



Brian D. Pagano, Esq
Burns White LLC
bdpagano@burnswhite.com





Different Types of Events

Event: A discrete, auditable, and clearly defined occurrence.

Adverse Event: An event that is a negative consequence of care that results in

unintended injury or illness, which may or may not have been

preventable.

Preventable Event: An event that could have been anticipated and prepared

against, but occurs because of an error or other system failure.

Serious Preventable

Adverse Event: An adverse event that is a preventable event and results in

death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the

time of discharge from a health care facility.

Near Miss: An occurrence that could have resulted in an adverse event, but

the adverse event was prevented.



What events <u>must</u> be reported?

- A facility shall report to the Department of Health & Senior Services <u>every serious preventable adverse event</u> that occurs in the facility. - N.J.A.C. 8:43-10.6(a)
 - However, home health care facilities, hospice facilities, assisted living residences, comprehensive personal care homes, and assisted living programs, shall report only those serious preventable adverse events that are within the control of the facility or directly caused by, or related to, services of the facility. N.J.A.C. 8:43-10.6(a)(2)
 - With respect to serious preventable adverse events related to health care services provided directly to residents of an assisted living residence, comprehensive personal care home or assisted living program by another health care facility, the facility directly providing the service shall report to the Department. N.J.A.C. 8:43-10.6(a)(2)(i)





Types of Serious Preventable Adverse Events

- Patient or resident care management-related events include, but are not limited to:
 - Medication Errors (wrong drug, wrong dose, wrong resident, wrong time, wrong rate, wrong preparation, or wrong route of administration);
 - Hemolytic reactions due to the administration of ABO/HLA-incompatible blood or blood products;
 - Hypoglycemic events; and
 - Stage III or IV pressure ulcers acquired after the resident's admission to a health care facility.
 - However, progression from Stage II to Stage III is not included for mandatory reporting, provided the Stage II was recognized and documented on admission.
 - N.J.A.C. 8:43(f)(1 7).





Types of Serious Preventable Adverse Events

- Environmental Events, including but not limited to:
 - Electric Shock (does not include planned treatments, such as electric counter shock or elective cardioversion);
 - Incidents in which a line for oxygen or other gas to be delivered to a resident contains the wrong gas or is contaminated by other toxic substances;
 - Burns from any source; and
 - Incidents associated with the use of restraints or bedrails.
 - N.J.A.C. 8:43-10.6(g)(1 5).



Types of Serious Preventable Adverse Events

Product or medical device-related events, including, but not limited to:

- Generally detectable contaminated drugs, medical devices, or biologics provided by the health care facility, regardless of the source contamination or product;
 - "Generally detectable" means capable of being observed with the naked eye or with the use of detection devices in general use.
- The use or function of a medical device in resident care in which the device is used or functions other than as intended, including but not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators;
- Intravascular air embolism that occurs while the resident is in the facility;
 - Does not include death or disability associated with neurological procedures known to present a high risk of intravascular air embolism.
 - *N.J.A.C.* 8:43E-10.6(h)(1 4).





Types of Serious Preventable Adverse Events

- Patient or resident protection-related events, including, but not limited to:
- Elopement (NOTE: For reporting purposes, an elopement is whenever facility staff are not aware of a resident's whereabouts outside of the building.)
- Suicide or attempted suicide while in a healthcare facility;
 - Does not include death or disability resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.
- Facilities are no longer required to report resident falls.
 - N.J.A.C. 8:43E-10.6(j)(1 3).



Other Reporting Requirements

- Physical Plant and Operational interruptions, such as loss of heat or air conditioning, significant reduction of water, electrical power, or any other essential utilities necessary to run the facility, fires, labor stoppage or staffing shortages sufficient require the temporary closure of a service, and notice of a potential strike from an employee bargaining unit; - N.J.A.C. 8:43E-10.11(c)(1-5)(i - iii)
- All Criminal Acts or Potentially Criminal Acts that occur within the facility, such as someone impersonating a physician, nurse, pharmacists or other licensed healthcare provider, abduction, sexual assault, or death or significant injury resulting from a physical assault on the ground of the facility; N.J.A.C. 8:43E-10.11(d)(1 4); 8:43F-3.4(a)(6)
- Any suspected cases of Resident or Participant Abuse or Exploitation; N.J.A.C. 8:39-9.4(f); 8:36-5.10(a)(3); 8:43-4.9(a)(3); 8:43F-3.3(d)(8)(i - iii)
- Termination of the employment of the Administrator or Director of Nursing; *N.J.A.C.* 8:39-9.4(e); 8:36-5.10(a)(1); 8:43-4.9(a)(1); 8:43F-3.4(a)(2 3)
- Incidents of infectious and communicable diseases or an occurrence of an epidemic disease in the facility; N.J.A.C. 8:43E-10.11(e); 8:39-19.4(f); 8:36-18.3(a)(1); 8:43-16.3(a)(1); 8:43F-16.2(i)(1); 8:43F-3.4(a)(4); and
- All residents who are missing for 24 hours; *N.J.A.C.* 8:43-4.9(a)(2).





ETHICAL CONSIDERATION No. 1:

To Report or Not to Report?

- If the incident at issue is not a "serious preventable adverse event," the facility is not required to report it. However, there may be still be issues with not reporting "adverse" events.
- The resident's family member or responsible party can still contact the DHSS, which can result in a Complaint Survey.
- The facility's staff members can submit anonymous reports to the DHSS regarding preventable adverse events that are otherwise not subject to mandatory reporting, as well as nearmisses. - N.J.A.C. 8:43E-10.8(a). The facility must inform employees and health care professionals practicing at the facility of their option to file such anonymous reports. -N.J.A.C. 8:43E-10.8(b).



ETHICAL CONSIDERATION No. 1 (continued):

To Report or Not to Report?

- If the matter proceeds to litigation, the attorney for the resident may try to place blame on the facility for failing to report (i.e. the suggestion that the facility was "hiding" something by not reporting).
- Alternatively, choosing to report something that is not mandatory can open the facility up to a survey and a possible deficiency.
 - Example 1: A 72-year old woman with a known history of elopement is residing in a long-term care facility. One day, she bolts for the door and makes it out of the facility. A CNA sees her leaving, chases after her, and catches up with her outside the building, never losing sight of her.
 - Example 2: A 54-year old male with a known history of depression and attention seeking behaviors tells his roommate he is going to kill himself. The roommate reports this immediately to a nurse. The nurse goes to the resident's room. When asked, the resident states he is only joking, and enjoys getting a rise out of his roommate.
 - Example 3: A 68-year old woman who is a known fall risk falls and breaks her wrist.





ETHICAL CONSIDERATION No. 2:

It wasn't me!

- Situations will arise where it is questionable as to whether a seriously
 preventable adverse event arose within the control of the facility, or was
 directly caused by, or related to, services of the facility.
 - Example 1: An 84-year old male with a known history of osteoporosis and osteopenia complains of pain in his left hip. An x-ray reveals a femoral neck fracture. An investigation does not show any trauma or falls. The facility staff believes the fracture is idiopathic.
 - Example 2: A 76-year old woman is a new admission to a long-term care facility. Her skin is intact; however, her sacral area has the appearance of a deep purple bruise. By Day 3 of her residency, the area has ulcerated into the appearance of a Stage III pressure ulcer.
 - Example 3: A 92-year old woman has just returned to the facility after a lengthy hospital stay. Shortly after returning, she begins exhibiting symptoms of an infection. She is given a urine culture, and found to have a urinary tract infection that becomes septic. Given the timeframe of events, the facility believes the UTI originated in the hospital. Who, if anyone, should report this? Does the facility have an obligation to report if the hospital refuses to do so?





ETHICAL CONSIDERATION No. 3:

We don't have to report it, now what?

- What should a facility do when there is an adverse event without mandatory reporting, and they have decided not to voluntarily report it?
 - Inform the resident's next of kin or responsible party, as well as the resident's physician;
 - Ensure that the adverse event is investigated and well documented.
 If an incident report is required, make sure one is completed.
 - Ensure that the documentation is accurate and factual. If a Care Plan or General Service Plan needs to be updated, make sure that it happens.
 - Keep any analytical or deliberative documentation regarding potential causation separate from the incident report and other documentation, as this would be privileged in a future lawsuit.