunications
	Repor	rt Number	Respond	d Comment Report
	20	<u>1220137</u>	Respond	Email Text Sent t Facility: There is a new comment available from the Patient Safety Reporting System. Please log into the web based system and check the Communication Log to review the comment and respond accordingly Reviewer Comments: Please explain how gas delivery will be checked'
Click on "Respond" to enter a response	Report	Number 20135	CA COIIII	ILEIILS CA Due Date 9/15/2022
Reviewer Comments Report Number: 20220137				
Email Text Sent to Facility: There is a new comment available from the Patient Safety Reporting System, Please		Othe	r Commu	nications
log into the web based system and check the	Report	Number	Respond	Comment
accordingly." Reviewer Comments: 'Please explain how gas delivery will be checked' Check Spelling	202	<u>20137</u>	Respond	Number:20220137 Email Text Sent to Facility: There is a new comment available from the Patient Safety Reporting System. Please log into the web based system and check the Communication Log to review the comment and respond accordingly.
Cancel\Close Send Response				Reviewer Comments:'Please explain how gas

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

Click and drag to expand

#### 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 <u>if the facility chooses to do so</u>. 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.

Logged in as:	patUser			HOME	ADE	VIEW EVENTS	•	RESOURCES 👻	Ac	lmin	•
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Expor	t to Excel										
		Show Custo	mizatio	on Dialog 🛛 🛅 Column C	Choo	oser 🛛 🛣 Clear Filter 🤅	🔍 Sea	erch Panel  🖶	Grou	p Pan	el
View	Report Year 👻	Facility Name	-	Event Type	-	Report Number	-	Event Status	5	ŀ	
<u>Clear</u>	Ŷ	test	9		9		Ţ				Q, Enter text to filter
<u>Detail</u>	2022	TEST FACILITY-FORT LEE		Care Management - Pressure Ulcers		20220136		Event-Facilit	y Edi	t	(Select All)
<u>Detail</u>	2022	TEST FACILITY-FORT LEE		Care Management - Medication Error		20220134		Event-Facilit	y Edi	t	Event-DOH Review     Event-Facility Edit
<u>Detail</u>	2022	TEST FACILITY-FORT LEE		Care Management - Pressure Ulcers		20220135		RCA-Facility	Edit		RCA-Facility Edit
<u>Detail</u>	2022	TEST FACILITY-FORT LEE		Care Management - Pressure Ulcers		20220137		Event-DOH F	Revie	w	VS OK Cancel
Page 1 of 1 (4 i	tems) < [1] >									L	
✓ ♥ Begins	with([Facility Name	] <u>, 'test')</u>								Cl	ear

- Click on "Detail" for the event to begin the RCA entry process.
- Then click on Root Cause Analysis
- Screen displayed below is shown:

Logged in as: patUser	HOME	ADD EVENT	VIEW EVENTS	•	RESOURCES	•	Admin	•
<ul> <li>Use the 'Report Menu' below to navigate this event.</li> <li>The menu will expand as the Event/RCA progresses</li> <li>Click on the link next to the red arrow→ to continue entering</li> <li>Click on the appropriate link below to edit information</li> <li>Click <u>HERE</u> to send DOH a comment</li> <li>Click <u>HERE</u> to see the Communication Log</li> </ul>	informa	tion						
Initial Event Root Cause Analysis								
Report Menu:								
Report Number: 20220134								
Event Classification: Care Management - Medication Error					Pri	nt Sc	reen	

- 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.

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t Number: 20220	134								
Classification: Ca	are Manageme	nt - Medica	ion Error						
			RCA: Gener	ral Informatio	n				
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#### 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.

<ul> <li>Click <u>HERE</u> to send DOH a comment</li> <li>Click <u>HERE</u> to see the Communication Log</li> <li>Click <u>HERE</u> to view all comments</li> </ul>	
Initial Event Root Cause Analysis	
Report Menu:	
Report Number:	
Event Status: General Info	
Event Classification: Surgical - Intra/Post-Op Coma/Death/Other Event	Print Screen
Patient Information	
* ( HOV HE HE FO GOD FRO COMMUNICATION LOG	
Comments	×
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PARK suggests that the healty perform an exercise text for this event.	
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Click here to acknowledge comments	*
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	RCA: Facts of the Event
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2000 dditic ality itting Aria A	Characters	left rmation: should b how the facility d was not included $R \approx   R   X^2$ (Font Size)	e clearly s letermined in the ini x,   = = =   B I	stated a d certai tial eve 는 I 亚 민 숙	and in chro n processo ent submis 로   @ @ &   E = E	onologica es did no sion.(Th : 3	ation ab al order: t contrib is is an u a b b b b c c c c c c c c c c c c c c c	Indicate future to the nlimited for the	g. Please he potent event. In ext field.)	ial areas of clude the
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2000 dditicy alitting Aria A	Characters	left rmation: should b how the facility d was not included was not included (Font Size)	e clearly s etermined in the ini x,   j =	stated a d certain tial eve 는 한 편 인 (	and in chra n processa int submis 호텔   윤 ( 용   트 프 용   트 프	anologica es did no sion.(Th = = = =	ation ab al order: t contrib is is an u		g. Please he potent event. In ext field.)	ial areas of clude the
2000 dditic Aria A	Characters	left rmation: should b how the facility d was not included was not included (Font Size)	e clearly s eterminec i in the ini X,   = = =   B I	stated a d certain tial eve E   E   U d	and in chro n processo ant submis al   s   t t t t	onologica es did no sion.(Th : = = =	al order: t contrib is is an u	Indicate 1 ute to the nlimited	g. Please	ial areas of

**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.

NJHeatth Nww Jenney Department of Health Patient Safety Reporting System								
Logged in as: patUser	HOME	ADD EVENT	VIEW EVENTS 🔻	RESOURCES	•	Admin 🔻		
Invalid Submission     Please return to the RCA:Facts of the Event and complete all fields     Enter 'NA' where not applicable     Click <u>HERE</u> to return to the RCA: Facts of the Event								
Department of Health P.O. Box 360, Trenton, NJ 08625-0360 Phone:(609) 633-7759	Priv	acy Notice	Legal Statemen	t & Disclaim	ers			

### **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

	mc Questions
<ol> <li>Does your facility have a fall team that regularly evaluate yours falls program?</li> </ol>	Yes O No
2. Was a Fall Risk Screening documented at admission?	⊖Yes ⊖No
3. When was the most recent fall assessment done prior to	o the Date:
fall?	Time: Enter Time in Military
	(e.g 1800=6:00PM)
4. Was a validated, reliable fall risk screening tool used?	○Yes ○No
5. Did the screening tool indicate that the patient was at ris a fall?	sk for Oyes ONO ONA
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	
Lignting was adequate     Ratient room close to purse's station	
Personal alarms on and functioning	
Room clear of clutter	
7. Was patient re-evaluated: a. During each nursing shift?	
b. Upon transfer between units?	
c. Upon change in status?	
d. Post-fall?	O Yes O No O NA
	O Yes O No O NA
<ol><li>Was there a visual indication alerting staff to patient's at status?</li></ol>	CYes ONO
9. Was a fall prevention intervention plan documented?	⊖Yes ⊖No
10. Did the intervention plan focus on the patient's specific factors?	c risk Oyes ONo
11. Was patient/family education completed?	○Yes ○No
12. When was patient rounding last conducted for this patient	ent to Please Select V
check for pain, positioning and toneting?	
13. Was the following equipment used to reduce falls for this	is patient <u>at the time</u> of the event :
a. Side rails in proper position?	is patient <u>at the time</u> of the event : Oyes ONo ONA
a.eck for pain, positioning and concurry 13. Was the following equipment used to reduce falls for this a. Side rails in proper position? b. Were restraints used?	is patient <u>at the time</u> of the event : Ores ONO ONA Ores ONO
13. Was the following equipment used to reduce falls for this a. Side rails in proper position? b. Were restraints used? c. If no, were restraints considered?	is patient <u>at the time</u> of the event : OYES ONO ONA OYES ONO OYES ONO OYES ONO
a.eck for pain, positioning and concurry r 13. Was the following equipment used to reduce falls for this a. Side rails in proper position? b. Were restraints used? c. If no, were restraints considered? d. Was the pt wearing non-skid foot wear?	is patient <u>at the time</u> of the event : OYES ONO ONA OYES ONO OYES ONO OYES ONO OYES ONO
<ul> <li>check for pain, positioning and concurring:</li> <li>13. Was the following equipment used to reduce falls for this</li> <li>a. Side rails in proper position?</li> <li>b. Were restraints used?</li> <li>c. If no, were restraints considered?</li> <li>d. Was the pt wearing non-skid foot wear?</li> <li>e. Did foot wear fit properly?</li> </ul>	is patient <u>at the time</u> of the event : Yes       No       NA         Yes       No       Yes
<ul> <li>check for pain, positioning and concurring:</li> <li>13. Was the following equipment used to reduce falls for this</li> <li>a. Side rails in proper position?</li> <li>b. Were restraints used?</li> <li>c. If no, were restraints considered?</li> <li>d. Was the pt wearing non-skid foot wear?</li> <li>e. Did foot wear fit properly?</li> <li>f. Other</li> </ul>	is patient <u>at the time</u> of the event : Yes No NA Yes No Yes No Yes No Yes No Yes No
<ul> <li>Lack for pain, positioning and tonening:</li> <li>13. Was the following equipment used to reduce falls for this</li> <li>a. Side rails in proper position?</li> <li>b. Were restraints used?</li> <li>c. If no, were restraints considered?</li> <li>d. Was the pt wearing non-skid foot wear?</li> <li>e. Did foot wear fit properly?</li> <li>f. Other</li> <li>14. Was the patient on culprit medication within 6 hours of the Ever Section question #2.</li> </ul>	the nt Oyes ONO
<ul> <li>Lack for pain, positioning and tonening:</li> <li>13. Was the following equipment used to reduce falls for this</li> <li>a. Side rails in proper position?</li> <li>b. Were restraints used?</li> <li>c. If no, were restraints considered?</li> <li>d. Was the pt wearing non-skid foot wear?</li> <li>e. Did foot wear fit properly?</li> <li>f. Other</li> <li>14. Was the patient on culprit medication within 6 hours of the larger address this issue in the Facts of the Eversection #2.</li> <li>15. Patient Characteristics (check all that apply):</li> </ul>	the organization of the event :
<ul> <li>Later tor pain, positioning and concurring:</li> <li>L3. Was the following equipment used to reduce falls for this <ul> <li>a. Side rails in proper position?</li> <li>b. Were restraints used?</li> <li>c. If no, were restraints considered?</li> <li>d. Was the pt wearing non-skid foot wear?</li> <li>e. Did foot wear fit properly?</li> <li>f. Other</li> </ul> </li> <li>14. Was the patient on culprit medication within 6 hours of the fail? If yes, please address this issue in the Facts of the Eversection question #2.</li> <li>L5. Patient Characteristics (check all that apply):</li> <li>Uses a hearing aid or hard of hearing</li> </ul>	the nt OYes ONO
I.3. Was the following equipment used to reduce falls for this a. Side rails in proper position? b. Were restraints used? c. If no, were restraints considered? d. Was the pt wearing non-skid foot wear? e. Did foot wear fit properly? f. Other I.4. Was the patient on culprit medication within 6 hours of t all? If yes, please address this issue in the Facts of the Ever section question #2. I.5. Patient Characteristics (check all that apply): Uses a hearing aid or hard of hearing Uses eye glasses or visually impaired	the of the event :
	the of the event :
	the mt
	the nt OYes ONO
	the nt Oyes ONO
	the of the event :
	is patient at the time of the event : Yes       No       NA         Yes       No       Yes         Yes       No       Yes         Yes       No       Yes         Yes       No       Yes         Yes       No       NA
	the original and confusion be barriers and confusion be barriers
	the organism and confusion experiments experiments and confusion experiments exp
	is patient at the time of the event : Yes       No         Yes       Yes         Yes       Yes         Yes

#### 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.

Logged in as: patUser		HOME	ADD EVENT	VIEW EVENTS 🔻	RESOURCES 👻	Admin 🔻
Report Menu:	Return to Detail					
Report Number: 20220138						
Event Classification: Environmental - Fall						
	RCA: Root Cause	e/Causality Stat	ement			
<ol> <li>Use this section to enter the</li> <li>Select the first root cause be statement.</li> <li>Click Save/Next</li> </ol>	root cause findings low and enter the o	s corresponding	causality		Using the Five Causation	<u>Rules of</u>
1. Root Cause Categories:						
O Behavioral assessment process	○ Staffing levels					
O Patient identification process	O Competency asse	ssment/credent	ialing			
O Care planning process	$\bigcirc$ Communication w	vith patient/fami	ily			
$\bigcirc$ Orientation and training of staff	$\bigcirc$ Availability of info	rmation				
$\bigcirc$ Supervision of staff	○ Equipment mainte	enance/manage	ment			
$\bigcirc$ Communication among staff members	$\bigcirc$ Security systems	and processes				
○ Adequacy of technical support	$\bigcirc$ Labeling of medic	ations				
$\bigcirc$ Control of medications(Storage/access)	O Physical environm	nent				
○ Physical assessment process	Other					
○ Patient observation procedures					-0	
If 'Other', please identify Root Cause						
2. Causality Statement:						
2000 Characters left				4		

Save/Next

#### 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 <u>section</u>. 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

Report Number: 20220138	
Event Classification: Environmental - Fall	

Causality Statement: The lack of a consistent process for medical order transcription has the potential for medical transcription error and allows for barriers.

- Enter the Action Plan for the causality statement displayed above
- Complete all RCA: Action Plan fields
- If more than one methodology is required (i.e. chart review and observational audits) a separate Action Plan is required for each.

See next screen for instructions on adding a new action plan.

Click 'Save/Next' when finished

RCA: Action Plan

1. Action Plan:

2.

2000	Characters left	
2000	Characters left	
2000	Characters left og Strategy: 🚱	

2000 Characters left

3. Methodology 🥝	Please Select				
4. Frequency 🥝	Please Select V				
5. Sample Size 🥺					
6. Implementation Start Date 🥝					
7. Staff position responsible for implementation:					
2000 Characters left					
8.Duration: 🥹					
9. Goal 😢	Please Select V				
10. Threshold 🤨	Please Select ✔				
11. How will effectiveness be monitored over time? : ${oldsymbol{arepsilon}}$					
2000 Characters left					
12. How will the Action Plan be communicated within a	nd across departments? :				

2000 Characters left

\*All Fields are Required Save/Next

 $\bigcirc$ 

#### 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."
  - o 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.

New Je	Healt President of Healt	State o Depart	f New Jersey ment of Health	n Patient	t Safety Repor	ting Sy	ystem				
Log	ged in as: p	oatUser				HOME	ADD EVENT	VIEW EVENTS 🔻	RESOURCES -	Admir	n ∓
Re	eport Menu	Retu	rn to Detail								
Re	port Numb	<b>er:</b> 2022013	38								
Ev	ent Classifi	cation: Env	ironmental - Fall								
Ca	• To E • To A • To A • To C ques	Add an Action Add an Action Add a Root Continue - V Stions. A Additional C	Cause - Edit the on Plan - Click or Cause - <u>Click to e</u> When the RCA(s) = Questions (Required	root cause n	e by clicking 'Edit' to expand root o ditional Root Cause n Plan(s) informat ent	on the ause the ion is co	the appropri en click on '4 omplete, clic	ate row in the g Add Action Plan' k the button bel	rid below . ow to answer	final RCA	A.
	Edit	Delete	RCA Category Te	xt	Causality Statem	ent					
Θ	<u>Edit</u>	<u>Delete</u>	Behavioral asses process	sment	A process was no resulting in the p	ot in plac atient ge	e to ensure th etting out of b	nat the bed alarm ed un-detected a	was functionin and falling	g properl	у
	RCA: Ac	tion Pla	in								
	Edit	Add	Delete	Action P	lan						
	Edit         Add Action Plan         Delete         Train staff on "Within Arm's Reach" with return demonstration on how to optimally position self in relation to the patient to prevent/assist falls and when to consider transport via wheelchair.										
Dej P.O Pho	oartment o Box 360, T ne:(609) 63	<b>f Health</b> irenton, NJ 0 33-7759	8625-0360			Priva	ncy Notice	Legal Statement	t & Disclaimer	5	

- Complete all fields in this section all fields are required.
- Click on "Save/Next" to save the completed information.

Event Classification: Environme	ental - Fall			
		RCA Addi	tional Questions	
1. What were the contributing	factors to the ever	nt? (Sele	ct all that apply):	
Team factors	Work environmen	t		
Task factors	□ Staff factors			
Patient characteristics	Organization/man	agement		
Medical devices	Medications	-		
Procedures	□ Transportation			
Equipment	Home care			
Patient record documentation	Imaging and X-ra	у		
□ Laboratory and diagnostics	Other			
Other:	]			
2. Evaluate the impact of even	nt for Patient (Selec	t all that	t apply):	
□Loss of limb(s)		🗆 Visit t	o Emergency Department	
□Loss of digit(s)		Hospit	al admission	
Loss of body part(s)		□ Transf	er to more intensive level of care	
□Loss of organ(s)		🗆 Increa	sed length of stay	
□Loss of sensory function(s)		OMinor	surgery	
Loss of bodily function(s)		OMajor	surgery	
Disability-physical or mental i	mpairment	Syster	m or processes delay care to patient	
□ Additional laboratory testing o	or diagnostic imaging	🗆 To be	determined	
Other additional diagnostic te	sting	Death		
Additional patient monitoring	in current location	Other		
Other:				

3. ICD Codes resulting from event:

		/
1000 Characters left		

4. Diagnosis resulting from event:



5. Information consulted such as clinical literature/other published guidelines (please provide specific citations otherwise leave blank): This information is automatically entered into the 'Information Consulted' document in the Resources tab and is accessible to all facilities.



\*All Fields are Required Save/Next

#### 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 <u>section</u>.
- 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.
- Use the 'Report Menu' below to navigate this event.
- The menu will expand as the Event/RCA progresses
- Click on the link next to the red arrow to continue entering information
- Click on the appropriate link below to edit information
- Click <u>HERE</u> to send DOH a comment
- Click HERE to see the Communication Log

<u>Pleas</u>	<u>Please click the 'Submit' tab below to notify DOH that this RCA is ready for review</u>													
	Initial Event	Root Cause Anal	ysis											
				1	1									
Rep	ort Menu:	General Info	Facts of Event	Root Cause\Action Plan	Additional Questions	→ Submit RCA								
Repo	ort Number	: 20220134												
Evor	Fuent Classification: Care Management Medication Error													
Ever	Vent Classification: Care Management - Medication Error         Print Screen													

#### 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.

Initial Event Comments									
Report Number Submit Date									
	No data to display								
F	No data to display								
F Report Number	RCA Comments								

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.

RCA: Facts of the Event
Edit
1. Facts of the Event (Answer all that apply or enter 'NA' where not applicable):
a. Patient's past medical and surgical history:
b. Clinical status of patient prior to event:
c. Clinical status of patient after the event:
d. Patient's course in facility prior to event (i.e. surgery, transfer to ICU):
e. Patient's course in facility after event:
f. Medication at home:
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
h.Other factors contributing to the event. Please include detailed information about staffing. Please include appropriate lab results.
2. Additional event information: should be clearly stated and in chronological order: Indicate the potential areas of

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.)

#### 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

Logged in as: patUser	HOME	ADD EVENT	VIEW EVENTS 🔻	RESOURCES 👻	Admin	•								
<ul> <li>Click on comments link(s) below to read DOH comments if there is a comment for that section.</li> <li>Click on "edit" as appropriate to make changes in response to comments.</li> <li>When all comments have been addressed click on "submit" to re-submit to DHSS.</li> <li>Click <u>HERE</u> to send DOH a comment</li> </ul>														
Click <u>HERE</u> to send DOH a comment     Click <u>HERE</u> to see the Communication Log														
Upload Supporting Documentation Please click the 'Submit' tab below to notify DOH that this RCA is ready for review Initial Event Root Cause Analysis														
Report Menu: General Info Facts of Event RCA Questions Root	Cause\Actio	on Plan Add	litional Questions	→ Submit RCA										
Report Number: 20220135														
Event Classification: Care Management - Pressure Ulcers				Print S	reen									

- 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.

Upload File												
		Browse										
	Upload											
		Current Files										
Delete & View	Date Uploaded	File Name	Uploaded By:									
Doloto View	8/3/2022	20220135 RCA Supporting Doc.docx	patUser									

## 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.

Logged in as:	patUser			ном	ADD EVENT	VIEW EVER	NTS 👻	RESOURCES -	Admin 🔻					
You can sort the data by clicking on the column headers <u>Show Customization Window</u> - Use the 'Customization Window' to add/remove fields from the grid. <u>Saved Reports</u> - Click to view your saved reports. <u>Save a Report</u> - Click to save the report.  Export to Excel														
😰 Show Customization Dialog 📲 Column Chooser 🛚 📡 Clear Filter 🔍 Search Panel  🖶 Grou														
View	Report Year 💌	Facility Name	Report Number	-	Event Status		Event	Туре	-					
<u>Clear</u>	2022 🕈	•		9		9			9					
<u>Detail</u>	2022	TEST FACILITY-FORT LEE	20220134		RCA-Facility Edit	:	Care M Error	lanagement - I	1edication					
Detail	2022	TEST FACILITY-FORT LEE	20220135		RCA-Facility Edit	:	Care Management - Pressure Ulcers							
Detail	2022	TEST FACILITY-FORT LEE	20220138		RCA-Facility Edit	Environmental - Fall								
Detail	2022	TEST FACILITY-FORT LEE	20220136		RCA-Facility Edit	:	Care M Ulcers	lanagement - I	Pressure					
Detail	2022	TEST FACILITY-FORT LEE	20220137		Event-DOH Revi	ew	Care M Ulcers	lanagement - I	Pressure					
•									۱.					
Page 1 of 1 (5 it	ems) < [1] >													
♥ (Report)	Year] Equals '2022								<u>Clear</u>					

• 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.

<u>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.</u> 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

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<u>Detail</u>	2022	TEST FACILITY-FORT LEE	20220136	F	RCA-Facility Edit		Care M Ulcers	anagement	- Pres	sure		are Management - Medication Error
Detail	2022	TEST FACILITY-FORT LEE	20220137	E	Event-DOH Review	I	Care M Ulcers	anagement	- Pres	sure	Care Management - Pressure Ulcers     Environmental - Fall	
Page 1 of 1 (3 it	ems) < [1] >										C	Cancel .::
♥ [Report ]	Year] Equals '2022'	And [Event Type] Equals 'Car	e Management - Pres	sure L	Ulcers					Cle	<u>ear</u>	

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

- You can sort the data by clicking on the column headers
- Show Customization Window Use the 'Customization Window' to add/remove fields from the grid.
- <u>Saved Reports</u> Click to view your saved reports.
   <u>Save a Report</u> Click to save the report.
- 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).

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<u>Detail</u>	2022	FORT LEE	20220137	Event-DOH Review	Admit Date	-	
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<u>Detail</u>	2022	TEST FACILITY- FORT LEE	20220138	RCA-Facility Edit	Ethnicity	-	
Detail	2022	TEST FACILITY-	20220135	RCA-Facility Edit	Event Date	-	
Detail	2022	TEST FACILITY-	20220134	RCA-Facility Edit	Event Date Discover		
		FORT LEE		,	Event Date Discover Late		
Page 1 of 1 (	(5 items) < [1]	>			Event Date Discover Time	-	
P Create Filt	<u>er</u>				Event Date Unknown	-	
					Event Description		
Departmen	nt of Health	08625-0360			Event Flagged	-	
Phone:(609	) 633-7759	00025 0500		Privacy Noti	Event Indeterminate Facility ID	-	
					Event Indeterminate Facility Name	-	

- 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

Ex	port to Excel									
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<u>Detail</u>	2022	TEST FACILITY- FORT LEE		20220134		RCA-Facility Edit		Facility Type ID	-	
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raye 1 01 1								First Name	~	
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Donartmo	nt of Hoalth							How Event Discover	-	

- 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."

Save Rep	You     Hid     Sav     Sav     ort	fields from the grid.					
Report	view		Save Report	w Customization D	ialog 🛱 Column Choo Report Number 🖃	ser 😨 Clear Filter 🔍 Sea	rch Panel 🗄 Group Panel
	<u>Clear</u> 2022		<b></b>	✓ ♥	Ŷ	9	Care Management - Press
	<u>Detail</u>	2022	TEST FACILITY- FORT LEE	7/31/2022	20220137	Event-DOH Review	Care Management - Press Ulcers
	<u>Detail</u>	2022	TEST FACILITY- FORT LEE	7/31/2022	20220136	RCA-Facility Edit	Care Management - Press Ulcers
	<u>Detail</u>	2022	TEST FACILITY- FORT LEE	7/31/2022	20220135	RCA-Facility Edit	Care Management - Press Ulcers
	✓ Page 1 of 1 (3 it	ems) < [1] >					•
	V (Event T	ype] Equals 'Care	Management - Pressure	Ulcers' And [Repo	rt Year] Equals '2022		<u>Clear</u>

- 4. Accessing Saved Reports
- You can access this new report anytime by clicking on "Saved Reports"
  - You can add as many reports as needed

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View	Report Year	⊽F	Facility Name	-	Event Date 🖃	Repo	ort Number	-	Event Status	Eve
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- 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.

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<ul> <li>In the test</li> </ul>	Columns to Group							
Exp	Report Year						0	
View	Facility Name						0	Group Panel

• The next tab shows us filtering on the Report Year

lea	×	Sorting Grouping	Filtering	Column Chooser		~	1
in a: • Y	Report Year				Tx	^	•
· · ·	Equals						l
Exp	2022						l
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• 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.

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to to to	Ξ	Report Year					0	
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View <u>Clear</u>	Ξ	Report Number					0	
ent Ty ent Ty	Ξ	Event Status					0	
rent Ty . of 1 (3	Ξ	Event Type					0	

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

	<ul> <li>You can sort the data by clicking on the column headers</li> <li><u>Show Customization Window</u> - Use the 'Customization Window' to add/remove fields from the grid.</li> <li><u>Saved Reports</u> - Click to view your saved reports.</li> <li><u>Save a Report</u> - Click to save the report.</li> </ul>												
	Export to Excel												
				보 Sł	iow C	ustomization Dialog	🛅 Column Choo	ser	🛣 Clear Filter	Q Search F	Panel	🖶 Group Pane	I
	View	Report Year	V	Facility Name	-	Event Date 🖃	Report Number	-	Event Status				
	<u>Clear</u>	2022	7		Ţ	~ ?		Ŷ		Ŷ			
÷	Event Type: Ca	are Manageme	ent	- Medication Err	or (C	Count=1)							
$\pm$	Event Type: Ca	are Manageme	ent	- Pressure Ulcer	s (Co	ount=3)							
$\oplus$	Event Type: Environmental - Fall (Count=1)												
Pag	Page 1 of 1 (3 items) < [1] >												
4	[ <u>Report Year</u> ]     ]	] Equals '2022'										Clea	ar

- 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 0 "Pressure." The grid automatically filters as you type and highlights the words as they are found.

🖸 Show Customization Dialog 🛛 🛅 Column Chooser 🛛 🛣 Clear Filter									🖶 Group Pan	iel
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w	Report Year ⊽	Facility Name	Event Date 🖃	Report Number	-	Event Status	-	Event Type		-
	<b></b>		♥ ♥		Ŷ		7			Ŷ
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<u>ail</u>	2022	TEST FACILITY- FORT LEE	7/31/2022	20220136		RCA-Facility Edit		Care Management - Ulcers	<b>Pressure</b>	
<u>ail</u>	2022	TEST FACILITY- FORT LEE	7/31/2022	20220135		RCA-Facility Edit		Care Management - Ulcers	<b>Pressure</b>	
4										l F
Page	Page 1 of 1 (3 items) < [1] >									
♥ <u>Cr</u>	eate Filter									

- 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.
  - · You can sort the data by clicking on the column headers
  - Show Customization Window Use the 'Customization Window' to add/remove fields from the grid.
  - <u>Saved Reports</u> Click to view your saved reports.
     <u>Save a Report</u> Click to save the report.

	Export to Excel											
				۵	Show Customization D	ialo	og 🔲 Column Chooser 🤇	🔀 Cle	ar Filter 🔍	, Search Panel	🖶 Gro	oup Panel
Drag a	column header	here to	group by that	colu	mn 🔶			Tyopt	Type			
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<u>Deta</u>	<u>il</u> 20	D22 TE FO	ST FACILITY- ORT LEE		20220135		RCA-Facility Edit	Ca Ulo	re Managem :ers	ient - Pressu	re	
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<u>Deta</u>	<u>il</u> 20	D22 TE FO	ST FACILITY- ORT LEE		20220137		Event-DOH Review	Ca Ulo	re Managem ters	ient - Pressu	re	
Page 1	of 1 (5 items) <	[1] >	)									
♥ <u>Creat</u>	e Filter											

- 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.

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Detail 2022 TEST FACILITY-	20220138 RCA-Facility	Edit	Environmental -	Fall				

## 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?
- ষষ্যয্যয্যযুষ্যয 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?
- প্র 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?
- **প্রথ**ম্ব প্রথ 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?
- Ø 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?
- ষষ্যয্যযথ্যয 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?
- Ø What information is required for immediate corrective actions to prevent future similar events?

## **RCA Questions**

- S How do I count the number of similar events in the last three years?
- Ø Where do I find reviewer's comments?
- S 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.

## Ø

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

## Ø

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. <u>The event</u> <u>should be discussed with one of the clinical staff in the Patient Safety Reporting System</u> 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.*

Ø

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: <u>http://nj.gov/</u> and log in. Then click on the Patient Safety Reporting System link located Page | 56

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: <u>https://www.nj.gov/health/healthcarequality/health-careportessionals/patient-safety-reporting-system/voluntary\_anonymous\_reporting.shtml</u>

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.

## Y

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:

Additional resources may be found on the Patient Safety website at: <u>Patient Safety</u>

The link to N.J.A.C 8.43:E regulations can be found on our <u>resources</u> page

#### 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**

S

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 <u>its own facility</u>, 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 <u>another facility</u>, 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.*

Click HERE to return to questions

## What types of pressure ulcers should be reported?

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

- This excludes progression from Stage II to Stage III, if Stage II was recognized and *documented upon admission*.
- Any Stage II pressure ulcer that progresses to a Stage IV ulcer must 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

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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?

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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.

Click HERE to return to questions



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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.

Click HERE to return to questions

## Bow 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**

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#### 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:

RCA: General Information
Edit
1. List the individuals on the RCA Team, including their titles:
<ol> <li>Konstan Parataly Administration</li> <li>Define Research response</li> <li>Research and Parataly Administration</li> <li>Define Research and Administration</li> <li>Surger Sciencistic Research and Administration</li> </ol>
2. How many similar events has your facility had for this 1 event type in the previous 3 full calendar years plus the current year? Do not include the current case in this count. (numbers only)
a. What changes did the organization make in response to these previous events? If this is an 'Other' event type, only include changes relevant for the specific situation. Examples include, but are not limited to, perforation, infection, delay in care).
b. How are you tracking the effectiveness of these changes?
3. What procedures are in place to ensure that the facility knows about all the reportable events? This question is pertinent to all RCAs regardless of whether there have been similar events in the last 3 years.
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RCA: Facts of the Event
Edit
1. Facts of the Event (Answer all that apply or enter 'NA' where not applicable): a. Patient's past medical and surgical history:

Click HERE to return to questions

## XII. Additional Guidance for Ambulatory Surgery Centers

## Questions

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

Responses to Questions Men 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. <u>N.B. Some events do not need to</u> <u>meet a threshold of injury due to the potential serious nature of the event.</u>

- 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 <u>prior to</u> 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

- *W*hat event type should be used for dialysis events?
- *W*hat 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.

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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.

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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.